

The Vaccine Adverse Event Reporting System (VAERS) Results

Messages:

- ▮ The full results are too long to be displayed, only non-zero rows are available.
- ▮ VAERS data in CDC WONDER are updated every Friday. Hence, results for the same query can change from week to week.
- ▮ These results are for 648 total events.
- ▮ When grouped by VAERS ID, results initially don't show Events Reported, Percent, or totals. Use Quick or More Options to restore them, if you wish.
- ▮ Click on a VAERS ID to see a report containing detailed information for the event.

Some measures are hidden, use Quick or More Options above to restore them.

Vaccine Type	Event Category	Age	Adverse Event Description	VAERS ID
COVID19 VACCINE (COVID19)	Death	1-2 years	death by suicide Narrative: death by suicide; 12/26/20, self inflicted gun shot wound; found deceased by family member	 
COVID19 VACCINE (COVID19)	Death	18-29 years	Patient received the vaccine on 12/22/20 without complication. It was reported today that the patient was found unresponsive and subsequently expired at home on 1/11/21.	
COVID19 VACCINE (COVID19)	Death	18-29 years	On day due for 2nd dose, Patient was found unresponsive at work in the hospital. Patient pupils were fixed and dilated. Full ACLS was initiated for 55 minutes with multiple rounds of bicarb, calcium chloride, magnesium, and epinephrine. Patient was intubated. Patient continued into V. Fib arrest and was shocked multiple times.	
COVID19 VACCINE (COVID19)	Death	18-29 years	Patient developed 104.4 temp approximately 48 hours after being given the vaccine. I treated him with antibiotics, IV fluids, cooling methods. CXR does show a new right perihilar infiltrate. However, his fever came down within the next 24-48 hours. Unfortunately, he suffered a cardiac arrest on 1/21/21 in the early morning and expired.	
COVID19 VACCINE (COVID19)	Death	30-39 years	LTCF Pfizer Vaccine clinic conducted 12/29/2020 Vaccine lead received a call indicating that a staff member deceased somewhere between 1/3/2021 and 1/4/2021. Cause of death is unknown, and an autopsy is being performed.	
COVID19 VACCINE (COVID19)	Death	30-39 years	Patient vaccinated on 12/28. Approximately one day later, develops cough and on azithromycin x 1 week. On 1/3, patient develops left-sided weakness and aphasia. Taken to the hospital, tested COVID+, required intubation -- acute hypoxic respiratory failure secondary to COVID - on H&P. Patient died on 1/4/21 at 7:20am.	
COVID19 VACCINE (COVID19)	Death	40-49 years	Expired on 1/12/2021; unknown cause of death	
COVID19 VACCINE (COVID19)	Death	40-49 years	The patient was found deceased at home about 24 hours after immunization. Date of Death:: 12/29/2020; estimated time of death 6:00pm	
COVID19 VACCINE (COVID19)	Death	40-49 years	Pronounced dead 1/9/2021 at 12:42. Received first dose of vaccine 1/8/2021	
COVID19 VACCINE (COVID19)	Death	40-49 years	unsure if related to vaccine, but was notified by her next of kin that she died on 1/4/2021. No reports of side effects or hospitalization were reported to the facility prior to the notification of death.	

	COVID19 VACCINE (COVID19)	Death	40-49 years
Sudden cardiac death			
	COVID19 VACCINE (COVID19)	Death	40-49 years
Patient suffered a cardiac arrest and was unable to give details about her symptoms. Per husband, patient did not complain of any symptoms after vaccine administration. She began seizing without warning which was complicated by cardiac arrest of uncertain etiology			
	COVID19 VACCINE (COVID19)	Death	40-49 years
possibly got it at clinic, possibly who administered shot. Pts. daughter said the pts boyfriend denied any symptoms the whole day but that in the middle of the night the pt passed away.			
	COVID19 VACCINE (COVID19)	Death	50-59 years
syncopal episode - arrested - CPR - death			
	COVID19 VACCINE (COVID19)	Death	50-59 years
Found deceased in her home, unknown cause, 6 days after vaccine.			
	COVID19 VACCINE (COVID19)	Death	50-59 years
Vaccine received at about 0900 on 01/04/2021 at her place of work, Medical Center, where she was employed as a housekeeper. About one hour after receiving the vaccine she experienced a hot flash, nausea, and feeling like she was going to pass out after she had bent down. Later at about 1500 hours she appeared tired and lethargic, then a short time later, at about 1600 hours, upon arrival to a friends home she complained of feeling hot and having difficulty breathing. She then collapsed, then when medics arrived, she was still breathing slowly then went into cardiac arrest and was unable to be revived.			
	COVID19 VACCINE (COVID19)	Death	50-59 years
Patient had been diagnosed with COVID-19 on Dec. 11th, 2020. Symptoms were thought to have started on 12/5/2020. Received Moderna vaccine on 12/23. Unexpected death on 1/8/2021. Resuscitation attempts unsuccessful			
	COVID19 VACCINE (COVID19)	Death	50-59 years
Patient received COVID vaccination around 12:15pm. Patient was monitored for the appropriate amount of time by nursing staff. Patient passed away at 2:15pm.			
	COVID19 VACCINE (COVID19)	Death	50-59 years
"Staff member checked on her at 3am and patient stated that she felt like she couldn't breathe. 911 was called and taken to the hospital. While in the ambulance, patient coded. Patient was given CPR and ""brought back"". Once at the hospital, patient was placed on a ventilator and efforts were made to contact the guardian for end of life decisions. Two EEGs were given to determine that patient had no brain activity. Guardian, made the decision to end all life saving measures. Patient was taken off the ventilator on 1/9/2021 and passed away at 1:30am on 1/10/2021. The initial indication from the ICU doctor was the patient had a mucus plug that she couldn't clear."			
	COVID19 VACCINE (COVID19)	Death	50-59 years
he passed away; not responsive; mind just seemed like it was racing; body was hyper dried; Restless; not feeling well; ate a bit but not much; kind of pale; Agitated; Vomiting; trouble in breathing; This is a spontaneous report from a contactable consumer (brother of the patient). A 54-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration, on 04Jan2021 (at the age of 54-years-old) as a single dose for COVID-19 immunization. Medical history included diabetes and high blood pressure. Concomitant medications included metformin (MANUFACTURER UNKNOWN) taken for diabetes, glimepiride (MANUFACTURER UNKNOWN) taken for diabetes, lisinopril (MANUFACTURER UNKNOWN), and amlodipine (MANUFACTURER UNKNOWN). The patient experienced not feeling well, ate a bit but not much, kind of pale, vomiting, trouble in breathing, and agitated on 04Jan2021; body was hyper dried and restless on 05Jan2021; mind just seemed like it was racing on 06Jan2021; and not responsive and he passed away on 06Jan2021 at 10:15 (reported as: around 10:15 AM). The clinical course was reported as follows: The patient received the vaccine on 04Jan2021, after which he started not feeling well. He went right home and went to bed. He woke up and ate a bit but not much and then was kind of pale. The patient then started to vomit, which continued throughout the night. He was having trouble in breathing. Emergency services were called, and they			

took his vitals and said that everything was okay, but he was very agitated; reported as not like this prior to the vaccine. The patient was taken to urgent care where they gave him an unspecified steroid shot and unspecified medication for vomiting. The patient was told he was probably having a reaction to the vaccine, but he was just dried up. The patient continued to vomit throughout the day and then he was very agitated again and would fall asleep for may be 15-20 minutes. When the patient woke up, he was very restless (reported as: his body was just amped up and could not calm down). The patient calmed down just a little bit in the evening. When the patient was awoken at 6:00 AM in the morning, he was still agitated. The patient stated that he couldn't breathe, and his mind was racing. The patient's other brother went to him and he was not responsive, and he passed away on 06Jan2021 around 10:15 AM. It was reported that none of the symptoms occurred until the patient received the vaccine. Therapeutic measures were taken as a result of vomiting as aforementioned. The clinical outcome of all of the events was unknown; not responsive was not recovered, the patient died on 06Jan2021. The cause of death was unknown (reported as: not known by reporter). An autopsy was not performed. The batch/lot number for the vaccine, BNT162B2, was not provided and has been requested during follow up.; Reported Cause(s) of Death: not responsive and he passed away

COVID19 VACCINE (COVID19)

Death 50-59 years

Patient received the 1st dose of Moderna and was found deceased in her home the next day.

COVID19 VACCINE (COVID19)

Death 50-59 years

on 1/8/2021 17:30 patient taken to ER, cerebellar hemorrhage, stroke, aneurysm

COVID19 VACCINE (COVID19)

Death 50-59 years

Resident began having fever on 1/11/21 @0600. VS= T-102 B/P- 100/57 P- 112 RR- 24 O2 Sat 92% on RA. MD called. Rapid COVID Test was negative. CBC,CMP, U/A were ordered as well as CXR. Resident's condition declined. At 3:00pm resident started having respiratory distress and hypoxia O2 Sat 89%. Supplemental O2/mask @ 5LPM. Neb TX, EKG, and Rocephin 1 GM ordered. Condition worsened. Resident sent to nearest ER for evaluation. Later in the evening the staff AT Medical Center called to inform staff that resident had expired @ 2230 as a result of Respiratory Failure and Sepsis.

COVID19 VACCINE (COVID19)

Death 50-59 years

54 y/o M with PMH of HTN, HLD, Alcoholic Cirrhosis, Aortic Valve Stenosis, and angina BIBA as a Medical Alert for cardiac arrest noted PTA. Per EMS, the patient called because he was having constant, diffuse abdominal pain x 1 day that radiated to his chest. On scene, the patient had a witnessed arrest with EMS starting CPR. He was given 3 rounds of epi without ROSC. Pt had no associated shockable rhythm. Of note, pt's wife, had noted pt had received covid vaccine the prior day.

COVID19 VACCINE (COVID19)

Death 50-59 years

Cardiac arrest within 1 hour Patient had the second vaccine approximately 2 pm on Tuesday Jan 12th He works at the extended care community and was in good health that morning with no complaints. He waited 10-15 minutes at the vaccine admin site and then told them he felt fine and was ready to get back to work. He then was found unresponsive at 3 pm within an hour of the 2nd vaccine. EMS called immediately worked on him 30 minutes in field then 30 minutes at ER was able to put him on life support yet deemed Brain dead 1-14-21 and pronounced dead an hour or so later

COVID19 VACCINE (COVID19)

Death 50-59 years

51 year old M with h/o O2 dependent COPD, Severe pulmonary fibrosis became increasingly hypoxic around 1800hours 1/7/2021. He was transported to hospital for acute on chronic hypoxia respiratory failure. On 1/12/2021 he decompensated further, and after discussing with family and palliative care, He was changed to comfort care. He expired on 1/12/2021@2325 at medical center.

COVID19 VACCINE (COVID19)

Death 50-59 years

""Moderna COVID-19 Vaccine EUA"" It has been reported to me that pt. had gone into hospital for a heart catheterization on 1/12/2021. It was found during this procedure that pt. had suffered a MI. She was release to home the following day and passed away at her residence on 1/15/2021."

COVID19 VACCINE (COVID19)

Death 50-59 years

COVID 19 Vaccination administered by pharmacy staff. No adverse effect at the present time. Staff will continue to observe adverse reaction. Will continue to monitor. Patient at start of shift awake in the bed. Pt at

3am was on the commode leaned to the side. Patient body still warm to touch no pulse. Called for assistance Asap. Cpr started promptly. Cpr given patient on floor 911 arrived at the scene at 3:10am Cpr rotated Between Nursing and EMT on Scene. Cpr was given to patient for over 45 minutes. Patient was pronounced at the scene at 3:50am. Call placed to Pt family by supervisor on shift. MD to be notified. AT 3:00am, I was notified by the nurse that resident is unresponsive. Upon entering room, resident was sitting on the commode unresponsive with absent respiration and pulse. Resident lowered down on the floor with 4 person assist. CPR initiated, AED pads placed on chest with no shock indicated. 911 called and EMT and paramedics arrived around 3:10am. ACLS performed until code stopped and pronounced death at 3:48am. I called and notified family member of his demise and awaiting for family to call us back for funeral arrangements.

COVID19 VACCINE (COVID19)

Death 50-59 years

Death

COVID19 VACCINE (COVID19)

Death 50-59 years

Resident received 1st on 1/11/21 at 12:10am (1/12/21) resident was found unresponsive. Code Blue, 911 called at 12:11am. FD and EMS arrived, resident pronounced at 12:51am.

COVID19 VACCINE (COVID19)

Death 50-59 years

Death 3 days after receiving 2nd dose of COVID vaccine, unknown if related to vaccine administration.

COVID19 VACCINE (COVID19)

Death 50-59 years

Patient woke apx 0200 complaining of nausea to group home staff. Vitals were checked at that time and WNL. Patient went back to bed. When staff went to wake patient apx 0530, he was unresponsive and had no pulse. Chest compressions were started and EMS called.

COVID19 VACCINE (COVID19)

Death 50-59 years

Pt died 4 days after vaccine, no known reaction to the vaccination

COVID19 VACCINE (COVID19)

Death 60-64 years

RESIDENT CODED AND EXPIRED

COVID19 VACCINE (COVID19)

Death 60-64 years

Death by massive heart attack. Pfizer-BioNTech COVID-19 Vaccine EUA

COVID19 VACCINE (COVID19)

Death 60-64 years

1/1/2020: Residents was found unresponsive. Pronounced deceased at 6:02pm

COVID19 VACCINE (COVID19)

Death 60-64 years

Patient was vaccinated Dec 30, 2020. Prime dose of Moderna vaccine. Observed for full 15 minutes post-injection. No complaints when asked during observation. Released. Subsequently, vaccine clinic staff learned from the patient's supervisor that on Jan 4, 2021 that the patient had expired on Jan 2, 2021. By report from the supervisor, the patient was found dead at his home. The patient's primary care provider was unaware of his death when contacted by this reporter today (Jan 6, 2021). Electronic Medical Record without any information since the vaccination.

COVID19 VACCINE (COVID19)

Death 60-64 years

coughing up blood, significant hemoptysis --> cardiac arrest. started day after vaccine but likely related to ongoing progression of lung cancer

COVID19 VACCINE (COVID19)

Death 60-64 years

Notified today that he passed away. No other details known at this time.

COVID19 VACCINE (COVID19)

Death 60-64 years

The patient had an apparent cardiac arrest on 12/23/20 and was admitted to the ICU. He was taken off of life support on 12/30/20. He had known cardiac disease.

COVID19 VACCINE (COVID19)

Death 60-64 years

Patient died, I have a copy of his vaccination card

COVID19 VACCINE (COVID19)

Death 60-64 years

Difficulty breathing, death.

COVID19 VACCINE (COVID19)

Death 60-64 years

patient reported expired 1/7/2021

COVID19 VACCINE (COVID19)

Death 60-64 years

This person was found to be deceased on routine rounds during the night, 3am. No symptoms of reaction noted post vaccine. No injection site reaction. No reports of any allergic reaction.

COVID19 VACCINE (COVID19)

Death 60-64 years

No adverse effects from vaccination seen on 1/2/21. On 1/6/21 resident was seen by Dr and her baclofen pump was refilled with 20 ml Baclofen 4,000mcg/ml. ITB Rate increased by 6% to 455.5 mcg/day simple continuous rate over 3 days. On 1/8/21 at 0615 resident was shaking, lower extremities mottled, SaO2 70%, pulse 45. Oxygen started at 2 L/m per NC. At 0715 her primary physician was notified as well as her daughter. Oxygen increased to 4 L/min, sats at 83%. SOA noted, reported all over pain. At 0850 when they attempted to reposition the resident, she was not responsive. Licensed nurse assessed her and no heartbeat heard or pulse found.

COVID19 VACCINE (COVID19)

Death 60-64 years

Resident expired on 1/2/21.

COVID19 VACCINE (COVID19)

Death 60-64 years

Around 00:50am on 01/15/21, C.N.A. reported that the resident looked different and not responding. Initiated Code Blue and started CPR. 911 arrived and pronounced resident dead at 1:01 am.

COVID19 VACCINE (COVID19)

Death 60-64 years

"On 1/15/2021 at 1800, resident noted to be lethargic and shaking, stating ""I don't care."" repeatedly. C/O head and neck pain. T100.6. Given Tylenol with no relief of pain. Order received for Aleve and administered.. Assisted to bed as usual in evening. Monitored during night shift and noted to be resting comfortably/sleeping.. Noted agonal breathing at 4:10 AM 1/16/2021 , T 99.4, Absence of vital signs at 4:15AM 1/16/21 and death pronounced at 4:40AM 1/16/21."

COVID19 VACCINE (COVID19)

Death 60-64 years

Resident expired 1/17/21

COVID19 VACCINE (COVID19)

Death 60-64 years

Weakness, Low O2, death. Positive for COVID on 1/12/21, dies on 1/16/21

COVID19 VACCINE (COVID19)

Death 60-64 years

Patient was vaccinated for SARS-CoV-2 on 6-Jan-21 at his site of employment, a Nursing Home. Patient presented to Urgent Care on 15-Jan-21 complaining of left sided chest pain that started the evening before with an associated slight cough. Pt was afebrile with a heart rate of 88 and an O2 sat on room air of 98% in triage. His EKG showed a sinus tachycardia of 114 with a slightly prolonged QTc of 463 ms. Physical exam was significant for bibasilar crackles and X-ray showed bibasilar infiltrates consistent with COVID pneumonia but bacterial pneumonia could not be excluded. The patients BP was documented as 97/64. He was treated with Zofran for nausea and tylenol. He was prescribed a five day course of Azithromycin, an Albuterol inhaler, guaifenesin with codeine cough syrup, and Zofran. Labs were drawn and he was discharged. His lab results were reported after his departure and were significant for a white blood cell count of 1.33, platelet count of 73, 2% myelocytes, 1% metamyelocytes, an absolute neutrophil count of 0.75 K/uL, a creatinine of 1.83, total bilirubin of 1.3, with direct bilirubin of 0.8, alkaline phosphatase of 294 and AST of 112 with ALT noted to be within normal limit. His COVID nasopharyngeal swab from the visit was reported as negative and a swab performed at his employment on 13-Jan-21 was also reported to be negative. Patient could not be reached by phone after discharge from Urgent Care about these labs. On the evening of 16-Jan-21, Police Department received a 911 call about an adult at the patient's address who was found unresponsive. Upon arrival on scene, the patient was found to be deceased and a decision was made not to attempt to resuscitate. The death was deemed to be non-suspicious and the patient's body was transported to a funeral home. On 19-Jan-21, I contacted the State Medical Examiner's Office. They have decided to perform an autopsy and have recovered the CBC and chemistry specimens obtained for further testing.

COVID19 VACCINE (COVID19)

Death 60-64 years

Shaking and then became unresponsive

COVID19 VACCINE (COVID19)

Death 60-64 years

approximately 3 hours prior to expiring the patient was experiencing forceful emesis. later was found to have expired, patient was comfort care only.

COVID19 VACCINE (COVID19)

Death 60-64 years

Patient deceased

COVID19 VACCINE (COVID19) Death 60-64 years

No immediate reaction. Patient-reported deceased four days later on Jan. 19, 2021. As of this date cause of death is unknown to our clinic.

COVID19 VACCINE (COVID19)

Death 60-64 years

Patient deceased on 01/17/2021

COVID19 VACCINE (COVID19) Death 60-64 years

Death - Hospice patient with metastatic CA admitted to facility and received vaccine during stay. No adverse sequelae noted from vaccine administration, but reporting as required because pt died 7 days later. Narrative: Reporting this event because patient died 7 days after receiving vaccine in the facility where he was in hospice care for metastatic cancer. Vaccine was administered by protocol without complications. The patient had been asked and denied any prior severe reaction to this vaccine or its components and gave permission to receive it. No vaccine adverse sequelae were documented after the immunization as monitored for 15 minutes nor in facility notes for 7 days after the immunization. The patient's death was felt to be due to underlying terminal illness.

COVID19 VACCINE (COVID19)

Death 65+ years

on 12/24/2020 the resident was sleepy and stayed in bed most of the shift. He stated he was doing okay but requested pain medication for his legs at 250PM. At 255AM on 12/25/2020 the resident was observed in bed lying still, pale, eyes half open and foam coming from mouth and unresponsive. He was not breathing and with no pulse

COVID19 VACCINE (COVID19)

Death 65+ years

Patient had mild hypotension, decreased oral intake, somnolence starting 3 days after vaccination and death 5 days after administration. He did have advanced dementia and was hospice eligible based on history of aspiration pneumonia.

COVID19 VACCINE (COVID19)

Death 65+ years

Vaccine administered with no immediate adverse reaction at 11:29am. Vaccine screening questions were completed and resident was not feeling sick and temperature was 98F. At approximately 1:30pm the resident passed away.

COVID19 VACCINE (COVID19)

Death 65+ years

My grandmother died a few hours after receiving the moderna covid vaccine booster 1. While I don't expect that the events are related, the treating hospital did not acknowledge this and I wanted to be sure a report was made.

COVID19 VACCINE (COVID19)

Death 65+ years

Spouse awoke 12/20 and found spouse dead. Client was not transferred to hospital.

COVID19 VACCINE (COVID19)

Death 65+ years

Resident in our long term care facility who received first dose of Moderna COVID-19 Vaccine on 12/22/2020, only documented side effect was mild fatigue after receiving. She passed away on 12/27/2020 of natural causes per report. Has previously been in & out of hospice care, resided in nursing home for 9+ years, elderly with dementia. Due to proximity of vaccination we felt we should report the death, even though it is not believed to be related.

COVID19 VACCINE (COVID19)

Death 65+ years

Within 24 hours of receiving the vaccine, fever and respiratory distress, and anxiety developed requiring oxygen, morphine and ativan. My Mom passed away on the evening of 12/26/2020.

COVID19 VACCINE (COVID19)

Death 65+ years

Injection given on 12/28/20 - no adverse events and no issues yesterday; Death today, 12/30/20, approx.. 2am today (unknown if related - Administrator marked as natural causes)

COVID19 VACCINE (COVID19)

Death 65+

years

pt passed away with an hour to hour and 1/2 of receiving vaccine. per nursing home staff they did not expect pt to make it many more days. pt was unresponsive in room when shot was given. per nursing home staff pt was 14 + days post covid

COVID19 VACCINE (COVID19)

Death 65+ years

pt was a nursing home pt. pt received first dose of covid vaccine. pt was monitored for 15 minutes after getting shot. staff reported that pt was 15 days post covid. Pt passed away with in 90 minutes of getting vaccine

COVID19 VACCINE (COVID19)

Death 65+ years

pt received vaccine at covid clinic on 12/30 at approximately 3:30, pt vomited 4 minutes after receiving shot-- dark brown vomit, staff reported pt had vomited night before. Per staff report pt became short of breath between 6 and 7 pm that night. Pt had DNR on file. pt passed away at approximately 10pm. Staff reported pt was 14 + days post covid

COVID19 VACCINE (COVID19)

Death 65+ years

Resident received vaccine per pharmacy at the facility at 5 pm. Approximately 6:45 resident found unresponsive and EMS contacted. Upon EMS arrival at facility, resident went into cardiac arrest, code initiated by EMS and transported to hospital. Resident expired at hospital at approximately 8 pm

COVID19 VACCINE (COVID19)

Death 65+ years

Patient died within 12 hours of receiving the vaccine.

COVID19 VACCINE (COVID19)

Death 65+ years

Resident received vaccine in am and expired that afternoon.

COVID19 VACCINE (COVID19)

Death 65+ years

After vaccination, patient tested positive for COVID-19. Patient was very ill and had numerous chronic health issues prior to vaccination. Facility had a number of patients who had already tested positive for COVID-19. Vaccination continued in an effort to prevent this patient from contracting the virus or to mitigate his risk. This was unsuccessful and patient died.

COVID19 VACCINE (COVID19)

Death 65+ years

At the time of vaccination, there was an outbreak of residents who had already tested positive for COVID 19 at the nursing home where patient was a resident. About a week later, patient tested positive for COVID 19. She had a number of chronic, underlying health conditions. The vaccine did not have enough time to prevent COVID 19. There is no evidence that the vaccination caused patient's death. It simply didn't have time to save her life.

COVID19 VACCINE (COVID19)

Death 65+ years

Prior to the administration of the COVID 19 vaccine, the nursing home had an outbreak of COVID-19. Patient was vaccinated and about a week later she tested positive for COVID-19. She had underlying thyroid and diabetes disease. She died as a result of COVID-19 and her underlying health conditions and not as a result of the vaccine.

COVID19 VACCINE (COVID19)

Death 65+ years

Resident found unresponsive without pulse, respirations at 04:30 CPR performed, expired at 04:52 by Rescue

COVID19 VACCINE (COVID19)

Death 65+ years

Resident became SOB, congested and hypoxic requiring oxygen, respiratory treatments and suctioning. Stabilized after treatment and for the next 72 hours with oxygen saturations in the 90s. On 1/3/2021 was found without pulse and respirations. Resident was a DNR on Hospice.

COVID19 VACCINE (COVID19)

Death 65+ years

Two days post vaccine patient went into cardiac arrest and passed away.

COVID19 VACCINE (COVID19)

Death 65+ years

Fever, Malaise

COVID19 VACCINE (COVID19)

Death 65+ years

Resident exhibited no adverse events during 30 minute monitoring following vaccine administration.
Resident found without pulse at 1900.

COVID19 VACCINE (COVID19)

Death 65+ years

Redness and warmth with edema to right side of neck and under chin. Resident was on Hospice services and expired on 1.1.21

COVID19 VACCINE (COVID19)

Death 65+ years

12/30/2020 07:02 AM Resident noted to have some redness in face and respiration were fast. Resident vital signs were abnormal except blood pressure. Temp at the time was 102.0 F taken temporal. Resident respirations were 22 labored at times. Pulse is 105 and pulse ox 94% on room air. Resident is made comfortable in bed. Notified triage of change in condition also made triage aware of resident receiving Covid vaccination yesterday morning. Resident appetite and fluid consumption has been poor for few days. 12/30/2020 07:32 AM Received order from agency to administer Acetaminophen 650mg suppos rectally due to resident not wanting to swallow anything including fluids, medications and food. This writer administered medication as NP ordered. Will monitor for effectiveness and adverse effects if any. 12/30/2020 08:41 AM Received new orders to obtain Flu swab, obtain CBC and BMP, and Chest Xray all to be obtained today. Notified family of resident having temperature and vital signs excluding b/p that was abnormal. Family was thankful for call and inierated to nurse that family does not want resident sent to hospital. Did educate family on benefits of Hospice services, but family persistant on continued daily care provided by nursing staff. Requests visits if decline continues. Family assured if resident continues to decline, facility will accomandate resident family to be able to be at bedside when time comes to do so. NP ordered IVF and IV Levaquin on 12/31/20. Family chose at that time to sign for Hospice services and not have resident provided with IVF or IV Antibiotics

COVID19 VACCINE (COVID19)

Death 65+ years

"The resident received is vaccine around 11:00 am and tolerated it without any difficulty or immediate adverse effects. He was at therapy from 12:36 pm until 1:22 pm when he stated he was too tired and could not do anymore. The therapist took him back to his room at that time and he got into bed himself but stated his legs felt heavy. At 1:50 pm the CNA answered his call light and found he had taken himself to the bathroom. She stated that when he went to get back into the bed it was ""abnormal"" how he was getting into it so she assisted him. At that time he quit breathing and she called a RN into the room immediately. He was found without a pulse, respirations, or blood pressure at 1:54 pm. He was a DNR."

COVID19 VACCINE (COVID19)

Death 65+ years

Vaccine 12/30/2020 Screening PCR done 12/31/2020 Symptoms 1/1/2021 COVID test result came back positive 1/2/2021 Deceased 1/4/2021

COVID19 VACCINE (COVID19)

Death 65+ years

Resident received Covid Vaccine, noted after 30 mins with labored breathing BP 161/77, HR 116, R 38, T 101.4,

COVID19 VACCINE (COVID19)

Death 65+ years

Vaccine given on 12/29/20 by Pharmacy. On 1/1/21, resident became lethargic and sluggish and developed a rash on forearms. He was a Hospice recipient and doctor and Hospice ordered no treatment, just to continue to monitor. When no improvement of codition reported, doctor and Hospice ordered comfort meds (Morphine, Ativan, Levsin). Resident expired on 1/4/2021

COVID19 VACCINE (COVID19)

Death 65+ years

DEATH ON 1/4/2021, RESIDENT RECIEVED VACCINE ON 1/2/20

COVID19 VACCINE (COVID19)

Death 65+ years

Resident had body aches, a low O2 sat and had chills starting on 12/30/20. He had stated that they had slightly improved. On 1/1/21 he sustained a fall with a diagnosis of a displaced hip fracture. On 1/2/21 during the NOC shift his O2 sat dropped again. He later went unresponsive and passed away.

COVID19 VACCINE (COVID19)

Death 65+ years

The resident was found deceased a little less than 12 hours following COVID vaccination, and he had had some changes over the last 2 days. He was 96 and had been on hospice care for a little while. Noone noticed any side effects from vaccine after it was given

COVID19 VACCINE (COVID19)

Death 65+

Fever, RespDepression & COVID positive REMDESIVIR (EUA) 200 mg x1 then 100 mg daily
COVID19 VACCINE (COVID19) **Death 65+ years**

resident expired 1/1/2021
COVID19 VACCINE (COVID19) **Death 65+ years**

Resident expired 1/3/21
COVID19 VACCINE (COVID19) **Death 65+ years**

Patient did not display any obvious signs or symptoms; the vaccination was administered at approximately 10:00 AM and the patient continued throughout her day without any complaints or signs of adverse reaction. Patient was helped to bed by the nursing assistant estimated at around 9:00 PM. The facility received notification from the lab around 11:00 PM that the patient's COVID-19 specimen collection from Sunday, 1/3/21, detected COVID-19. When the nursing staff went to the room to check on the resident and prepare her to move to a COVID-19 care area the patient was found unresponsive, no movement, no chest rises, noted regurgitated small amount of food to mouth left side, lying on left side. Pupils non reactive.

COVID19 VACCINE (COVID19) **Death 65+ years**

At approximately, 1855, I was alerted by caregiver, resident was not responding. Per caregiver, she was doing her rounds and found resident in bed, unresponsive, mouth open, observed gurgling noises and tongue hanging out of mouth. This primary caregiver observed resident at baseline and ambulating after dinner at approximately, 1800 less than an hour prior to incident. This PCG called 911 for EMS and gave report of incident. Resident was taken to Medical Center Emergency Department. At ER, CT scan and X-ray was performed. Per report from ER RN, CT scan and x-ray revealed an intracranial aneurysm and fluid in the lungs. Per RN, resident was still unresponsive and was admitted to Medical Center for observation and comfort measures. This primary caregiver reported to RN, resident recently received the first dose of COVID-19 vaccine on 1/2/21. Primary caregiver received a call from Castle RN at 0700, resident expired at 0615.

COVID19 VACCINE (COVID19) **Death 65+ years**

Deceased
COVID19 VACCINE (COVID19) **Death 65+ years**

PT was found deceased in his home on 1/5/2021
COVID19 VACCINE (COVID19) **Death 65+ years**

Expired 1/05/2021
COVID19 VACCINE (COVID19) **Death 65+ years**

"Pt last seen at 1200 by nurse for ID band check. No visible signs of distress noted. Pt states ""I just want to be left alone"". 1230 nurse was called to pt room. Pt was noted unresponsive, no pulse and respiration noted. CPR started immediately, at 1239 first shock given. 1245 EMT took over, at 1319 EMT called time of death"

COVID19 VACCINE (COVID19) **Death 65+ years**

Patient developed hypoxia on 1/4/2021 and did not respond to maximal treatment and passed way on 1/5/2021
COVID19 VACCINE (COVID19) **Death 65+ years**

patient declined 12/30/2020 and was transferred to hospital where he did not respond to treatment and passed away 1/4/2020
COVID19 VACCINE (COVID19) **Death 65+ years**

Patient did not report any signs or symptoms of adverse reaction to vaccine. Patient suffered from several comorbidities (diabetes and renal insufficiency). Patient reported not feeling well 01/06/2021 and passed away that day.

COVID19 VACCINE (COVID19) **Death 65+ years**

had a vaccination on 12/31/2020 late morning passed away early morning 01/01/2020. This is a 93 year old with significant heart issues. EF of 20% among other comorbidities. He died suddenly approximately 0430, it is unlikely it was related to receiving the vaccine.

COVID19 VACCINE (COVID19) **Death 65+ years**

Patient was vaccinated at 11am and was found at the facility in his room deceased at approximately 3:00pm. Nurse did not have cause of death

COVID19 VACCINE (COVID19)

Death 65+ years

No adverse effects noted after vaccination. Patient with cardiac history was found unresponsive at 16:45 on 1/6/21. Abnormal breathing patterns, eyes partially closed SPO2 was 41%, pulseless with no cardiac sounds upon auscultation. CPR and pulse was regained and patient was breathing. Patient sent to Hospital ER where she remained in an unstable condition had multiple cardiac arrest and severe bradycardia and in the end the hospital was unable to bring her back.

COVID19 VACCINE (COVID19)

Death 65+ years

vomiting later on 01/05/21. Lethargy and hypoxia in pm of 01/06/21. Hypotension am of 01/07/21. Hospitalized, intubated, cardiac arrest, died 01/07/21.

COVID19 VACCINE (COVID19)

Death 65+ years

Resident passed away in her sleep

COVID19 VACCINE (COVID19)

Death 65+ years

3:07 pm lung sounds diminished oxygen sats 68%, oxygen applied Oxygen sats remained low for next 36 hours (patient on Hospice care) expired 6:22 am 1-8-21

COVID19 VACCINE (COVID19)

Death 65+ years

Patient received vaccine on 1/4/2021. He was in Hospice for CHF and renal failure, but was able to get up in his wheelchair and eat and take medications and talk. On 1/5/2021 am, he was noted to be very lethargic and could only mumble, could not swallow. No localizing neurologic findings. He was too lethargic to get up in chair.

COVID19 VACCINE (COVID19)

Death 65+ years

Patient received first dose of vaccine on 12/28, developed COVID-19 infection shortly thereafter and expired on 1/6/2021.

COVID19 VACCINE (COVID19)

Death 65+ years

Patient received first dose of vaccine on 12/28, developed COVID-19 infection shortly thereafter and expired on 1/4/2021

COVID19 VACCINE (COVID19)

Death 65+ years

Fever, shortness of breath and chest pain that resulted in a heart attack a few hours after vaccination

COVID19 VACCINE (COVID19)

Death 65+ years

Medical doctor state patient has a acute cardiac attack

COVID19 VACCINE (COVID19)

Death 65+ years

Death

COVID19 VACCINE (COVID19)

Death 65+ years

Diarrhea followed by death 24 hrs after vaccination

COVID19 VACCINE (COVID19)

Death 65+ years

1/7-21 - Received second dose of pfizer covid-19 vaccine 1/8/21 - Fever, dizziness, headache 1/10/21 0250 was found not breathing. EMS performed CPR and patient deceased

COVID19 VACCINE (COVID19)

Death 65+ years

RECEIVED VACCINE 1/8/21 EXPIRED UNEXPECTED 1/10/21, NO ADVERSE REACTIONS NOTED

COVID19 VACCINE (COVID19)

Death 65+ years

"1-2-2021 10:30 PM Complained Right arm/back hurt - took Tylenol 1-3-2021 Complained Right arm hurt, dizzy 1-4-2021 Felt better - did laundry, daughter found her deceased at 3:30 pm. Dr. at hospital said it was ""cardiac event"" according to death certificate."

COVID19 VACCINE (COVID19)

Death 65+ years

Staff reported that patient was found Friday morning (Jan 8) sitting at a table with his head tilted forward and unresponsive to verbal or physical stimuli. Staff lowered patient to floor and started CPR. EMS was called and continued CPR at scene, however they were not able to revive patient. Patient was pronounced dead at the scene. Staff written statements following the death of patient show that he had a fall about 1 hr. prior. It is unknown if this fall contributed to patient's death. An autopsy has been requested.

COVID19 VACCINE (COVID19)

Death 65+ years

Acute anterior MI with death

COVID19 VACCINE (COVID19)

Death 65+ years

The resident resides in an independent living facility/apartment. The reporter at the center was informed by his daughter he was not feeling well on 1/1/2021 (specific symptoms could not be ascertained). He reportedly went to be COVID tested on 1/1/2020 and observed to be deceased in his apartment on 1/2/2020. I do not have confirmation of his COVID results, although the reporter indicates his daughter reports his test was positive.

COVID19 VACCINE (COVID19)

Death 65+ years

Patient went to bed around 11pm on Saturday PM and sometime between then and 1:30am on Sunday morning got up and went into the living room without waking up her husband (which is normal). At 1:30am, the husband got up to use the restroom and she was out of bed then, but the husband did not know if she was having any problems at this time. When he got up at 7:45am, she was in the recliner and did not move or anything, which is normal for her. At 8:45am, the husband went back into the living room and tried to wake his wife and that is when he noticed there was no pulse and he called 9-1-1 at this time. EMS got on scene and did CPR for 30 mins and she was pronounced dead at 9:21am.

COVID19 VACCINE (COVID19)

Death 65+ years

Resident died suddenly and expectantly on 01/05/2021

COVID19 VACCINE (COVID19)

Death 65+ years

Patient received COVID-19 (Moderna) vaccine from the Health Department on afternoon of January 8, 2021 and went to sleep approximately 2300 that night. Was found unresponsive in bed the following morning and pronounced dead at 1336 on January 9, 2021

COVID19 VACCINE (COVID19)

Death 65+ years

Patient was reported to be deceased at home by law enforcement on 1/7/21

COVID19 VACCINE (COVID19)

Death 65+ years

There were no adverse reactions. Resident Died, she had a history of issues with her health prior to the vaccine.

COVID19 VACCINE (COVID19)

Death 65+ years

Patient was found unresponsive at home with SpO2 20% 1/2/2021

COVID19 VACCINE (COVID19)

Death 65+ years

My mother was given Pfizer vaccine on Thursday and she died 3 days later yesterday on Sunday!!!

COVID19 VACCINE (COVID19)

Death 65+ years

RESIDENT 1ST DOSE OF MODERNA VACCINE ADMINISTERED ON 01/04/2021 AT 8:30PM, RESIDENT FOUND UNRESPONSIVE ON 01/05/2021.

COVID19 VACCINE (COVID19)

Death 65+ years

loss of consciousness Narrative: Patient received COVID-19 vaccine dose #1 on 1/6/21 w/o complications. Per 1/6/21- 1/9/21 nursing notes, patient did not experience any injection site reactions, denied pain or tenderness at injection site, no dizziness, no n/v, remained afebrile. Around 1/9/21 @1810, patient became acutely nonresponsive after being helped to the edge of bed. Per nurses, he was previously awake/alert, talking and asymptomatic. Patient is DNR/DNI but facility rapid response emergency team called d/t patient's sudden change of condition. Emergency team helped patient into lying position. Per 1/9/21 ICU emergency team note, patient appeared comfortable w/ no palpable radial pulse and had minimal shallow agonal breathing. Pulse ox 94%, HR in 60s per machine. BP unmeasurably low by BP cuffx3. Resident passed at 18:20 pm.

COVID19 VACCINE (COVID19)

Death 65+ years

The facility had positive cases of COVID when we were able to begin vaccinating residents. Within about a week of vaccination, patient was tested positive for COVID. He was 91 years old and his immune system did not have the time to allow the vaccine to begin working before exposure. His age was a major contributing factor to his death.

COVID19 VACCINE (COVID19)

Death 65+ years

The facility had positive cases for COVID 19 when the vaccine was received and administered to patient. With her advanced age and chronic conditions, she did not have time to build immunity between the time of vaccination and her testing positive.

COVID19 VACCINE (COVID19)

Death 65+ years

The facility had a number of positive COVID 19 cases prior to patients vaccination. Due to her advanced age, chronic condition, and exposure, patient did not have the time to build immunity after exposure before becoming positive.

COVID19 VACCINE (COVID19)

Death 65+ years

Pt expired due to possible cardiac arrest. Unsure if this was vaccine related.

COVID19 VACCINE (COVID19)

Death 65+ years

Resident was found deceased at approximately 6pm in her apartment

COVID19 VACCINE (COVID19)

Death 65+ years

Patient was sent to the ED due to significant hematuria. He was afebrile.

COVID19 VACCINE (COVID19)

Death 65+ years

Hospice Resident received first Covid 19 vaccine dose on 1/6/21. 1/7/21 resident had decreased appetite noted in am but ate 100% of meal at dinner. 1/9/21 resident had decreased appetite with emesis x 2, loose BM x 2. Call placed to hospice. 1/10/21 5:44 am resident able to take HS meds, ingest 2 cups of shake. No emesis or loose stool noted. 12PM nurse noted resident not eating meals but ingesting milkshake and medications without any problems. Hospice contacted for change in condition. 1:00 pm hospice ordered Phenergan 12.5 mg Q 6 hrs PRN. Labs to be drawn 1/11/21. Hospice notified POA. 1/11/21 12:24am Resident had blood in stool. Resident denies any pain, on 2L of O2 for comfort.

COVID19 VACCINE (COVID19)

Death 65+ years

Three hours after receiving COVID 19 vaccination, Patient oxygen level decreased to a critical level and went into cardiac arrest. Staff performed full code but was unable to bring back patient from cardiac arrest.

COVID19 VACCINE (COVID19)

Death 65+ years

"Patient received vaccine on 1/8/2021. On 1/9/2021 I checked on patient via phone for symptoms or problems and he reported none but mild soreness at injection site. On 1/10/2021 family friend called me to tell me that patient had expired at about 8:00 pm. Patient reportedly complained of ""pain"" unspecified and collapsed at home. Hospital reportedly told family that it appeared to be a ""heart attack""."

COVID19 VACCINE (COVID19)

Death 65+ years

patient passed away after receiving the Covid vaccine; This is a spontaneous report from a contactable nurse. An 81-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE), intramuscular into the right arm on 07Jan2021 at 0.3 mL, single for covid-19 immunization. There was no medical history and no concomitant medications. On 08Jan2021, the patient passed away after receiving the COVID vaccine. The patient died on 08Jan2021. An autopsy was not performed. Investigations indicate that unspecified labs were done, but nothing two weeks prior; no further details were provided. The patient received the first dose the day prior. The reporting nurse discussed it with the medical director, and he thought that he potentially passed away from the COVID vaccine. The relatedness of the event to the suspect vaccine was reported as related by the reporting nurse per The Agency. The batch/lot number for the vaccine, BNT162B2, was not provided and will be requested during follow-up .; Sender's Comments: Based on the limited information available, it is medically not possible to make meaningful causality assessment, it is unlikely the vaccine could have contributed to the death of the patient based on the known safety profile. However case will be reevaluated when additional information is received during the follow-up The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.; Reported Cause(s) of Death: Stated that the patient passed away after receiving the Covid vaccine

COVID19 VACCINE (COVID19)

Death 65+ years

Patient received her vaccination on 1/12/21 administered by pharmacy*+. She expired on 1/12/21 an approximately 7:30pm. Resident did not have any adverse reactions and was a hospice patient.

COVID19 VACCINE (COVID19)

Death 65+ years

"Patient was found ""acting abnormal"" on 1/9/2021 at 1215. VS HR 20-30's. EMS activated. EMS arrived and patient was found pulseless in PEA/ asystole, CPR and ACLS initiated and then transported to the MC. Unsuccessful resuscitation and expired on 1/09/2021 at 1348. Clinical impression Cardiopulmonary arrest."

COVID19 VACCINE (COVID19)

Death 65+ years

"Heart attack; This is a spontaneous report from a contactable consumer. An 82-year-old female patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot Number: and Expiration Date: Unknown), via an unspecified route of administration in the left arm on 05Jan2021 at 13:00 at a single dose for COVID-19 immunization; administered in doctor's office/urgent care. The patient's medical history and concomitant medications were not reported. It was unknown if the patient received any other vaccines within four weeks prior to the COVID vaccine. Prior to the vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. On 05Jan2021, the patient experienced heart attack; which resulted in death and was assessed as medically significant. The patient also experienced the associated symptoms of cold sweats, chest pain, shortness of breath. Therapeutic measures were taken as a result of heart attack, which included ""life saving measures"" by the paramedics performed upon arrival with no success. The clinical outcome of the event, heart attack, was fatal. The patient died on 05Jan2021 due to heart attack; as ruled by the paramedics. It was unknown if an autopsy was performed. The batch/lot numbers for the vaccine, PFIZER-BIONTECH COVID-19 MRNA VACCINE, were not provided and will be requested during follow up.; Reported Cause(s) of Death: Heart attack"

COVID19 VACCINE (COVID19)

Death 65+ years

"Cardiac Arrest; Patient was found pulseless and breathless 20 minutes following the vaccine administration.; Patient was found pulseless and breathless 20 minutes following the vaccine administration.; This is a spontaneous report from a contactable other healthcare professional (HCP). A 66-year-old female patient (pregnant at the time of vaccination: no) received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EL1284) via intramuscular at left arm on 11Jan2021 12:15 PM at single dose for COVID-19 immunization. Medical history included diastolic CHF, spinal stenosis, morbid obesity, epilepsy, pulmonary hypertension and COVID-19 (Prior to vaccination, the patient was diagnosed with COVID-19). The patient received medication within 2 weeks of vaccination included amiodarone, melatonin, venlafaxine hydrochloride (EFFEXOR), ibuprofen, aripiprazole (ABILIFY), lisinopril, cranberry capsules, diltiazem, paracetamol (TYLENOL), famotidine, furosemide (LASIX [FUROSEMIDE]), ipratropium bromide, salbutamol sulfate (IPRATROPIUM/ALBUTEROL), buspirone, senna alexandrina leaf (SENNA [SENNA ALEXANDRINA LEAF]), polyethylene glycol 3350 and morphine. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Patient used took Penicillin, propranolol, quetiapine, topiramate, Lamictal and had allergy to them. Patient used took the first dose of BNT162B2 (lot number: EJ1685) via intramuscular at right arm on 21Dec2020 12:00 PM at single dose for COVID-19 immunization. Since the vaccination, the patient been tested for COVID-19 (Sars-cov-2 PCR) via nasal swab on 06Jan2021, covid test result was negative. Patient was found pulseless and breathless 20 minutes following the vaccine administration (11Jan2021 12:30 AM). MD found no signs of anaphylaxis. Patient died on 11Jan2021 12:30 AM because of cardiac arrest. No treatment received for the events. Outcome of pulseless and breathless was unknown. the autopsy was performed, and autopsy remarks was unknown. Autopsy-determined cause of death was unknown. It was reported as non-serious, not results in death, Life threatening, caused/prolonged hospitalization, disabling/Incapacitating nor congenital anomaly/birth defect.; Sender's Comments: Based on the available information this patient had multiple underlying medical conditions including morbid obesity, diastolic CHF, epilepsy, pulmonary hypertension and COVID-19 diagnosed prior to vaccination. All these conditions more likely contributed to patients cardiac arrest resulting in death. However, based on a close temporal association (""Patient was found pulseless and breathless 20 minutes following the second dose of BNT162B2 vaccine administration, contributory role of BNT162B2 vaccine to the onset of reported events cannot be completely excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.; Reported Cause(s) of Death: Cardiac arrest; Autopsy-determined Cause(s) of Death: autopsy remarks was unknown. Autopsy-determined cause of death was unknown"

COVID19 VACCINE (COVID19)

Death 65+ years

Actual event and cause of death were unknown; This is a spontaneous report from a non-contactable consumer. A

90-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 06Jan2021 at single dose for COVID Prevention. The relevant medical history included aortic valve replacement from Nov2019. Concomitant medications were not reported. The consumer stated that she was taking the reporting responsibilities to report that a friend of hers, informed that the patient passed away on Friday, and had received the COVID vaccine on Wednesday. The consumer stated that it was unknown to her at this time, if the friend had called to complete a report herself, regarding the incident. Their conversation was very brief. The patient was 90 years old, and it was her friend's mother that was the patient. Actual event and cause of death were unknown. The patient had her vaccine on Wednesday 06Jan2021, and then the patient collapsed in front of the reporter at Friday night on 08Jan2021 and passed away that same day. The autopsy was unknown. The outcome of the event was fatal. No follow-up attempts are possible; information about lot/batch number cannot be obtained.; Reported Cause(s) of Death: Actual event and cause of death were unknown

COVID19 VACCINE (COVID19)

Death 65+ years

Staff walked into resident's room around 10:00am and noted resident's left side of his face was flaccid. Nurse was called and upon assessment resident noted to have an unequal hand grasp with left worse. He was able to talk but was mumbled and hard to understand. Physician, hospice, and family were notified. Resident had a stroke at 10:06 am on 1/8/2020. He lost all ability to use his left side. Resident passed away on 1/11/2020.

COVID19 VACCINE (COVID19)

Death 65+ years

The patient passed away today, 1/13/2021. She was a hospice patient. She showed no adverse effects after receiving the vaccine on 1/12/2021. This morning she woke up as normal and during her morning shower she had a bowel movement, went limp and was non-responsive. The patient passed away at 7:45 am.

COVID19 VACCINE (COVID19)

Death 65+ years

little bit of a reaction light headed after 5 minutes. vitals were low, so observed for 30 minutes after being light headed. Patient was found unresponsive and pronounced dead later that day.

COVID19 VACCINE (COVID19)

Death 65+ years

Death occurred 3 days after vaccine receipt; attributed to complications of her chronic advanced dementia with aspiration at age 87. No evidence of acute vaccine reaction.

COVID19 VACCINE (COVID19)

Death 65+ years

Resident received 1st dose on 1/4/2021. On 1/6/2021 resident having SOB, increased weakness with O2 sats at 91% RA. On 8th resident sustained a fall, O2 sats 88-92, dizzy, weakness. Rapid COVID test performed with negative results. Evening of 8th resident was lethargic and diaphoretic with fever of 99.9. Resident transferred to ER, on 5lt of oxygen. Resident returned from the ER on 1/9/2021 with new diagnosis of Leukemia and orders for hospice. Continued with fever, crackles and N/V and loss of appetite from the 9th and 10th of January. Resident expired at 820am on 1/11/2021.

COVID19 VACCINE (COVID19)

Death 65+ years

Initial pain in back of head and extreme headache. Some vomiting. At emergency, went into coma and was intubated. Hole drilled in skull to relieve pressure. MRI taken. Lot of bleeding in brain - aneurism lead to death approximately 14 hours after initial symptoms.

COVID19 VACCINE (COVID19)

Death 65+ years

Pt collapsed at home approx 5:30 pm and died

COVID19 VACCINE (COVID19)

Death 65+ years

Systemic: reported by staff patient expired under suspicious circumstances after receiving vaccine. Patient was on hospice, reported not expected to pass this soon; symptoms lasted 0 days

COVID19 VACCINE (COVID19)

Death 65+ years

No adverse reactions observed after administration of medication. Patient starting complaining of shortness of breath around 0500 the following morning. SP02 checked in the 80s. Patient expired 01/09/2021;

COVID19 VACCINE (COVID19)

Death 65+

years

resident coded on 09Jan at 8am and expired; This is a spontaneous report from a contactable Other Health Professional. A 70-year-old male patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EL0140), intramuscularly in left arm on 05Jan2021 15:15 at single dose for COVID-19 immunization. Medical history included DM2(Type two diabetes mellitus), CHF(congestive heart failure), open wound, wound infection, heart failure. Allergies to medications, food, or other products: none. Concomitant medications included unspecified products (List of any other medications the patient received within 2 weeks of vaccination: yes). If the patient received any other vaccines within 4 weeks prior to the COVID vaccine: Unknown. Facility where the most recent COVID-19 vaccine was administered: Nursing Home/Senior Living Facility. The resident coded on 09Jan2021 at 8 AM and expired. The patient died on 09Jan2021. An autopsy was not performed. AE resulted in: patient died. Death cause: unknown at this time. Was treatment received for the adverse event: Unknown. Prior to vaccination, was the patient diagnosed with COVID-19: No. Since the vaccination, has the patient been tested for COVID-19: No. Serious: Yes. Seriousness criteria-Results in death: Yes. Seriousness criteria-Life threatening: No. Seriousness criteria-Caused/prolonged hospitalization: No. Seriousness criteria-Disabling/Incapacitating: No. Seriousness criteria-Congenital anomaly/birth defect: No.; Sender's Comments: The old patient had diabetes mellitus, congestive heart failure, open wound complicated by infection, all these pre-existing medical conditions contribute to the patient death. More information including complete medical history, concomitant medications and event term details especially death cause and autopsy results are needed for a full assessment of the case. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate; Reported Cause(s) of Death: resident coded on 09Jan at 8am and expired

COVID19 VACCINE (COVID19)

Death 65+ years

Resident expired on 12/30/20, dx cardiac arrest.

COVID19 VACCINE (COVID19)

Death 65+ years

Patient died on 1/21-2021

COVID19 VACCINE (COVID19)

Death 65+ years

Resident found unresponsive and without pulse at 05:45am.

COVID19 VACCINE (COVID19)

Death 65+ years

On 1/11/21 noted with headache, nausea/vomiting, severe melaise. On 1/12/21 resident expired.

COVID19 VACCINE (COVID19)

Death 65+ years

71yo female resident who died after receiving Pfizer BioNTech vaccine. On 1/14/2021, VS taken at 10am, B/P 99/60, O2 sats, 95% (trach w/O2). At 11:30am, Patient showed no s/sx of distress, A&Ox3. At 11:50am, a nurse went to perform a COVID test and assessment (the facility is experiencing an outbreak), and found the patient unresponsive on the bathroom floor. CPR was immediately started; no shock advised per AED; 12:15pm EMS arrived and took over. At 12:38pm, EMT called time of death.

COVID19 VACCINE (COVID19)

Death 65+ years

Has underlying dementia and often with difficulty eating. 1 week after immunization she developed a stroke with left sided weakness and difficulty swallowing. Comfort measures instituted. Not sure if this is related to the vaccine, but thought I should report

COVID19 VACCINE (COVID19)

Death 65+ years

"83yo female resident who died after receiving Pfizer BioNTech vaccine. On 1/14/2021, the patient reportedly got up in the middle of the night with c/o feeling ""blah"", restlessness, and nausea. VS normal, no other s/sx. At 4:15am, the patient was asked to go back to bed, assisted by a nurse and GNA. At 6am, GNA was going to do morning VS and found the patient unresponsive, no pulse, no respirations. GNA notified the nurse. At 6:03am, CPR started and EMS called. At 6:15am, EMS arrived and took over. At or around 6:30am, EMT called time of death"

COVID19 VACCINE (COVID19)

Death 65+ years

No reactions immediately after vaccine was given. Resident has dementia, has had multiple hospitalizations related to a renal stone recently. Had a tooth that was bothering her, went to see her dentist and it was extracted on 1/6/21. On 1/10 they noted feet and ankles are dark purple with white splotches appears to be mottling.

Minimally responsive to voice and touch. Not eating. Compassionate visit with family. Family did not want hospice, did not feel it was needed, said, what more could they do for her than you're already doing? On 1/11 at 1950 was determined to be deceased.

COVID19 VACCINE (COVID19)

Death 65+ years

Had no immediate issues with the vaccine. He had returned from the hospital on 12/21 and had some concerns about his weight which were shared with his physician on 1/4/21. On 1/5/21 had a visit with his cardiologist for a pacemaker check. On 1/8/21 staff were called to his room, he was on the floor, bluish skin color. No vital signs found, no heart rhythm heard at 2200.

COVID19 VACCINE (COVID19)

Death 65+ years

At approximately 10:30pm on 1/14/2021, resident was noted to have a rash on her face, hands, arms, and chest. VS:100.2, 113, 20,108/59, 84% room air. applied nasal cannula at 4-L, telephoned Physician orders 6mg Decadron one time order, a second set of Vitals, reads 99.3, 110, 20, 106/60, 90% on 4-L N/C. On coming shift advised. At approximately 2:00am on 1/15/2021, resident congested and coughing. BP 151/70, pulse 124, temp 98.1 forehead, resp 20 and pulse oc 79% on 3L. At approximately 2:30am PRN cough syrup and breathing tx. Resident's condition began to worsen with breathing tx. This LPN updated at 0248 doctor on resident's condition. Doctor gave permission for resident to go to hospital. At 4:19am the Er called to say resident passed away.

COVID19 VACCINE (COVID19)

Death 65+ years

Sudden death 18 hours post vaccine.

COVID19 VACCINE (COVID19)

Death 65+ years

Resident received Moderna vaccine on 12/23/2020 around 5 pm. At approximately 3:35 am on 12/25/2020, resident had a CVA and died on 1/1/2021 at 3:00 am.

COVID19 VACCINE (COVID19)

Death 65+ years

died two days after receiving the vaccine; Fever; This is a spontaneous report from a contactable consumer (patient's stepchild). A 66-year-old male patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), via an unspecified route of administration, on 07Jan2021 (at the age of 66-years-old) as a single dose for COVID-19 immunization. The patient's medical history was not reported. Concomitant medications included an unspecified statin. The patient experienced fever on 08Jan2021. The patient died two days after receiving the vaccine on 09Jan2021, which was reported as fatal. The clinical course was reported as follows: The patient had a fever the day after getting the vaccine and then he just died in the middle of night. It was reported that it was not clear what exactly happened, but they are looking into this. The clinical outcome of fever was unknown and of died two days after receiving the vaccine was fatal. The patient died on 09Jan2021. The cause of death was not reported. An autopsy was not performed (was reported to be taking place soon). The batch/lot number for the vaccine, BNT162B2, was not provided and has been requested during follow up.; Reported Cause(s) of Death: died two days after receiving the vaccine

COVID19 VACCINE (COVID19)

Death 65+ years

Accelerated decline in condition with decreased input, decreased responsiveness, somnolence, and death

COVID19 VACCINE (COVID19)

Death 65+ years

Patient had no immediate effects from the vaccine, but died approximately 8 hours after receiving first dose of vaccine.

COVID19 VACCINE (COVID19)

Death 65+ years

Resident was found without a pulse and not breathing 20 minutes after vaccine administration. Upon MD review, no signs of anaphylaxis were noted.

COVID19 VACCINE (COVID19)

Death 65+ years

increase weakness and fatigue, weakness in extremities, incontinent, jerky arm movements, within first 24 hours, continue to decline sent to hospital returned weaker, within 24 hrs hours BP dropped, low pulse oximeter reading, diaphoretic, lung sounds diminished, loss consciousness and passed away. 01-12-2021

COVID19 VACCINE (COVID19)

Death 65+ years

Abdominal pain, Headaches, chest pain, loss of appetite, confusion, elevated liver enzymes 1/8-1/15/21

COVID19 VACCINE (COVID19)

Death 65+ years

Death Chest pain; irreg heart rhythm; evening of vaccine; death on toilet on 1/13/21

COVID19 VACCINE (COVID19)	Death 65+ years
Patient reportedly expired the day following receipt of the vaccine.	
COVID19 VACCINE (COVID19)	Death 65+ years
We got a call from a home health nurse Brandu Talamo, stating that the patient passed away.	
COVID19 VACCINE (COVID19)	Death 65+ years
Resident had lunch on 01/14/21 and after lunch around 2:00pm, he vomited and stopped breathing. We coded the resident and 911 paramedics came. They pronounced him dead at 2:18pm.	
COVID19 VACCINE (COVID19)	Death 65+ years
"The patient stated "" I just feel Blah"". vital signs obtained. 156/75 p-84 spo2 94% via NC 2L. T-96.7, c/o feeling restless, c/o nausea with no vomiting. Patient observed at 0600 nonresponsive, CPR initiated, and EMS notified Patient expired"	
COVID19 VACCINE (COVID19)	Death 65+ years
This patient has been under hospice care for over 2 years at the nursing home. She has had a steady decline with gradual weight loss. She was totally dependent in her care needs. She received the vaccine on 1/2/2021 as part of the facility vaccination campaign. No adverse events noted initially. On 1/3/2021 at 6:06 pm, she was noted on vital sign checks (done every 4 hours for first 72 hours after vaccination) with BP 64/52 but otherwise asymptomatic. Subsequent BP improved. On 1/4/2021 at 4:45 am, pt found with respiratory rate of 30 with otherwise normal vital signs. Tachypnea persisted, so she received liquid morphine 2.5 mg without improvement. Supplemental oxygen was applied. Tachypnea persisted. She had poor oral intake after that point had persistent tachypnea and worsening hypoxemia despite clear lungs on exam. She remained under hospice care and comfort measures were continued. No blood testing or imaging tests were done. She required increasing amounts of oxygen, became hypotensive, and died peacefully on 1/8/2021 at 7:45 pm.	
COVID19 VACCINE (COVID19)	Death 65+ years
Veteran was found by family slumped over and unresponsive at the breakfast table on 1/13/21, had expired	
COVID19 VACCINE (COVID19)	Death 65+ years
Patient 101 years old, nursing home resident, received vaccine 1/11, on 1/13 found on floor without obvious trauma, unresponsive. Brought to ED and was bradycardic, hypotensive, hypothermic and refractory to aggressive medical management. No obvious cause of death found on exam or labs, cxr. Unknown if event could be related to vaccine or not. Medical Examiner accepted case although initially unknown that patient had recently received vaccine. ME updated with that information today as soon as discovered.	
COVID19 VACCINE (COVID19)	Death 65+ years
Pt had witnessed arrest by wife. Pt wife started CPR and called EMS. CPR started at 15:12. Continued by EMS. Pt arrived to medical center asystole with CRP in progress and ventilated via igel device. He was in refractory ventricular fibrillation and continued CPR for a total of 1 hour. At that point, we checked a bedside ultrasound which showed his heart at a standstill. He was unresponsive to verbal and tactile stimulus and had fixed unreactive pupils. He was pronounced at 16:13.	
COVID19 VACCINE (COVID19)	Death 65+ years
Death	
COVID19 VACCINE (COVID19)	Death 65+ years
Headache after dose was given at 10:00 a.m Died at after 7:30 pm the same night the dose was given.	
COVID19 VACCINE (COVID19)	Death 65+ years
PATIENT GOT HER FIRST COVID PFIZER VACCINE AT 12/31 IN THE AM. HAD GOTTEN FLU LIKE SYMPTOMS AND HAD BEEN SICK FOR A COUPLE OF DAYS. HAD NAUSEA AND VOMITTING DURING THIS TIME AS WELL. ON 1/3 THE CARE GIVER WENT TO CHECK ON HER PT AT HER LTC FACILITY WHERE SHE LIVES AND SHE WASN'T ACTING RIGHT. SHE WAS UNABLE TO DO A STROKE EXAM. PT HAD NO MOVEMNET IN ARMS OR LEGS AND WAS UNABLE TO SPEAK. PT WAS VITALLY STABLE AT THE TIME. EMS RECORDED THAT THEY THOUGHT DIAGNOSIS WOULD BE STROKE, PNEUMONIA OR SEPSIS. AFTER ARRIVAL AT THE HOSPITAL DETERMED THAT SHE HAD A STORKE, ACUTE KIDNEY INJURY, ABNORMAL LFTS.	
COVID19 VACCINE (COVID19)	Death 65+ years

"Narrative: Patient with severe aphasia and only able to say ""hey, hey, hey"" or ""uh huh"" or shake his head no as a way to communicate. Patient previously able to ambulate with significant limp and hyperextension of right knee, but mostly wheelchair bound over last several years as he had had a slow and steady decline in overall health and mobility. Patient developed aggressive behavior of shouting ""hey"" and grabbing of groin in 2016. This was worked up with CT scans, labs, referral to urology, neurology, and referrals to psychiatry. The exact etiology of this action was never able to be affirmed, but thought to be more psychiatrically related. It improved significantly with addition of antipsychotics, worsened when antipsychotics were reduced, and improved again with addition of injectable antipsychotic on 12-10-2020. Patient suffered from falls on occasion given his significantly impaired physical mobility. His last documented fall was 8-31-2019. Patient began utilizing wheelchair most of time following that fall. No significant injuries noted in documentation of the falls. In the last 3 months, patient would often refuse medications. He would sometimes indicate that they would cause dizziness, and other times he would simply refuse. We attempted to hide medications in his food/fluid (with wife's blessing) and when he detected this he would occasionally refuse to eat. Patient previously on DOAC. After pharmacy review in 12/2020 it was recommended to discontinue this as no clear indication to continue use. He was high fall risk and would often refuse this medication as well since 10/2020. Noted to be in NSR on EKGs and decision made to discontinue the DOAC. Patient had no evidence of adverse effects noted after vaccination on December 28th. Patient seen by provider on the morning of his death (1/4/2021) with no noticeable significant change in health condition. Temperature 36.8C on January 4th at 19:45. During routine bedtime cares, patient suddenly collapsed and death was pronounced January 4, 2021 at 20:05. Autopsy was requested from next of kin and no autopsy was granted. Symptoms: & DEATH Treatment:"

COVID19 VACCINE (COVID19)

Death 65+ years

Narrative: Symptoms: Palpitations & Syncope Treatment: EPINEPHRINE 1 MG ONCE ,EPINEPHRINE 1 MG ONCE ,SODIUM BICARBONATE 50 ML ONCE

COVID19 VACCINE (COVID19)

Death 65+ years

Heart attack death medical test

COVID19 VACCINE (COVID19)

Death 65+ years

Patient became sick 3 hours after the vaccine and was found deceased 1 day after his vaccination. He passed away in his sleep.

COVID19 VACCINE (COVID19)

Death 65+ years

Daughter call in for VAERS report to file for father whom committed suicide 1/16/2021 in the AM after reportable ae of COVID 19 vaccine administered 1/14/2021. Patient sought care twice at ER; first visit by ambulance around 5PM and Friday 1/15/2021 Medical Center: Emergency Room. 1st Discharge summary diagnosis: adverse reaction to COVID shot; 2nd Discharge summary diagnosis: adverse reaction to COVID shot, fever, Panic Disorder-- ER. Medical Center Discharge summary diagnosis: Adverse reaction to the vaccine, acute anxiety. Reportable patient symptoms at, 1st visit : fever, shaking stomach cramps, breathing issues. Medical Center -- No fever, confusion and dementia type, patient would not stay in patient bed; patient would get up and sit down again repeatedly, agitated and anxious. Attempted to urinated hospital bed. Patient committed suicide in home.

COVID19 VACCINE (COVID19)

Death 65+ years

On 1/17/2021 at 4:35 am resident found apneic and pulseless, at 4:40am death confirmed

COVID19 VACCINE (COVID19)

Death 65+ years

Resident was seen by MD on 1/11/2021 due to increasing in edema and shortness of breath. Lasix 40 mg STAT given. New orders to get a STAT CBC, CMP, and BNP. Resident has been dependent on Oxygen since his diagnosis of COVID-19 on 11/23/2020. Labs were abnormal. Continued on the lasix 40 mgs. Resident remained short of breath with exertion and on oxygen. He was assisted to the toilet on 1/15/2021 in the morning where he subsequently passed away.

COVID19 VACCINE (COVID19)

Death 65+ years

Patient presented to our Emergency Department via EMS in full code status; asystole. Patient expired. Per nursing, husband stated patient awoke this AM and reported pain in back between shoulders and in bilateral shoulders. Patient then went unresponsive and husband called EMS.

COVID19 VACCINE (COVID19)

Death 65+ years

1/11/21 at 8:57 Resident with fever and at 11 am saturation down to 83 O2 to 10 liters. Resident continued to

decline until CTB on 1/14/2021 at 1325

COVID19 VACCINE (COVID19)

Death 65+ years

Patient was living in a nursing home with positive cases when administered. His age and chronic condition was such that he did not have time after the vaccination to avoid exposure or develop immunity.

COVID19 VACCINE (COVID19)

Death 65+ years

resident expired; This is a spontaneous report from a contactable healthcare professional. An 82-year-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot number: EL0140), intramuscular in the left arm on 05Jan2021 15:00 at a single dose for COVID-19 immunization. Medical history included metabolic encephalopathy from, failure to thrive (FTT), diabetes mellitus (DM) 2, chronic obstructive pulmonary disease (COPD), arthritis, weakness, hyperlipidemia, chronic kidney disease (CKD), dementia. Known allergies was none. The patient took unspecified concomitant medication. On 11Jan2021, the resident expired. The patient underwent lab tests and procedures which included nasal swab: negative on 09Jan2021. There was no treatment given for the event. The patient died on 11Jan2021. An autopsy was not performed.; Sender's Comments: Lacking information on the cause of patient's demise, the Company cannot completely exclude a causal relationship between COVID 19 vaccine, BNT162B2, and patient's death of unknown cause, as a cautionary measure and for reporting purposes. The patient's pre-existing medical condition of metabolic encephalopathy from, failure to thrive (FTT), diabetes mellitus (DM) 2, chronic obstructive pulmonary disease (COPD), arthritis, weakness, hyperlipidemia, chronic kidney disease (CKD), dementia may have provided the contribution to the event in this 82-year-old male patient. The impacts of this report on the benefit/risk profile of the product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.; Reported Cause(s) of Death: resident expired

COVID19 VACCINE (COVID19)

Death 65+ years

patient suddenly developed pneumonia 7 days after vaccination and died the evening of developing pneumonia

COVID19 VACCINE (COVID19)

Death 65+ years

Death

COVID19 VACCINE (COVID19)

Death 65+ years

patient started to decline 1/10/2021, patient seen at facility by medical professional - patient deceased 1/13/2021

COVID19 VACCINE (COVID19)

Death 65+ years

REPORTING ONLY AS RESIDENT EXPIRED ON 1/17/2021 3 DAYS AFTER. S/S HYPOXIA/CONGESTED LUNG SOUNDS

COVID19 VACCINE (COVID19)

Death 65+ years

The day following the vaccine, the patient complained of throat issues and anxiety. This was not new... however . That evening he reported difficulty breathing and was placed on oxygen; a COVID test was performed and was negative. On 12/30/2020, patient complained of sternal pressure and was transferred to the hospital. The patient died 12/31/2020 and records obtained from the hospital indicated the patient died from a massive myocardial infarction.

COVID19 VACCINE (COVID19)

Death 65+ years

71 year old woman at rehabilitation center for physical therapy with history of cirrhosis of the liver, asthma, and heart condition was tested for COVID-19 on 01/07/21, received 1st dose of Pfizer COVID-19 vaccine on 01/08/21, positive test result for COVID-19 received on 01/09/21. She was sent to the hospital and admitted on 01/12/21 after O2 was 70% and was in a confused state. Patient passed away on 01/17/21.

COVID19 VACCINE (COVID19)

Death 65+ years

On 1/13/2021, resident had sudden emesis. Immediately following emesis he was noted without a pulse and pronounced deceased. No acute symptoms noted prior to this episode. Resident does have a significant cardiac history.

COVID19 VACCINE (COVID19)

Death 65+ years

She had the first dose of Pfizer vaccine at the Campus on Friday 1/15 at 4:30 pm. After the vaccine, she had no new symptoms or signs of vaccine reaction and MD friend reports that he checked her pulse which was not elevated from baseline. On 1/16, she awakened and continued to feel at her recent baseline. However, in the early afternoon, she complained of headache, nausea/epigastric pain, and chest heaviness. These apparently were not unusual symptoms for her to feel intermittently. Per her niece, who has a home O2 sat device, her O2 sat that morning was 97 with a HR of 87 irregularly irregular. She was afebrile. (continue on page 2)

COVID19 VACCINE (COVID19)

Death 65+ years

Patient was vaccinated in right arm. Within 5 to 10 seconds after vaccination, patient started clinching his hands tightly and became unresponsive. Patient was lowered to the floor and did not exhibit a pulse. CPR was initiated and 911 was called. An AED was used and healthcare professionals onsite continued compressions until the paramedics arrived.

COVID19 VACCINE (COVID19)

Death 65+ years

Death

COVID19 VACCINE (COVID19)

Death 65+ years

Resident received vaccination on January 15, 2021. She was found unresponsive with shallow respirations on the morning of January 16, 2021 and was sent to ER via ambulance. The resident was admitted to medical center ICU where she passed away later that day.

COVID19 VACCINE (COVID19)

Death 65+ years

resident had a pressure ulcer to RT hip, was getting treatment on. Was scheduled to have wound debrided and wound vac applied on 1-19-2021. Appetite was poor, not wanting to get out of bed, and decline in alertness. Passed away on 1-16-2021

COVID19 VACCINE (COVID19)

Death 65+ years

patient received vaccine 12/29. Unexpected death 1/5.

COVID19 VACCINE (COVID19)

Death 65+ years

Patient died 1 week after vaccination. According to family was having very rapid decline in status in recent weeks and they did not think related to vaccination.

COVID19 VACCINE (COVID19)

Death 65+ years

Systemic: Pt monitored by nursing for 30min after inj, pt was stable/no reaction. At ~1hr post inj pt was unresponsive. Pt was a hospice/dnr per director

COVID19 VACCINE (COVID19)

Death 65+ years

12/28/2020: generalized weakness and fell twice at home, cough, nausea, 1/04/2021: cough, nausea, fever and chronic pain when she fell from being weak. admitted to hospital with Covid pneumonia, shortness of breath, covid positive, 1/09/2021: pt on bipap, 1/15/2021: pt was intubated, on TPN, pt DNR, 1/18/2021: was extubated and put on comfort measures and passed away

COVID19 VACCINE (COVID19)

Death 65+ years

Family was told that Patient expired in his sleep during the early morning hours of 1/15. I spoke with him the evening before (on 1/14), which was a day after he had received the Covid vaccine. He was not having any symptoms of allergy or reaction then. He did say that he felt tired, but he often complained of feeling tired over time.

COVID19 VACCINE (COVID19)

Death 65+ years

Resident was noted unresponsive, no respiration, no blood pressure, no pulse, code blue called according to facility protocol, resident is full code, CPR started, 911 called, arrived and took over from staff. Resident was pronounced dead at 1:16pm 1/18/21

COVID19 VACCINE (COVID19)

Death 65+ years

Resident was found deceased in his bed at 7:15 am.

COVID19 VACCINE (COVID19)

Death 65+ years

mi Narrative: patient with asymptomatic covid 19, covid positive 12/10/2020.

COVID19 VACCINE (COVID19)

Death 65+ years

COVID 19 vaccine, unknown which company Chronically ill in a skilled nursing facility found diaphoretic, hypotensive, hypoxia to 85% arrived to Emergency dept in cardiac arrest Died within 65 minutes of nursing finding patient in distress Wife felt it may have been related to vaccine date of vaccination 1/6/20 hx covid 19 PNA in April 2020

COVID19 VACCINE (COVID19)

Death 65+ years

hypoxia, secretions,cough, dyspnea Narrative: ALS patient on hospice with ongoing history of aspiration pna, receiving tube feeds. Developed incr in secretions, hypoxeia, temp and with recently noted clogged feeding tube.

COVID19 VACCINE (COVID19)

Death 65+ years

The patient had severe shortness of breath resulting in cardiac arrest on the 5th day after the vaccine. Shortness of breath started 12 hours after injection. On the 5th day, the patient was discovered to also have a rash throughout his body, but it is unknown when this rash started.

COVID19 VACCINE (COVID19)

Death 65+ years

Sudden death without warning symptoms 4 days after vaccine. Many medical problems which most likely explain the outcome but spouse feels it is related and it is a new vaccine. Monitor for pattern?

COVID19 VACCINE (COVID19)

Death 65+ years

Presented to Urgent Care for weakness and confusion, transferred to ED, patient had a cardiac arrest and was unable to be resuscitated

COVID19 VACCINE (COVID19)

Death 65+ years

Started with cough, mild shortness of breath and feeling terrible in evening of 1/19.

COVID19 VACCINE (COVID19)

Death 65+ years

Patient has end stage renal disease and rapidly worsening dementia, family could no longer care for him at home, and he was admitted for 14-day quarantine prior to admission to inpatient hospice. Received vaccine on 1/12 without apparent adverse reactions. Patient started refusing oral intake on 1/16, and CMP on 1/17 showed hypernatremia 165 (new issue). His BUN 138 CREAT 6.93 K 5.2 were his baseline. He was found to be deceased on 1/18 at 11:18 pm.

COVID19 VACCINE (COVID19)

Death 65+ years

Resident was noted to have increase weakness on 1/15/2021. Resident was warm to touch with low grade fever of 99.3 F. Resident was up propelling self in w/c on 1/16/2021 he was pleasant, accepted medications and ate lunch. He was found slumped over in his w/c not responding and vital signs absent.

COVID19 VACCINE (COVID19)

Death 65+ years

Death on 1/15/2020

COVID19 VACCINE (COVID19)

Death 65+ years

Sudden Death within 24 hours of vaccine

COVID19 VACCINE (COVID19)

Death 65+ years

Hemorrhagic Stroke, Right Basal Ganglion

COVID19 VACCINE (COVID19)

Death 65+ years

On 1/9/2021 observed with elevated respirations of 38-42 per minute, BP manually 72/50. pulse is jumping rapidly between 110-16 bpm. oxygen sat 76% RA, resident refusing oxygen at first attempt, allowed oxygen to be placed, is now 84% on 4L. resident shaking head yes that he is hurting, and yes that he would take medication for pain. Dr. notified, branch block. Received order for morphine 2mg per hr as needed for elevated respirations and pain. Dr. also gave orders to D/C Tamsulosin and finasteride. Resident continue with decreased O2 sats and elevated respirations. Absence of vital signs on 1/10/21 at 826PM.

COVID19 VACCINE (COVID19)

Death 65+ years

Unknown as to any correlation with vaccine as this was a hospice patient that was already experiencing decline. Patient became Jaundice for approximately one week prior to expiring.

COVID19 VACCINE (COVID19)

Death 65+ years

Patient received COVID 19 vaccine 01/14/2021. Patient died in his sleep 01/16/2021.

COVID19 VACCINE (COVID19)

Death 65+ years

Patient received COVID-19 vaccination on 1/14/2021. On 1/17/2021, patient was transferred to Hospital s/p multiple cardiac arrests. Patient was hyperkalemic and in acute renal failure at time of transfer. Hyperkalemia was treated, but the patient suffered PEA vs VFib. At the time of transfer, patient was on vasopressin, norepinephrine, and epinephrine. The patient had an EF of 40-45% and elevated troponins. Patient was made DNR and placed on comfort care. Patient passed away on 1/18/2021. Ultimately we suspect that the patients condition was a direct result of his underlying disease states, but wanted to make sure reporting was made available.

COVID19 VACCINE (COVID19)

Death 65+ years

Patient died 4 days after immunization. Probably unrelated to immunization, as patient has been in poor health and was receiving hospice services. I have no details related to his illness or symptoms. Daughter is the HIPAA/emergency contact and will have all the information needed.

COVID19 VACCINE (COVID19)

Death 65+ years

Pt passed away the day after the vaccine was given.

COVID19 VACCINE (COVID19)

Death 65+ years

Patient received her first dose of the Moderna COVID-19 Vaccination on Saturday January 16th 2021 at approximately 12pm. She completed all necessary screening forms and was deemed to be at low risk for serious allergic reactions. She tolerated the vaccination well, and no complications or immediate adverse events occurred. She was observed for a full 15 mins per CDPHE/CDC guidelines and left the Clinic in stable condition after her observation period was complete. On the morning of Tuesday, January 19th, 2021, the patient was found unconscious and unresponsive by her husband. She was transferred by Ambulance to Hospital shortly thereafter. She was diagnosed with a brain bleed that was determined to be inoperable. She was transferred to other Hospital for higher level care. She was seen by neurosurgery and diagnosed with a ruptured aneurysm. She was treated in the ICU for 24 hours, at which point her team determined that the severity of her brain bleed would not respond to treatment. Supportive cares were withdrawn on Wednesday Jan 20th, and she passed away shortly thereafter.

COVID19 VACCINE (COVID19)

Death 65+ years

Resident has increase weakness and lethargy with abnormal labs. He was transferred to the ER. He was admitted to the hospital and treated for worsening AKI and hypotension.

COVID19 VACCINE (COVID19)

Death 65+ years

Per Nursing Staff- patient died within 24 hours of receiving the vaccine. patient has hospice. Please contact director of nursing for more details.

COVID19 VACCINE (COVID19)

Death 65+ years

per staff at facility patient died 24 hours post vaccination. Please contact Director of Nursing for further details.

COVID19 VACCINE (COVID19)

Death 65+ years

"Narrative: Patient seen in ED 1-17-21 with c/c of ""bloated with epigastric pain"". Patient with complicated medical history including stage 1B pancreatic cancer (was currently on chemotherapy mFOLFIRINOX), and a leadless permanent pacemaker implantation on 1-11-21 for long episodes of SR with complete heart block following symptoms of syncope (other cardiac history: CAD s/p CABG 2009, PAF, and HTN). Regarding ER visit for epigastric pain, nothing notable was found on workup and patient was to discharge home to rest. There were available doses of COVID-19 Vaccine following a vaccine clinic that same day, and patient was offered and agreed to a dose of vaccine. Patient was monitored for 15 minutes post vaccine with no notable issues. The following day, Monday 1-18-21, patient's caregiver called facility at 22:30 to report he had a fever of 102.8 degrees and that he had been ""feeling kind of bad all day"". Patient was advise to seek urgent medical care and reported back to ED on 1-19-21 at 00:55. Patient was admitted for SIRS (tachycardia and febrile) -- patient also reported diffuse myalgia. WBC WNL, CXR unremarkable for infection, UA neg for bacteria, LFTs WNL, blood cultures negative. Procalcitonin elevated at 17.8 -- suggesting inflammatory response. Patient initially reported feeling better on the morning of 1-19-21, but around 13:00 began rapidly declining (confusion, unable to walk) and started

experiencing EKG changes (9 beats of SVT). Patient then coded and resuscitation was attempted for approximately 30 minutes. Patient did not survive the code. Coroner has been notified and family is considering autopsy at time of this report."

COVID19 VACCINE (COVID19)

Death 65+ years

"died; tested positive for COVID; tested positive for COVID; This is a spontaneous report from a contactable consumer from a Pfizer-sponsored program, Pfizer First Connect. A 97-year-old male patient received the first dose of the bnt162b2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), via an unspecified route of administration on 30Dec2020 at 97-years-old at a single dose for COVID-19 immunization; administered by the nursing home. Medical history included glaucoma from an unknown date and unknown if ongoing. Concomitant medications included: ""used a sav for skin tears"", and ""eye drops for glaucoma"" from an unknown date to an unknown date. On 07Jan2021, the patient experienced: tested positive for COVID (medically significant). The patient died (death, medically significant) on 17Jan2021. The clinical course was reported as follows: The reporter stated that in regard to the patient's height and weight: ""was probably getting down to about five foot eight. Shrinking."" The reporter stated that if she remembered correctly, they were trying to maintain the patient's weight 135 to 136 pounds. The reporter stated that her father was in a nursing home. The patient received his first dose of the COVID vaccine on 30Dec2020. The patient died on 17Jan2021. The reporter stated that she ""wanted Pfizer to know that the little old people in the nursing might not be strong enough for the vaccine."" The reporter stated that she was ""not calling to complaining."" The reporter stated that there was nothing wrong with her dad. He was elderly with no health issues. ""He was literally on no medications. The only reason he was in the nursing home was because he was afraid to walk."" The reporter stated that she received a call about giving the patient the vaccine and she said yes because she wanted him to have the vaccine. One week after the vaccine, the patient tested positive for COVID ""like all the other people"" (no further details provided). The reporter stated that her dad had no symptoms of COVID. The director of nursing said the patient was doing so well. The patient ate his lunch, he laid down for nap, and at 14:30 he was gone. The patient ""went peacefully in his sleep."" The reporter then again stated that the patient literally had nothing wrong with him. ""They were shocked. They fed him and he took a nap. He was sleeping, but it was eternally."" The reporter stated that, ""it might not have been the Pfizer vaccine, maybe his heart wore out."" In regard to an autopsy: the reporter stated that they would get it done if needed. The patient underwent lab tests and procedures which included COVID-19 virus test: positive on 07Jan2021. History of all previous immunization with the Pfizer vaccine considered as suspect: none. It was unknown if there were additional vaccines administered on the same date of the Pfizer suspect, but the reporter doubted it. There were no prior vaccinations within 4 weeks. There were no adverse events following the prior vaccinations. The clinical outcome of the event, died, was fatal. The clinical outcome of the event, tested positive for COVID, was unknown. The patient died on 17Jan2021 due to an unknown cause of death. An autopsy was not performed. The batch/lot numbers for the vaccine, PFIZER-BIONTECH COVID-19 MRNA VACCINE, were not provided and will be requested during follow up.; Reported Cause(s) of Death: died"

COVID19 VACCINE (COVID19)

Death 65+ years

At approximately 930am I arrived at Memory Care. I met with the director of the facility and she directed me to where my team would be setting up. My team consisted of (technician), (nurse) and I. As we were setting up, the director asked how she can help. I explained to her that we would need a designated area for patients to be monitored after vaccination for 15 minutes and maybe even longer. I also explained that we would need one of her staff monitoring while we vaccinate. She agreed, and proceeded to designate her staff and the cafeteria area, facing the vaccination station, the monitoring station. Throughout the day, nurse and I were both vaccinating, while the staff of the facility would monitor the vaccinated patients. I would also stop occasionally to mix the vaccine and check the temperature of the aero safe. At approximately 12:50pm, the director rushed in and stated that a patient is not responding, and that she had been vaccinated. At that point, I grabbed epipens and a thermometer and I also instructed nurse to grab an Epipen and come with me. We followed the director to pt's room. Once we got to the room, the patient was in bed and there were 4 staff members standing bedside and one of them turned and stated the patient has passed. At that point I asked the staff how long ago did the patient get the vaccine, they stated about 30 minutes ago. They also stated that the patient was a hospice patient and that the patient had declined, and was rapidly deteriorating and had not eaten or drank anything all day. They also stated that the patient had been monitored for 15 minutes post vaccination. I then left the room and grabbed the patient's COVID Vaccine intake consent form. I looked at the answered questionnaire and all the responses were circled NO. Patient had a temp of 96.5 at the time of vaccination. The vaccine administration information for Immunizer Section was filled out by Nurse. I then proceeded to ask the director once again if there were staff that was monitoring her for 15 minutes, the director stated they had staff monitoring her. She also stated the Hospice nurse has to announce her death, so they waited for the Hospice Nurse to come. I then called Corporate and explained the situation. After speaking to corporate, I also asked nurse, if she remembered the patient. She

stated that she did and at the time of the vaccination the patient was not alert, there were two staff members with the patient. She was non oriented and she kept closing her eyes. At that point, Nurse stated that she asked the two staff members with her if this is how she usually is and if its ok to vaccinate her. Both Staff members stated that it its ok,this is how she is. The Nurse then proceeded to vaccinate. At approximately 3:10pm, as I was leaving I spoke to the director, and one of her Staff members. Staff that the patient has actually not eaten/ or drank anything for the past several days, including today(01/18/21). Staff also stated that on Friday, Jan 15th,2021, they had informed the family that the patient was rapidly deteriorating. Staff also stated that the family knowingly gave the consent to vaccinate her. She also stated that the hospice Nurse believes that the death was primarily caused by her deteriorating state. She also stated that the hospice Nurse informed that the death was not due to the Vaccine. Per Lead Pharmacist at the clinic.

COVID19 VACCINE (COVID19)

Death 65+ years

Extreme Fatigue

COVID19 VACCINE (COVID19)

Death 65+ years

Resident returned to the memory support unit at 1500. Resident was than toileted and transferred in to bed per his request. At 1515 resident was observed face down beside bed, resident sustained a 1inX1in ecchybotic/hematoma to the forehead. Neuro Checks with in normal limes Vital signs: 100/52, 100, 97.2, 28. Resident sent to ED for further medical evaluation via EMS.

COVID19 VACCINE (COVID19)

Death 65+ years

This is a 94-year-old male who is brought in by ambulance after being found on the floor with unknown downtime. He was in asystole upon EMS arrival. He remains in asystole. No advanced airway is in place. The patient is getting compressions from Lucas device upon arrival. It was reported that he was last talked to by family at 2 PM. The patient got his SARS-CoV-2 vaccination this morning. The patient is evaluated emergently. CPR was ongoing with 3 rounds of epinephrine given. The patient remains in asystole. He has rigor mortis. The patient's pupils are fixed and dilated. The patient has compressions paused and ultrasound is used to evaluate for cardiac activity. None is detected. The patient has no electrical activity on monitor. The patient's time of death is 2113.

COVID19 VACCINE (COVID19)

Death 65+ years

The patient received his vaccine in the am morning of 1/20/2021, while getting into a car to go see his pulmonologist, about 2 hours after onset prior to other than chronic dyspnea. No allergic type symptoms reported by family. Asystole with EMS, no response to ACLS, ap

COVID19 VACCINE (COVID19)

1/13/2021 12:00 PM: Patient received COVID-19 Vaccine. 1/14/2021 21:00: Nurse performed routine rounds and the patient appeared okay. 1/14/2021 22:00: CNA discovered patient unresponsive in bed, began CPR, and called 911. 1/14/2021 23:08: Pronounced deceased.

COVID19 VACCINE (COVID19)

Death 65+ years

Narrative:

COVID19 VACCINE (COVID19)

Death 65+ years

"Narrative: Was pt previously covid positive?- Yes. Initial- 10/27/2020, 11/29/2020, 12/22/2020 Are there any predisposing factors for patient experiencing adverse drug event?- Yes, patient had multiple co-morbidities including GI bleed, hepatitis congestion due to cardiac issues, treatment for PE, NSTEMI, or antibiotics for PNA, also on concurrent medications APAP, Atorvastatin, Mirtazapine and Duloxetine. Pt with 2 doses of covid-19 vaccine, second one on 01/08/2021, 2 days pre-death Any occurrence of an ADR at time of administration? Did not specify injection site issues, per RN admin note- Vaccine ""administered without complications."" Did patient recover from event? Not s/p dose on 01/08/2021. First dose given on 12/21/2021, LFTS increased ~01/01/2021, peaked on 01/03/2021 and were decreasing on 01/07/2021 Was there an ADR between observation period and date of death? No Did patient recover from event? No (01/08/2021 event, died 01/10/2021) Was patient hospitalized prior to vaccination? Yes, in between inpatient and nursing home Was patient hospitalized prior to death--was hospitalization attributable to ADE? Yes re-admitted to inpatient on 12/31/2020. GI bleed Is there an alternative cause of death? Yes, as noted above. Quite a complicated case with many comorbidities/concurrent medications as noted above. Primary Diagnosis: Upper GI Bleed in the death note from 01/10/2021"

COVID19 VACCINE (COVID19)

Death 65+ years

tired; legs felt heavy; stopped breathing; This is a spontaneous report from a Pfizer-sponsored program a non-contactable consumer. A 93-year-old male patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 04Jan2021 11:00 at single dose for covid-19 immunisation. The patient medical history and concomitant medications were not reported. Patient received vaccine around 11:00 a.m. About two hours later, he said he was tired and couldn't continue with the physical therapy he was doing. He was taken back to his room, where he said his legs felt heavy. Soon after, he stopped breathing. A nurse declared a do-not-resuscitate order. The patient died on 04Jan2021. It was not reported if an autopsy was performed. Outcome of stopped breathing was fatal. Outcome of tired and legs felt heavy was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.; Reported Cause(s) of Death: stopped breathing

COVID19 VACCINE (COVID19)

Death 65+ years

"Called to schedule second vaccine and daughter reports that he died on 01/19/2021 with ""COVID""

COVID19 VACCINE (COVID19)

Death 65+ years

"Patient's wife called this morning stating that her husband has passed away last night. After receiving first dose of Pfizer COVID-19 vaccine at around 0830, patient remained in the Immunizations Department for the 15-minute monitoring period. Per wife, patient's only complaint was pain at the injection site. At 1300, wife states that patient complaint of dizziness which ""dissipated after a few minutes"" followed by a headache which ""dissipated after a few minutes"" as well. Then patient complained of nausea, no vomiting and ""couldn't relax."" Per wife, from around 1400/1500, patient stayed on his recliner while still having a conversation with her--""he didn't get up to eat."" Last conversation they had was around 2000/2100. Per wife, at around 2100/2200, patient was quiet and when she checked on him, ""he wasn't responding anymore."" Wife then called 911, ""but they couldn't revive him.""

COVID19 VACCINE (COVID19)

Death 65+ years

Admitted to hospital after vaccination with Acute hypoxemic respiratory failure, Septic shock; Aneurysm of arteriovenous dialysis fistula; expired 1/16/2021

COVID19 VACCINE (COVID19)

Death 65+ years

We do not believe that the patient's death was an adverse event from the vaccine. Patient received COVID vaccine from Pfizer Dose #1 12/19/2020 (lot # EK5730) and Dose #2 1/7/2021 (lot # EL1284). No side effects or adverse events noted; lived in 24/7 care facility and monitored twice daily for reaction. Patient died 1/10/2021 from chronic respiratory failure and congestive heart failure after recent aspiration pneumonia requiring hospitalization. Death was anticipated and not sudden. We were told to report his death to VAERS even though his death was anticipated and not related to his vaccination.

COVID19 VACCINE (COVID19)

Death 65+ years

Patient did not have any adverse reaction to the COVID vaccine, but we were asked by our health dept to submit a VAERS report since the patient died between his first and second dose. Received Pfizer Dose #1 12/17/2020. No side effects or adverse events noted; lived in 24/7 care facility and monitored twice daily for reaction. Date of death 12/23/2020 from aspiration pneumonia complicated by end-stage heart failure and ischemic cardiomyopathy. Death was anticipated and not sudden.

COVID19 VACCINE (COVID19)

Death 65+ years

patient expired 1/15/2021; had been treated as outpatient for pneumonia, likely COVID-19 but no positive test result in December 2020. PMH diabetes

COVID19 VACCINE (COVID19)

Death 65+ years

Admitted 1/14/21: Patient is an elderly 93-year-old female with multiple medical problems including chronic combined CHF, P 80, diabetes mellitus, HTN, hyperlipidemia, CKD stage 3, has been complaining of generalized weakness, fatigue, decreased appetite for the past few days. She had an outpatient COVID-19 vaccine earlier today. Within 2 hr of admitting the patient to the hospital, condition clinically deteriorated. Patient elected to be DNR/DNI while in the ED. Patient was pronounced dead at 10:30 p.m. earlier today. Preliminary cause of death: Hypoglycemia induced lactic acidosis.

COVID19 VACCINE (COVID19)

Death 65+ years

Pt received second dose of COVID vaccine on 01/20/2021 at 1430. At 1600 Pt developed a wet productive cough with coarse crackles. Pt ate dinner at 5 pm cough persisted. At 18:30 the nurse went to Pt's room to give him his

medications. Pt still had a cough, denied shortness of breath. Pt was in a good mood and joking with staff. Pt asked to be shaved. At 19:45 Pt was sitting in the lounge and a CNA noticed that Pt was pale/white in color and clammy. O2 Sat was 85%. Respirations were labored. Pt was placed on 4 L of O2. Increased to 5 L via face mask and O2 sat was 89-90%. Ambulance was called at unknown time. Pt arrived at Medical Center at 2120 and was pronounced dead at 2127.

COVID19 VACCINE (COVID19)

Death 65+ years

On Saturday, 1/16/2021, Patient went to the grocery store. Upon her return, she indicated she was experiencing N/V and some throat swelling. Patient subsequently collapsed and expired before she could be brought to an emergency room. During investigation by Coroners Office, it has been reported that Patient may have gotten some takeout food while she was out. Labs are pending and the Coroners investigation is ongoing. Spouse believes that her death was caused by the vaccine.

COVID19 VACCINE (COVID19)

Death 65+ years

unknown. Event occurred after leaving vaccination site

COVID19 VACCINE (COVID19)

Death 65+ years

presented to ED 1/9/21 with abdominal pain, progressive worsening weakness and fatigue and new onset A fib with RVR likely due to hypertensive urgency. Patient progressed clinically with severe hypoxia and transferred to ICU and started on BiPAP; progressive decline with decreased urinary output with uremia likely secondary to sepsis. Concern with patient worsening clinical decline, palliative care had been consulted on end of life care. Patient expired 1/17/21

COVID19 VACCINE (COVID19)

Death 65+ years

Narrative:

COVID19 VACCINE (COVID19)

Death 65+ years

Narrative: Symptoms: & Cardiac Arrest; Death Treatment: EPINEPHRINE

COVID19 VACCINE (COVID19)

Death 65+ years

Patient diagnosed with COVID on January 9, 2021 after being exposed to family member that was under quarantine in the same household. Admitted to the hospital and was discharged on January 14, 2021 with home hospice. Patient passed away on January 18, 2021

COVID19 VACCINE (COVID19)

Death 65+ years

Patient passed away on 01/18/2021

COVID19 VACCINE (COVID19)

Death 65+ years

Patient died unexpectedly 5 days after receiving vaccine (1/10/2021).

COVID19 VACCINE (COVID19)

Death 65+ years

Death, which I believe is unrelated to vaccination

COVID19 VACCINE (COVID19)

Death 65+ years

Pt on hospice in facility for severe cardiomyopathy unable to perform interventions received vaccine without adverse sequelae died 5 days later. Reporting as required. Narrative: Reporting as required patient death 5 days after immunization with Pfizer vaccine. However, no adverse sequelae were noted to the vaccine in the 15minute observation period, nor in the days following the immunization related to the vaccine. The patient denied any prior severe reaction to this vaccine or its components, and the patient gave verbal consent to receive the vaccine. Patient had been in the facility on hospice since 11/18/20 for severe decompensated HF and newly diagnosed cardiomyopathy, unable to perform interventions, also LE ischemic wounds with very poor potential to heal due to advanced PVD.

COVID19 VACCINE (COVID19)

Death 65+ years

loss of consciousness; respiratory distress Narrative: Patient tolerated his 1st dose of the COVID-19 vaccine well, on 12/16/2020, and received his 2nd dose on 1/6/2021. Patient had some mild clinical decline the past few days prior to 2nd vaccination, with a decreased appetite and some increased fatigue per nursing report, but no significant changes. He experienced nausea on the evening of 1/6/21, which was effectively managed, but by early morning he spiked a fever of 102.9 with a sat of 86.1%. He continued to deteriorate from that point on and died 1/7/21 @13:20. Clinically, the presentation was most consistent with an aspiration pneumonia.

COVID19 VACCINE (COVID19)**Death 65+ years**

Death on 1-5-21

COVID19 VACCINE (COVID19)**Death 65+ years**

Death 1-15-21

COVID19 VACCINE (COVID19)**Death Unknown**

Cardiac event, 2 days after vaccination, patient expired.

COVID19 VACCINE (COVID19)**Death Unknown**

Death; This is a spontaneous report from a contactable Physician. An elderly male patient received BNT162B2 (COVID vaccine), via an unspecified route of administration on an unspecified date in Dec2020 at single dose for COVID-19 immunisation. The patient's medical history and concomitant medications were not reported. The patient experienced death in Jan2021. It was unknown if an autopsy was performed. It was unknown if any treatment was received for the event. It was unknown if the patient was diagnosed with COVID prior vaccination or if the patient had been tested for COVID post vaccination. Seriousness criteria for the event was reported as death and hospitalization. Pfizer is a marketing authorization holder of [COVID vaccine] in the country of incidence or the country where the product was purchased (if different). This may be a duplicate report if another marketing authorization holder of [COVID vaccine] has submitted the same report to the regulatory authorities. Information about lot/batch number has been requested.; Sender's Comments: Current information is very limited for full assessment. Further information such medical history, concomitant medications, concurrent illness and event term details especially death cause and autopsy results are needed for meaningful evaluation. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.; Reported Cause(s) of Death: Death

COVID19 VACCINE (COVID19)**Death Unknown**

COVID-19; COVID-19; Pneumonia; respiratory failure; This is a spontaneous report from a contactable consumer. An 80-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on 02Jan2021 for COVID-19 immunization. Medical history included Alzheimer's and others. No known allergies. Concomitant medications included unspecified medications. The reporter's mother in law was tested for COVID-19 at a nursing facility on 25Dec2020 and she was negative. On 02Jan2021, she received the first dose of Pfizer vaccine. On 04Jan2020, she developed a high fever, needed oxygen and was positive for COVID-19. Date of death was 04Jan2021. The cause of her death was listed as pneumonia, respiratory failure and COVID-19. No autopsy performed. No treatment received. No one knew if the vaccination contributed to her death. It was hard to know if her death was due to the administration of the vaccine or it exacerbated the COVID19 symptoms which led to her death. Since this was unknown, it could have been a possibility. The reporter wanted to give us this information because we might want to consider having high risk population, patients with underlying conditions, older population tested for COVID-19 prior to the vaccination, as this is not currently a recommendation or a requirement. All is very new and they are all learning so the reporter wanted to share this information with us. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. There are medications the patient received within 2 weeks of vaccination. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient has been tested for COVID-19. The outcome of the events was fatal. Information about Lot/Batch has been requested.; Sender's Comments: The association between the fatal event lack of effect (pneumonia, respiratory failure and COVID-19) with BNT162b2 can not be fully excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.; Reported Cause(s) of Death: Pneumonia, respiratory failure and COVID-19; Pneumonia, respiratory failure and COVID-19; Pneumonia, respiratory failure and COVID-19; Pneumonia, respiratory failure and COVID-19

COVID19 VACCINE (COVID19)**Death Unknown**

died; This is a spontaneous report from a non-contactable consumer via a Pfizer-sponsored program. A patient of unspecified age and gender received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, via an unspecified route of administration on an unspecified date at single dose for covid-19 immunisation. The

patient medical history and concomitant medications were not reported. It was reported the patient was a doctor, died after the vaccine with no apparent disease. It was not reported if an autopsy was performed. No follow-up attempts are possible. Information about lot/batch number cannot be obtained.; Reported Cause(s) of Death: Unknown cause of death

COVID19 VACCINE (COVID19)

Death Unknown

thrombopenia; pulmonary embolism; neutropenia fever; This is a spontaneous report from a Pfizer-sponsored program . A contactable consumer reported for a patient that received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), via an unspecified route of administration on an unspecified date at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced thrombopenia, pulmonary embolism and neutropenia fever on an unspecified date. The clinical outcome of thrombopenia, pulmonary embolism and neutropenia fever was fatal. The patient died on an unspecified date. It was unknown if an autopsy was performed. The batch/lot number for the vaccine, BNT162B2, was not provided and will be requested during follow-up.; Reported Cause(s) of Death: thrombopenia; pulmonary embolism; neutropenia fever

COVID19 VACCINE (COVID19)

Death Unknown

Resident expired

COVID19 VACCINE (COVID19)

Death Unknown

his platelet levels dropped and he had a hemorrhagic stroke; his platelet levels dropped and he had a hemorrhagic stroke; This is a spontaneous report from a contactable consumer. A male patient of unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The relevant medical history and concomitant medications were not reported. The patient died 2 weeks after his COVID shot because his platelet levels dropped and he had a hemorrhagic stroke. No further information provided. The autopsy was unknown. The outcome of the events was fatal. Information on the lot/ batch number has been requested.; Reported Cause(s) of Death: his platelet levels dropped and he had a hemorrhagic stroke; his platelet levels dropped and he had a hemorrhagic stroke

COVID19 VACCINE (COVID19)

Death Unknown

expired before receiving the second dose; This is a spontaneous report from a contactable nurse. This nurse reported similar death events for 8 patients. This report is for 5th of 8 patients. A patient of unspecified age and gender received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on 22Dec2020 at single dose for COVID-19 immunisation. The patient medical history and concomitant medications were not reported. The patient expired before receiving the second dose on an unspecified date. The patient died on an unspecified date. It was unknown if an autopsy was performed. Information on the lot/batch number has been requested.; Sender's Comments: The limited information provided in this report does not allow a full assessment of the case. The event death with unknown cause is assessed as related to the suspect drug per company guidance. This case will be reassessed when additional information, particularly the clinical course before death, complete medical history and concomitant medication and autopsy report, becomes available.; Linked Report(s) : US-PFIZER INC-2021034595 same drug, reporter and event but different patient; Reported Cause(s) of Death: expired before receiving the second dose

COVID19 VACCINE (COVID19)

Death Unknown

passed unexpectedly; This is a spontaneous report from a contactable nurse communicated to a Pfizer colleague. This nurse reported similar death events for 8 patients. This report is for 8th of 8 patients. A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on 22Dec2020 at single dose for COVID-19 immunisation. The patient medical history and concomitant medications were not reported. The patient passed unexpectedly on an unspecified date. The patient died on an unspecified date. It was unknown if an autopsy was performed. Information on the lot/batch number has been requested.; Sender's Comments: The limited information provided in this report does not allow a full assessment of the case. The event death with unknown cause is assessed as related to the suspect drug per company guidance. This case will be reassessed when additional information, particularly the clinical course before death, complete medical history and concomitant medication and autopsy report, becomes available. The case will be reassessed if additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.; Linked Report(s) : US-PFIZER INC-2021034595 same drug, reporter and

event but different patient; Reported Cause(s) of Death: passed unexpectedly

COVID19 VACCINE (COVID19)

Death Unknown

expired before receiving the second dose; This is a spontaneous report from a contactable nurse. This nurse reported similar death events for 8 patients. This report is for 1st of 8 patient. A patient of unspecified age and gender received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 22Dec2020 at single dose for covid-19 immunisation. The patient medical history was and concomitant medications were not reported. The patient expired before receiving the second dose on an unspecified date. It was not reported if an autopsy was performed. Information about Lot/Batch number is requested.; Sender's Comments: Current information is very limited for full assessment. The patient died following the vaccine use; further information such as patient demographics, complete medical history, concomitant medications, concurrent illness and event term details especially death cause and autopsy results are needed for meaningful evaluation. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.; Linked Report(s) : US-PFIZER INC-2021034597 same drug, reporter and event but different patient;US-PFIZER INC-2021034598 same drug, reporter and event but different patient;US-PFIZER INC-2021034599 same drug, reporter and event but different patient;US-PFIZER INC-2021034600 same drug, reporter and event but different patient;US-PFIZER INC-2021034601 same drug, reporter and event but different patient;US-PFIZER INC-2021034603 same drug, reporter and event but different patient.; Reported Cause(s) of Death: expired before receiving the second dose

COVID19 VACCINE (COVID19)

Death Unknown

expired before receiving the second dose; This is a spontaneous report from a contactable nurse. This nurse reported similar events for 8 patients. This report is for 2nd of 8 patients. A patient of unspecified age and gender received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 22Dec2020 at single dose for covid-19 immunisation. The patient medical history and concomitant medications were not reported. The patient expired before receiving the second dose on an unspecified date. It was not reported if an autopsy was performed. Information about Lot/Batch number is requested.; Sender's Comments: Current information is very limited for full assessment. The patient died following the vaccine use; further information such as patient demographics, complete medical history, concomitant medications, concurrent illness and event term details especially death cause and autopsy results are needed for meaningful evaluation. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.; Reported Cause(s) of Death: expired before receiving the second dose

COVID19 VACCINE (COVID19)

Death Unknown

expired before receiving the second dose; This is a spontaneous report from a contactable nurse. This nurse reported similar events for 8 patients. This report is for 3rd of 8 patients. A patient of unspecified age and gender received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 22Dec2020 at single dose for covid-19 immunisation. The patient medical history and concomitant medications were not reported. The patient expired before receiving the second dose on an unspecified date. It was not reported if an autopsy was performed. Information about Lot/Batch number is requested.; Sender's Comments: Based on the reasonable temporal association, the Company cannot completely exclude the possible causality between the reported death and the administration of COVID 19 vaccine, bnt162b2. However, more information on the patient's underlying medical condition, concomitant medications, patient's age group, clinical course and relevant lab tests would be helpful for the Company to make a more meaningful causality assessment. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RA, IEC, as appropriate.; Reported Cause(s) of Death: expired before receiving the second dose

COVID19 VACCINE (COVID19)

Death Unknown

expired before receiving the second dose; This is a spontaneous report from a contactable nurse. This nurse reported similar events for 8 patients. This report is for 4th of 8 patient. A patient of unspecified

age and gender received the first dose bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 22Dec2020 at single dose for covid-19 immunization. The patient's medical history and concomitant medications were not reported. The patient expired before receiving the second dose on an unspecified date. The patient died on an unspecified date. It was not reported if an autopsy was performed. Information about Lot/Batch number has been requested.; Sender's Comments: Current information is very limited for full assessment. The patient died following the vaccine use; further information such as patient demographics, complete medical history, concomitant medications, concurrent illness and event term details especially death cause and autopsy results are needed for meaningful evaluation. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.,Linked Report(s) : US-PFIZER INC-2021034595 same drug, reporter and event but different patient; Reported Cause(s) of Death: expired before receiving the second dose

COVID19 VACCINE (COVID19)

Death Unknown

7 residents expired before receiving the second dose; This is a spontaneous report from a contactable nurse. This nurse reported similar events for 8 patients. This report is for 6th of 8 patients. A patient of unspecified age and gender received first dose bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date at SINGLE DOSE for covid-19 immunisation. The patient's medical history and concomitant medications were not reported. The patient expired before receiving the second dose on an unspecified date. It was not reported if an autopsy was performed. Information on the lot/batch number has been requested.; Sender's Comments: The event death is assessed as related to BNT162b2 vaccine and documented as such in the global safety database until sufficient information is available to allow an unrelated causality assessment. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.,Linked Report(s) : US-PFIZER INC-2021034595 same drug, reporter and event but different patient; Reported Cause(s) of Death: 7 residents expired before receiving the second dose

COVID19 VACCINE (COVID19)

Death Unknown

expired before receiving the second dose; This is a spontaneous report from a contactable nurse. This nurse reported similar death events for 8 patients. This report is for 7th of 8 patient. A patient of unspecified age and gender received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 22Dec2020 at single dose for covid-19 immunisation. The patient medical history was and concomitant medications were not reported. The patient expired before receiving the second dose on an unspecified date. It was not reported if an autopsy was performed. Information about Lot/Batch number is requested.; Sender's Comments: Current information is very limited for full assessment. The patient died following the vaccine use; further information such as patient demographics, complete medical history, concomitant medications, concurrent illness and event term details especially death cause and autopsy results are needed for meaningful evaluation. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.,Linked Report(s) : US-PFIZER INC-2021034595 same drug, reporter and event but different patient; Reported Cause(s) of Death: expired before receiving the second dose

COVID19 VACCINE (COVID19)

Death Unknown

platelets dropped so low/thrombocytopenia; Hemorrhagic stroke/brain hemorrhage; This is a spontaneous report from a contactable nurse. A 56-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on 18Dec2020 at single dose for covid-19 immunisation. Medical history and concomitant medications were unknown. The reporter read about the doctor that died that developed thrombocytopenia after taking the vaccine, stated it was in the news yesterday. The patient received the Pfizer Covid vaccine on 18Dec2020, and he died 16 days later from a brain hemorrhage. Autopsy stated that said he had a hemorrhagic stroke on 03Jan2021. His platelets dropped so low that he had specialists that tried to get his platelet count back up again and they could not get his platelets back up again and he ended up having the hemorrhagic stroke. The reporter already had thrombocytopenia and she was debating what she should do about getting vaccine. Outcome

of the events was fatal. Information on the lot/batch number has been requested.; Sender's Comments: Very limited information is currently available. Lacking patient's underlying medical conditions, clinical course, relevant lab data, the Company cannot make a meaningful causality assessment. The reported hemorrhagic stroke following low platelet count are managed as related to the suspect, BNT162B2, for reporting purpose only. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RA, IEC, as appropriate.; Reported Cause(s) of Death: Hemorrhagic stroke/brain hemorrhage; platelets dropped so low/thrombocytopenia

COVID19 VACCINE (COVID19)

Death Unknown

died; This is a spontaneous report from a Pfizer-sponsored program. A contactable consumer reported that an 83-year-old female patient (reporter mother) received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection), via an unspecified route of administration on an unspecified date at single dose for covid-19 immunization. Medical history included hospice care and dementia. The patient's concomitant medications were not reported. The patient died one day after getting vaccine. She was reportedly in good health the day before receiving vaccine. She was on hospice, frail, but in good condition and checked by a hospice nurse the day before which she reported her in good health considering. She was with dementia but stable in her health. The reporter read investigating 23 deaths of people receiving vaccine in similar conditions. The patient died on an unspecified date. It was not reported if an autopsy was performed.; Reported Cause(s) of Death: died

COVID19 VACCINE (COVID19)

Death Unknown

Death; This is a spontaneous report from four non-contactable consumers via a Pfizer-sponsored program Corporate (Pfizer) Social Media Platforms. A 78-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), via an unspecified route of administration, on 28Dec2020 at a single dose for COVID-19 immunization. Ongoing medical history included Alzheimer's Disease, encephalopathy, hypertension, acute kidney failure, urinary retention and recent urinary tract infection (UTI), all from an unspecified date. Concomitant medication included acetaminophen (MANUFACTURER UNKNOWN), bisacodyl (MANUFACTURER UNKNOWN), bupropion (MANUFACTURER UNKNOWN), escitalopram (MANUFACTURER UNKNOWN), hydrocodone bitartrate, paracetamol (HYDROCODONE/ACETAMINOPHEN), loperamide (MANUFACTURER UNKNOWN), ondansetron (MANUFACTURER UNKNOWN), senna alexandrina (SENNA PLUS), vitamin d3 (MANUFACTURER UNKNOWN). The patient had no known drug allergies. The patient experienced death on 30Dec2020. The vaccine was given on 28Dec2020 with no adverse events and no issues on 29Dec2020. The patient died on 30Dec2020, at approximately 2:00 AM. It was unknown if an autopsy was performed. It was unknown if the event was related to the suspect drug, the administrator marked as natural causes. No follow-up attempts are possible; information about batch/lot number cannot be obtained.; Reported Cause(s) of Death: Death

COVID19 VACCINE (COVID19)

Life Threatening 6-17 years

Administered first dose of COVID19 vaccine at 1:29pm on 1/4/21. At approximately 11:00pm resident exhibited acute respiratory decompensation with very limited air entry and hypoxemia. Patient received Benadryl, steroids, epinephrine, and Duoneb without improvement. Resident was referred to the emergency room and found to be COVID positive. No fever or rash were reported.

COVID19 VACCINE (COVID19)

Life Threatening 18-29 years

Swelling of hands followed by angioedema

COVID19 VACCINE (COVID19)

Life Threatening 18-29 years

Angioedema, hives, tachycardia, shortness of breath

COVID19 VACCINE (COVID19)

Life Threatening 18-29 years

throat swelling, SVT

COVID19 VACCINE (COVID19)

Life Threatening 18-29 years

O had the vaccine at 9 am this morning waited 15 mins after vaccine before leaving while driving I had a pounding heart rate and hot I rolled down the window felt better. 1 hour later while at home.e started with nausea diarrhea rapid heart rate headed to medical office while in care tongue swelled I called 911 pulled over when the ambulance got to me my throat swelled and I had hives on chest they took me emergency while there I had sever pounding heart and vomiting treated with meds sent

home with medication and benadryl

COVID19 VACCINE (COVID19)	Life Threatening	18-29 years
<p>"Patient was monitored for >15 minutes after vaccination. Patient told a nurse that her knees felt weak. Patient then fainted and was laying on the floor when i arrived. Patient reported she felt like she was ""floating"" and she did not want to ""fall"". She was also nausea and wanted to vomit and did not end up vomiting anything up. Patient fainted several more times. Her BP was around 143/80 and unsure about the pulse. Patient then become unresponsive for 20-30 seconds."</p>		
COVID19 VACCINE (COVID19)	Life Threatening	18-29 years
<p>Pt developed anaphylaxis, was given IM Benadryl, and was sent to the ED. Pt spent 1 night in the hospital, went home, and has come back and is in the ICU. Pt had hives, itching, chest tightness, swollen lips.</p>		
COVID19 VACCINE (COVID19)	Life Threatening	18-29 years
<p>10 minutes after receiving vaccine, patient reported numbness across upper lip which progressed to her tongue. Felt tingling and dryness of tongue and swelling. No difficulty breathing or swallowing, no chest pain, no wheezing, no rash, no itching. Taken to ED and given methylprednisolone 125mg IV, diphenhydramine 50mg IV, famotidine 20mg PO. Patient improved and monitored x 4 hours with resolution of symptoms. Prescribed prednisone 50mg po x 4 days.</p>		
COVID19 VACCINE (COVID19)	Life Threatening	18-29 years
<p>Acute appendicitis, onset morning of 1/1/2021 (Reporting this because Pfizer covid vaccine had 3-4x higher risk of appendicitis, although data not reported for Moderna covid vaccine)</p>		
COVID19 VACCINE (COVID19)	Life Threatening	18-29 years
<p>Within 15 minutes of receiving the vaccine I began to get very itchy and blotchy with a hoarse voice. The paramedic downstairs walked me up to the emergency room. I was treated with medications to help calm the itching and burning feeling. By 940 I went anaphylactic and had several doses of epinephrine to help calm this. I continued to have rashes and the feeling of my throat closing. I was transferred by ambulance to medical center in the ICU. I am still here and have had two toner anaphylactic episodes since. I have been on a epi drip, steroids, famotidine, Ativan and Benadryl. I also had a picc line placed.</p>		
COVID19 VACCINE (COVID19)	Life Threatening	18-29 years
<p>Anaphylaxis. The COVID shot was given, no reaction then. After 7 minutes, congestion, severe cough, vomiting phlegm, feeling like throat closing started happening. Code was called, Benadryl was immediately given intramuscular in the left arm, blood pressure, pulse ox was taken, and then was taken to the Emergency Department. In the ED, I was given prednisone, one EPI, anti-nausea medication all through I.V. and many more medications given to me via I.V. that I don't sincerely remember. I was under observation for 4 hours. I was discharged after all symptoms dissipated and was given Prednisone 20 MG (3 tabs a day) to take to help my lungs. Management followed up almost immediately, everyone from the moment I had the anaphylactic reaction was quick and prepared.</p>		
COVID19 VACCINE (COVID19)	Life Threatening	18-29 years
<p>Tactile fever ,arm pain, headache and malaise in 24 hrs following injection Next day generalized achiness ,retrosternal chest pain and bilateral forearm tingly pain similar to Nov 2019 and went to Hospital UC,CXR and EKG normal but with short PR interval on EKG ,elevated troponin 3.5 Transferred to hospital troponin 12.1 ng/ml IVIG given SARS IGG positive on admission PCR negative</p>		
COVID19 VACCINE (COVID19)	Life Threatening	18-29 years
<p>Employee received COVID 19 vaccination at 9:45am on 12/30/20. ~15 min. later she developed a rash down her left arm, then down her Rt. arm. about 4 hours later she decided to go to the emergency room for Hearty Palpitations, Fever, Chest discomfort and feeling of generalized sunburn. Later developed severe headache..</p>		
COVID19 VACCINE (COVID19)	Life Threatening	18-29 years

			years
Swelling of throat and tongue, anaphylaxis, hives, redness, swelling	COVID19 VACCINE (COVID19)	Life Threatening	18-29 years
Severe thrombocytopenia (plts 3k/uL), oral mucosal bleeding, bruising	COVID19 VACCINE (COVID19)	Life Threatening	18-29 years
Scratchy throat, dizziness and eventually feeling like her throat is closing in	COVID19 VACCINE (COVID19)	Life Threatening	18-29 years
Approx 10-15 post vaccine, employee said she felt lightheaded and like her heart was racing. Within 10 minutes she said she felt difficulty breathing, She then vomited. The observation nurse at the clinic administered Epi Pen and called a Code. The employee was transported to the Emergency Dep't and then to intensive care. She was placed on an Epi drip.			
	COVID19 VACCINE (COVID19)	Life Threatening	18-29 years
Patient presented with myalgias, fevers, and chest pain on 1/10/21 and was found to have diffuse ST elevation and elevation troponin. He was evaluated by cardiology and diagnosed with acute myopericarditis. He was treated with NSAIDs and colchicine. He improved with this treatment and was discharged on 1/12/21 with ibuprofen and colchicine and outpatient cardiology follow up.			
	COVID19 VACCINE (COVID19)	Life Threatening	18-29 years
Blurred vision, difficulty breathing (pale skin/blue lips), profuse sweating, muscle fatigue, headache. This lasted about 15 minutes. Until severity went down. Followed by 20 minutes of profuse sweating and headache. I thought I was going to die			
	COVID19 VACCINE (COVID19)	Life Threatening	18-29 years
Employee was awoken at 5:30 am on 1/13/2021 by chills and a feverish feeling. She then became nauseous and faint. She passed out and was noted by her mother who is a RN to have a seizure. She remained out for several minutes and then aroused. She has remained groggy the rest of today but has improved. She has a history of non-epileptic seizures since she was 14 and has been on medications for this. Employee stated she has not has any seizure activity in over a year. She did not see medical attention due to recovering quickly from this.			
	COVID19 VACCINE (COVID19)	Life Threatening	18-29 years
she was diagnosed with bilateral deep vein thrombosis (DVT) and pulmonary embolism (PE); she was diagnosed with bilateral deep vein thrombosis (DVT) and pulmonary embolism (PE); This is a spontaneous report from a contactable nurse (patient). A 22-year-old female patient received 2nd dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot# EK9231), via an unspecified route of administration in left arm on 06Jan2021 13:45 at single dose for COVID-19 immunisation. Medical history included allergy to all fish, and clots. The patient was not pregnant. There were no concomitant medications. The patient previously received 1st dose of BNT162B2 (lot numer: EH9899) in left arm on 16Dec2020 13:45 for COVID-19 immunisation and experienced left sided lower back pain on 20Dec2020. No other vaccine received in four weeks. It was reported that the patient had the first covid vaccine on 16Dec2020 and on 20Dec2020 started with left sided lower back pain and then received the second on 06Jan2021 and then on 09Jan2021 11:00 her legs became blue and swollen and she was diagnosed with bilateral deep vein thrombosis (DVT) and pulmonary embolism (PE). The patient otherwise healthy and had never had covid. Other than the clots, she had no other health issues. The patient underwent lab tests and procedures which included nasal swab: negative on 09Jan2021. Events resulted in doctor or other healthcare professional office/clinic visit, emergency room/department or urgent care, hospitalization, and life threatening illness (immediate risk of death from the event), hospitalized for 2 days (in Jan2021). Adverse event treatment: heparin drip and xarelto at home. Recovered with lasting effects on an unspecified date of Jan2020. This case was reported as serious, serious criteria was life threatening, caused/prolonged hospitalization.; Sender's Comments: The underlying risk factors/predisposing condition of thrombotic diathesis have been assessed to have played a contributory role toward the events.			
	COVID19 VACCINE (COVID19)	Life Threatening	18-29 years
Per pt, sx onset began at 1520 with pruritus/hives of the scalp. She was in the post vaccine			

observation area at this time. At 1530, EE returned to vaccination room to alert staff of her reaction. Upon hearing her new onset cough, an assessment was performed immediately. Reported tingling and swelling of her lips, cough, minor difficulty breathing with mask on, facial flushing and feeling hot, and severe pruritus, especially on the scalp. 50 mg IM Benadryl administered and was taken to ED via wheelchair which is 7 minutes away. Epi Pen administered in ED and admitted overnight for observation d/t irregular HR and ST depression on monitor.

COVID19 VACCINE (COVID19)

Life Threatening

18-29 years

"12/23/2020: 2 hr after injection, patient noted swollen lymph nodes, nausea, room spinning (motion sickness-like) sx. Stayed home from work that day and slept. 12/24/2020: ""typical injection site pain"" 12/30/2020: injection site hot, itchy, welts 12/31/2020: area of welts doubled in size to entire upper left arm; throat starting to close up"

COVID19 VACCINE (COVID19)

Life Threatening

18-29 years

Day after vaccine : mild shortness of breath, sensation of swelling in my throat/neck area. Took Benadryl 50mg before bedtime. 2 days after vaccine: woke up with voice changes, coughing/choking with speaking. Used epipen once, felt full relief for about 1-2 hours. Trouble speaking again. Then went to ER, had epipen again twice, over two hours, Benadryl 50IV and Pepcid and steroids. Sitting in the ER now debating admission. Likely being admitted., home epipen are too expensive to treat q2h by myself.

COVID19 VACCINE (COVID19)

Life Threatening

18-29 years

started with left sided lower back pain; This is a spontaneous report from a contactable Nurse (patient). A 22-year-old female patient received the first dose of BNT162B2 (lot number: EH9899), via an unspecified route of administration at left arm on 16Dec2020 13:45 at single dose for covid-19 immunization. Medical history included allergies for All fish. The patient's concomitant medications were not reported. The patient had the first covid vaccine on 16Dec2020 and on 20Dec2020 started with left sided lower back pain. The event resulted in Doctor or other healthcare professional office/clinic visit, Emergency room/department or urgent care, Hospitalization (2 days), Life threatening illness (immediate risk of death from the event). The patient received the Heparin drip and xarelto at home for the event. The patient was not pregnant. The patient received the covid test post vaccination on 09Jan2021. Test type was Nasal Swab. The result was negative. The outcome of the event was recovered with sequel on unspecified date.; Sender's Comments: From the information provided it is unclear what is the nature of the reported event and what are the reasons that have put the subject at immediate risk of death. The event is considered possibly related to the suspect product based on the positive temporal association.

COVID19 VACCINE (COVID19)

Life Threatening

18-29 years

anaphylaxis by lethargy, nausea, vomiting, palpitations, funny feeling in chest, swollen lips

COVID19 VACCINE (COVID19)

Life Threatening

18-29 years

Tingling and throat swelling to Moderna COVID-19 Vaccine EUA

COVID19 VACCINE (COVID19)

Life Threatening

18-29 years

29yo female patient reports feeling her throat tingling and closing sensation in her throat with a metallic taste and diaphoretic approximately 3 minutes after receiving vaccine. She did not report these sensations until about 15min after injection. EMS assist was immediately called and pt was brought into one of the patient rooms. She was given Epipen injection approx. 20min after injection and EMS arrived to transport patient down to ER within 1-2 minutes after Epipen administered. Patient was monitored in ER and recovered well

COVID19 VACCINE (COVID19)

Life Threatening

18-29 years

Patient presented to ED with complaint of chest pain, radiating down left arm, not relieved with Tums. Symptoms started at 0530 1/12/2020. Patient presented to ED b/c of strong family history of CAD, with father having MI in his 50s.

COVID19 VACCINE (COVID19)

Life Threatening

18-29 years

WITHIN 30 SECONDS OF RECEIVING VACCINE PATIENT STATED THAT SHE DID NOT FEEL WELL. HER

FACE BECAME FLUSHED. HER LIPS BECAME NUMB AND HER TONGUE AND THROAT STARTED SWELLING. AN EPIPEN WAS ADMINISTERED AND 911 CALLED. AFTER THE EPIPEN SYMPTOMS BEGAN TO RESOLVE. EMS CHECKED HER OUT AND SHE REFUSED TRANSPORT.

COVID19 VACCINE (COVID19)

Life Threatening

**18-29
years**

Received shot Wednesday night, developed arm soreness and mild flu like symptoms on left side of my body and facial paresthesias on the left side of my face. Twelve hours later, after waking up those same symptoms were only on the right side of my body. Friday morning, mostly normal physically just with some overall fatigue. Friday afternoon I started to get hives on my chest and overnight into Saturday they were on my lower back, sides, and legs. I took 50 mg of Benadryl every 6-12 hours until Monday mid-day when Benadryl was not helping reduce the hives and so I had full body hives. I did try an drugstore cortisone cream which did not help. Sought treatment at an urgent care as I was feeling anxious and could not control the itching. I and was diagnosed with likely allergic reaction to the covid-19 vaccine.

COVID19 VACCINE (COVID19)

Life Threatening

**18-29
years**

One week after the shot (1-14-2021) Patient (19 y.o.)reported side pain and appeared constipated, Laxatives given along with Tylenol, on further assessment Patient was noted to have left leg redness and abdominal fullness. Dr. was updated and we had orders for close monitoring, the next day when she got up, her leg appeared better, and she had passed a small BM, but by lunch she had developed significant pain and edema in her left leg, and the color of her leg was reddened again. She was sent to the emergency room with her symptoms. She was admitted back to our facility yesterday, her diagnoses included Acute provoked left external iliac, femoral, popliteal, and peroneal DVT. Elevated Factor II levels, Elevated APC resistant, May-Thurner Syndrome, history of developmental disabilities, fecal impaction and urinary retention - suspected related to her fecal impaction. Vascular surgery was consulted, and pt. was started on a heparin drip, and mechanical thrombectomy was needed for both legs due to multiple clots. She was started on Eliquis and Plavix, and thigh high compression stockings were ordered, ace wraps being used until these are supplied. Her Fecal impaction was addressed also and the urinary retention resolved.

COVID19 VACCINE (COVID19)

Life Threatening

**18-29
years**

27-year-old female with past medical history of anxiety, allergic to shellfish, presented for COVID-19 vaccination, developed shortness of breath after COVID-19 Moderna injection, felt lightheadedness and noted with cyanosis as per nursing, received epinephrine injection and transferred to ED. In ED she received solumedrol, benadryl and pepcid. Vitals in the ER Revealed tachycardia HR 95-105 , Sat 96% on room air not in distress. Patient was admitted for further observation

COVID19 VACCINE (COVID19)

Life Threatening

**30-39
years**

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

COVID19 VACCINE (COVID19)

Life Threatening

**30-39
years**

40 min after injection my throat and tongue started to feel weird and tight, pharmacy at my work hospital gave me 25 mg Benadryl and 650mg Tylenol. At about 1 hr 45 min after injection my throat got to the point of so swollen and itchy I couldn't swallow. I went to nearest emergency room hospital they administered decadron orally, Pepcid P.O., and Toradol via IM.

COVID19 VACCINE (COVID19)

Life Threatening

**30-39
years**

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

COVID19 VACCINE (COVID19)

Life Threatening

**30-39
years**

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

COVID19 VACCINE (COVID19)

Life Threatening 30-39 years

Within a few minutes of taking the vaccine, my lower lip began swelling. I was moved to the emergency department of Hospital and monitored and treated for four hours. Then I was released. At around 1:30 p.m. I felt my skin singling and started having difficulty breathing. Since I was no longer at my work (Hospital) I went to the closest hospital. This reaction was much worse. My husband drove. My heart rate increased. I was released at around 6:30 pm

COVID19 VACCINE (COVID19)

Life Threatening 30-39 years

Approximately 2 minutes after injection, felt flushed and tingly. This subsided, but developed a cough. Felt fine enough to leave the vaccination area after being monitored for 15 minutes. Cough continued, and developed a scratchy throat that eventually led to swelling of the throat at approximately 30-35 mins post administration. Sought care in the ED, where I was tachycardic and hypertensive. Received IV Benadryl, steroids, and IV fluids. Discharged home, but symptoms returned around 2pm. Sought care in a different ED, where I remained hypertensive and tachycardic. Received additional IV fluids, IV Benadryl and steroids. Eventually was treated with IM epinephrine after my heart rate was decreased to about 100bpm with IV metoprolol.

COVID19 VACCINE (COVID19)

Life Threatening 30-39 years

At the time of the injection sharp pain across my back , then at about 5 mins after feelings of light headedness, progressing pain across my back, trouble feeling like I could get enough air in with breathing and dizziness and I tried to get to the floor to sit or lay down but passed out. Then the next event I recall was a sharp pain in my thigh (apparently administered Eli pen) . I regained consciousness and was gasping and I was told I had been given a shot of epi.

COVID19 VACCINE (COVID19)

Life Threatening 30-39 years

Rapid onset of hoarseness, throat tingling and tightness

COVID19 VACCINE (COVID19)

Life Threatening 30-39 years

Was given the vaccine and about 5 minutes later started having swelling and my eyes and face. It was watched for a few minutes and was assessed by EMS and taken to the emergency department. I was given epinephrine, Benadryl, Solu-Medrol, Pepcid, IV fluids, DuoNeb and observed overnight. I was given multiple rounds of Benadryl, steroids, Pepcid, DuoNeb

COVID19 VACCINE (COVID19)

Life Threatening 30-39 years

Received vaccine at 1:30 pm yesterday, noted onset of symptoms at 8:45 pm. Numbness and tingling to mouth and bilateral upper and lower extremities, mild vision change, feeling of some swelling to bilateral eyelids. Also swelling to lips. She also did take zinc gluconate 50 mg last night and this morning. Has never taken zinc 50 mg, but has taken zinc as component of multivitamin/pre-natal vitamins. Patient was prescribed Pepcid 20 mg BID, Medrol 4 mg dose pack 21 pill taper until complete. Also given Benadryl 25 mg - 50 mg every 4 - 6 hours for allergy symptoms. And provided with an Epi-Pen for home.

COVID19 VACCINE (COVID19)

Life Threatening 30-39 years

Monitored x 15 min per guidelines. Began to experience SOB and throat swelling, after which pt presented to the ED for tx, dx acute hypertensive urgency with severe hypertension.

COVID19 VACCINE (COVID19)

Life Threatening

30-39 years

10 minutes after receiving vaccination, a significant increase in HR was noted, along with a tingling sensation through out body. Also, scratchy throat was noted. Alert by patient made to staff at vaccination site. Sweating noted and shortness of breath at that time. Epi pen given via L thigh IM. PIV started and benadryl and solumedrol given. Relief of symptoms noted very shortly after Epi administration. Taken to ER for 4 hour observation. Sent home after 4 hours and given prednisone to be taken at home, 50mg daily for 4 days. No further adverse symptoms noted.

COVID19 VACCINE (COVID19)

Life Threatening

30-39 years

Anaphalaxis reaction, stridor an unable to breathe. Happened in 30 seconds

COVID19 VACCINE (COVID19)

Life Threatening

30-39 years

Itchy throat, red eyes after 30 minutes. EMS on site gave IV Benadryl, epi pen shot and took to ER for monitoring. Vitals were good so he was discharged.

COVID19 VACCINE (COVID19)

Life Threatening

30-39 years

Started feeling a reaction immediately after the vaccine, felt blurred vision, dizziness, racing heartbeat, chest rash and face, itching all over, difficulty swallowing, tongue tingling and wheezing. Sent to ED. EPI and Benadryl. 1800 Went to see her in the ED, room 33. She has red rash to neck, shaky hands itching to neck and chest. ED Dr to discharge, she stated husband to pick her up and she will follow up with OH tomorrow. -----RN ED gave her Epinephrine 0.3 mg, Methylprednisolone 125mg, Diphenhydramine HCL 50 mg, Zofran 4mg, Lorazepam 1 mg, Hydroxyzine HCL 50 mg Sumatriptan 6mg , Discharge from ED at 1902 ----- RN 12/29/2020 1715 called to check on patient. left voicemail for her to call OH. ??????..? 12/29/2020 1838 left voicemail for patient to call OH. ??????????????????????. 12/30/20 2030 spoke with her. Tuesday 12/29 3pm-4pm dizziness, confusion, sob. Wheezing. Ambulance called. Hospital admitted. Intubated for less than 24 hours. Breathing treatments, epi drip. Now just on steroids and walking around and feeling better. Still admitted at hospital. Hoping discharged tomorrow. -----RN

COVID19 VACCINE (COVID19)

Life Th

"15-20 mins after receiving the vaccine she reported she had difficulty swallowing and difficulty breathing and was 'shaking.'" a PA wrote in her note that when she ran in to help, she found the patient to be tachypneic, diaphoretic, warm with some red blotchy patches on face, chest & neck. Able to speak easily c/o trouble breathing & sensation of throat swelling & extremities feeling abnormal. No stridor. No facial edema noted by that clinician. Administered epi-pen 0.3mg - IV started , Benadryl 50mg IVP and solumedrol 125mg IVP. Patient reports she subsequently arched her back and had rigidity of her arms/legs and tremors. Clinic PA reports that while she was there, pt was never hypotensive. Initially hypertensive after epi as expected with some favorable response after 10-15 min Staff there gave her IM epinephrine, IV Solu-Medrol and 50 mg IV Benadryl. EMS was contacted and transported to the emergency room. She arrived at the ER, was monitored for 2 hours, was started on pepcid and benadryl and discharged from the ER. She had a diffuse itchy rash. The following day she again developed recurrence of throat swelling. Went back to a different ER. Developed dyspnea immediately prior to arrival at ER. There was again given solumedrol and benadryl and pepcid and developed muscle rigidity and arched back for 10 minutes. Symptoms of SOB and dyspnea resolved with epinephrine. Was discharged from the ER with prednisone after being monitored for 5 hours. Is continuing to take prednisone and benadryl. Rash is still present but improving with scheduled benadryl. Has new redness at injection site today. Continues to feel some throat swelling but no tightness today. This information was gathered from talking with pt today for a phone appt and also from her medical chart regarding her vaccination visit and two ER visits."

COVID19 VACCINE (COVID19)

Life Threatening

30-39 years

The vaccine was received at 1:12 PM, and I felt fairly fine, aside from injection site pain and some tingling in my left arm until I had sudden significant elevation of heart rate, with shortness of breath, and throat swelling/tightening at approximately 1:26PM. I cold compress was applied to my forehead and I was put in a reclining position & then received Epinephrine at 1:28PM. EMS (present onsite) arrived for transport at 1:31PM. 4L of oxygen was applied after O2 sat of 89% noted by EMS. Blood pressure was elevated to >200/100 initially by EMS. Symptoms improved quickly following epinephrine, with some residual feelings of very mild throat fullness, and I developed chills which improved over

time. I was transported to emergency department where I was evaluated (symptoms mostly resolved at that time, but ED physician noted a little swelling remaining in my uvula), then IV Benadryl and Decadron were given. Later acetaminophen was also given for headache that developed during my ED stay. My vitals were monitored throughout and observation occurred until I was discharged at approximately 5:00PM, as symptoms had not recurred.

COVID19 VACCINE (COVID19)

Life Threatening

30-39 years

HIVES, SOB, THROAT CLOSING UP, WHEEZING

COVID19 VACCINE (COVID19)

Life Threatening

30-39 years

30YO F ICU nurse obesity (BMI 35) COVID 19 on Dec 2 symptoms, Dec 3 tested positive for COVID-19. never hospitalized, outpatient only. 12/12 completed isolation 12/21 received vaccine 12/7 developed Fever chills diarrhea SOB cough Urgent care visit. RLL consolidation on CXR given doxycycline 100 mg po bid worse, fever 40 targetoid lesions to LE (started before doxy) WBC 22K tachycardic tachypneic admitted requiring 2-4L oxygen CT angio without clot, diffuse ground glass and RML dense infiltrate DDimer 7.8 LDH 599 CRP 41 procal 0.67 ferritin 500 Viral respiratory PCR negative Sputum cx with oral flora (pending) COVID ag testing neg COVID PCR 1/3 targets positive (called as indeterminate).

COVID19 VACCINE (COVID19)

Life Threatening

30-39 years

Gallbladder removed, septic, 11mm axillary lymph node.

COVID19 VACCINE (COVID19)

Life Threatening

30-39 years

Presented to the ED after developing chest tightness, cough, lightheadedness, and throat closing sensation. She received the Moderna COVID-19 vaccine on the morning of presentation. Within 15 minutes of receiving the vaccine she developed pain and numbness, starting at the injection site traveling down the ulnar aspect of her arm, and nausea. Over the next several hours she continued to develop worsening nausea, chest tightness, cough, lightheadedness, and the sensation that her throat closing. She took PO Benadryl 25mg; however, her symptoms were not alleviated. She was subsequently evaluated in the ED. Received PO Benadryl 25mg, IV Benadryl 25mg, Epinephrine 0.3mg x 2, IV Famotidine 20mg, IV Solumedrol 125mg & 60mg, DuoNeb x 3, Raccpinephrine x 1.

COVID19 VACCINE (COVID19)

Life Threatening

30-39 years

had a positive COVID test; had a positive COVID test; O2 Saturation of 80% / Hypoxia; shortness of breath; He has a CT scan which showed extensive infiltration in the lungs; muscle pain; chills; body aches; low grade fever; cough; This is a spontaneous report from a contactable physician (pulmonary medicine). This physician reported similar events for 2 patients. This is 1st of 2 reports. A 35-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 18Dec2020 at single dose for covid-19 immunization. There were no medical history and concomitant medications. Caller stated that his close friend who was ER physician (front line worker) and within 24 hours after receiving the COVID vaccine, developed COVID or symptoms of COVID. Patient received the COVID vaccine on 18Dec2020 and the same night patient started with a low grade fever, body aches, chills, muscle pain, shortness of breath, cough, O2 saturation of 80% (hypoxia) and was in the intensive care unit now. Patient swore this was related to the vaccine. This patient tested positive for COVID. He had a CT (computerised tomogram) scan which showed extensive infiltration in the lungs in Dec2020. Patient was admitted to the hospital on 24Dec2020 and then was moved to the ICU 2 days later, on 26Dec2020. Caller thought patient had a positive COVID test at another hospital. Caller did know that tested positive at the current hospital on 26Dec2020 which was done to confirm the previous positive test. Caller thought patient had his first positive COVID test either the same day or the next day after receiving the vaccine. Event of O2 Saturation of 80% / hypoxia was reported as hospitalization from 24Dec2020 and life threatening; infiltration in the lungs and shortness of breath caused hospitalization from 24Dec2020, muscle pain, chills and positive COVID test was reported as medically significant; and other events were reported as non-serious. Outcome of O2 saturation of 80% / hypoxia and shortness of breath was not recovered, outcome of cough was recovering; and outcome of other events were unknown. Information about lot/batch number has been requested. ; Sender's Comments: Based on the information currently available, a lack of efficacy with suspected vaccine BNT162B2 in this patient cannot be completely excluded.,Linked Report(s) : US-PFIZER INC-2020519020 same reporter/drug , different patient/AE.

COVID19 VACCINE (COVID19)

Life Threatening

30-39 years

Immediate warm rush to my head and body. Heart was beating out of my chest and difficultly breathing. Heart rate spiked to 150 (normal around 55). Hand, legs, and mouth started to go numb. Eventually settled down after about 1 hr. Have not felt normal since which has been 3 days.

COVID19 VACCINE (COVID19)

Life Threatening

**30-39
years**

PATIENT REPORTING ITCHING AT 30 MINUTES POST INJECTION. AT 1.5 HOURS POST INJECTION PATIENT REPORTED ITCHY THROAT AND NUMBESS OF LEFT SIDE OF FACE. AT THAT TIME ADVISED TO GO TO EMERGENCY ROOM. NEXT DAY WHEN I FOLLOWED UP WITH PATIENT, SHE REPORTED HER AIRWAY STARTED TO CLOSE AND SHE RECEIVED EPINEPHRINE, AFTER 5 HOURS HER STARTED TO CLOSE AGAIN AND RECEIVED ANOTHER DOSE OF EPINEPHERINE, WAS RELEASED FROM HOSPITAL ROUGHLY 15-16 HOURS AFTER GOING TO ER.

COVID19 VACCINE (COVID19)

Life Threatening

**30-39
years**

Guillain Barre syndrome/AIDP event. Paresthesia and nerve pain developed in bilateral legs 4 hours after shot and progressed slowly for 4 days in intensity and area involved. Symptoms progressed distally to superior. On the 5th day symptoms progressed rapidly and involved bilateral legs up to the groin, left arm up to lateral shoulder, and right hand. I went to the hospital and was admitted to start IVIG treatment for Guillain Barre Syndrome/AIDP.

COVID19 VACCINE (COVID19)

Life Threatening

**30-39
years**

Nausea, hives, anaphylactic shock, throat swelling, hypotension, headache, dizziness, weakness . The symptoms returned at 1:25pm the best day as well. I've now had two anaphylactic reactions

COVID19 VACCINE (COVID19)

Life Threatening

**30-39
years**

Less than 5 minutes after vaccine, nose drained, weird taste in mouth, tingle in nose and on tongue. Throat and tongue swelled, couldn't speak. Dizzy and slurring speech. Was taken to ambulance outside, BP was 191/101. Given beta blockade. Confused and dizzy for next 2 hours in ER. Evaluated for stroke and given a 12-lead ECG. Given benedryl and prednisone. Felt better after 3 1/2 hours. Continued steroids for 5 days and had to take benedryl every 4 hours for 3 days or swelling/itching/bad taste in mouth would return. Sore arm on day 3.

COVID19 VACCINE (COVID19)

Life Threatening

**30-39
years**

1/6/21 Pt received vaccine and complained of difficulty swallowing and rapid heart rate. Pt received methylprednisolone 125mg IVP, diphenhydramine 25mg IVP, & famotidine 20mg IVP. Pt reported improvement and was discharged. Sent home on diphenhydramine and oral prednisone. 1/7/21 Pt unable to swallow her own secretions and experienced eyelid swelling. Pt vomitted. Pt received epinephrine and Benadryl X 1 dose each. Pt then transported to hospital via ambulance. Reason for admission - acute respiratory failure secondary to anaphylactic reaction. Decision was made to emergently intubate the patient for airway protection despite aggressive intervention. Pt successfully extubated 1/8/21. Plan to discharge home and start Medrol Dose Pack 1/9/21.

COVID19 VACCINE (COVID19)

Life Threatening

**30-39
years**

Anaphylactic reaction 6 days post vaccine 24Dec2020; I had severe chest tightness; SOB; throat soreness; hoarse voice; mouth swelling; This is a spontaneous report from a contactable physician, the patient. A 34-year-old non-pregnant female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE; Lot Number: EL0140), via an unspecified route of administration in the left arm on 18Dec2020 at 15:30 (at the age of 34-years-old) as a single dose for COVID-19 immunization. Medical history included severe dust mite allergy (based on skin test). Prior to the vaccination, the patient was not diagnosed with COVID-19. Concomitant medications included cetirizine hydrochloride (MANUFACTURER UNKNOWN), hydrocodone bitartrate/paracetamol (NORCO), ibuprofen (MANUFACTURER UNKNOWN), and ondansetron (ZOFTRAN); all for unspecified indications from unknown dates and unknown if ongoing. The patient did not receive any other vaccines within four weeks prior to the vaccination. On 24Dec2020 at 10:00, 6 days post vaccination, the patient experienced anaphylactic reaction, severe chest tightness, shortness of breath, throat soreness, hoarse voice, and mouth swelling; all reported as life threatening. The events led to an emergency room visit and she was given epinephrine (EPI-PEN), methylprednisolone (SOLUMEDROL), and diphenhydramine hydrochloride (BENADRYL) as treatment. The patient stated that she developed the reactions 45

minutes after she took premedications for a dilatation and curettage procedure. The premedications included ibuprofen, hydrocodone bitartrate/paracetamol, ondansetron. She stated she had taken these medications several times before and this was the first time she had this reaction. Since the vaccination, the patient had not been tested for COVID-19. The clinical outcomes of the anaphylactic reaction, severe chest tightness, shortness of breath, throat soreness, hoarse voice, and mouth swelling were recovered on unknown dates.; Sender's Comments: Anaphylactic reactions presented as chest tightness, shortness of breath, throat soreness, hoarse voice, and mouth swelling, developed 45 minutes after premedications including included ibuprofen, hydrocodone bitartrate/paracetamol, ondansetron for a dilatation and curettage procedure and 6 days post vaccination with BNT162B2, the event therefore is most likely attributed to these premedications unrelated to the vaccine use. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

COVID19 VACCINE (COVID19)

Life Threatening 30-39 years

Patient presented to the emergency department with sensory loss and loss of reflexes, evaluated by neurology and diagnosed with Guillain- Barre Syndrome thought to be secondary to the Pfizer Covid Vaccine

COVID19 VACCINE (COVID19)

Life Threatening 30-39 years

Anaphylaxis

COVID19 VACCINE (COVID19)

Life Threatening

30-39 years

I am currently breastfeeding my 5-month-old son. I received my first vaccine on 12/28/2020 and directly breastfed within 4 hours of receiving the vaccine. Two days after my vaccine my son was at daycare and had two large diarrhea blowouts and two large emeses followed by a 1-minute episode where he was limp with entire body cyanosis and in-and-out of consciousness. He also had a maculopapular rash on his torso. EMS was called. He was observed in the emergency department for a few hours then recovered well without intervention and did not require hospitalization. EKG was normal. He has continued to be well and back to baseline since the event.

COVID19 VACCINE (COVID19)

Life Threatening 30-39 years

The patient presented with left eye peripheral visual loss, left upper and lower extremity and facial numbness sensation and weakness. This started 1 hour after receiving COVID-19 vaccine at her place of employment. Pt was brought to CRMC via EMS.

COVID19 VACCINE (COVID19)

Life Threatening 30-39 years

38-year-old female who is healthcare worker and received first dose of COVID vaccine (Pfizer). Immediately after receiving the vaccine, patient developed lightheadedness, flushing, hives, wheezing and throat swelling. Patient was treated in an emergency department with epinephrine, gradually improved and was able to be sent home with an EpiPen, prednisone, hydroxyzine, and famotidine. The next day, patient again developed shortness of breath and her husband administered the EpiPen. EMS arrived and gave another dose of IM epinephrine and IV diphenhydramine. On arrival to the emergency department, the patient was altered, diaphoretic, tachypneic, tachycardic, and stridorous. Patient was given multiple doses of IM epinephrine and started on epinephrine drip. Stridor continued and was unresponsive to nebulized albuterol. Patient was then intubated and placed on mechanical ventilation. Other treatments included solumedrol, pepcid, magnesium sulfate, nebulized epinephrine, and IV fluids. admitted to the intensive care unit, weaned off epinephrine drip, and extubated the next day. Patient was monitored on hospital floor for one additional day and was then discharged with no residual symptoms.

COVID19 VACCINE (COVID19)

Life Threatening 30-39 years

right after vaccine was given i got a head to toe hot flush. i thought it was just anxiety. within 2 minutes i had explosive diarrhea, felt dizzy. looked in the mirror and saw my neck and chest covered in red rash and hives. felt hot flush again. dr came in noticed hives all over both my arms as well. felt sob and if someone was holding my neck with their hand. given benadryl and epi taken to local er.

<p align="center">COVID19 VACCINE (COVID19)</p> <p>Metallic taste in the back of throat between 15-20 minutes post vaccination, noticeable swallowing and throat irritation at 20-25 minutes post vaccination, tongue and lip numbness and throat tightness at 25-30 minutes, dry hacking cough at 30 minutes. Treated in the ED approximately 1 hour post vaccination, at time of arrival in respiratory distress with subcostal retractions, coughing, speaking 1-2 word sentences, with tachycardia and tachypnea. Treated with IM epinephrine, IV solumedrol and IV Benadryl and IV Benadryl with marked improvement in symptoms.</p>	Life Threatening	30-39 years
<p align="center">COVID19 VACCINE (COVID19)</p> <p>Anaphylaxis within 5 minutes of dose given. Tachycardia 130-140s, hot body temperature, trouble swallowing, lightheaded/dizzy, ekg changes, feeling like I was going to pass out even when in bed. IV fluids, benedryl, soul-medrol, famotadine and IM epi given.</p>	Life Threatening	30-39 years
<p align="center">COVID19 VACCINE (COVID19)</p> <p>Trouble swallowing, tingling around the mouth within 5 minutes of vaccine administration. IV started with 25mg Benadryl within 5 minutes of symptom onset. Transfer to ER at 1430. Symptoms unresolved, hr - 120, bp 140/100, O2 sats 100, resp: 21 Additional 25mg Benadryl, 125mg solumedrol, 1ml Ativan given IV at 1435. Symptoms began to resolve, patient discharged at 1600 to home with instructions to return if needed. Patient returned to ER Sunday January 10 at 1300 complaining of throat tightness. Patient was seen by doctor, no acute distress and airway issues seen. Patient elected to stay for 50mg benadryl and 40mg prednisone PO. Patient was discharged to home with script for 40mg prednisone q day for 3 days. Patient feels any remaining allergic symptoms have resolved.</p>	Life Threatening	30-39 years
<p align="center">COVID19 VACCINE (COVID19)</p> <p>Soreness at injection site started at 1600 Body aches, headache, and low grade fever woke me up around 0100</p>	Life Threatening	30-39 years
<p align="center">COVID19 VACCINE (COVID19)</p> <p>Within 3 minutes of receiving vaccine felt flush and throat swelling, responded to Epi Pen and Benadryl p.o. EMS took him to ED where he remained several hours receiving 1 liter NS 125 mg solumedrol IV, discharge with 4 days of prednisone 40 mg daily and a prescription for an Epi Pen. As of 1.12 he is totally okay with no after effects.</p>	Life Threatening	30-39 years
<p align="center">COVID19 VACCINE (COVID19)</p> <p>-0715 vaccine administered. -0735 started to feel dizzy/off and right side of tongue felt like it was mildly swelling and itchy. -0735 asked to have blood pressure taken as know when I am having anaphylaxis my blood pressure escalates. -0740 took blood pressure and it was 141/86 in right arm. Normal is 110s/60s-70s. No anxiety feelings. -0740 throat started to have increased mucous production. Had the tickle and tightness in throat. Asked and received 25mg Benadryl with cup of water. -0742 started clearing throat frequently and slight cough. Knew it was anaphylaxis and told the team I need to go to the ER. Asked for additional 25mg Benadryl. Also took 20mg Famotidine and 2 puffs Albuterol inhaler--this is my prescribed anaphylaxis routine. Had Epipens on standby. -0743 put on O2 saturation monitor and watched O2 drop into 90-92 range. Asked for epipen on standby as I know when I need to start it. Didn't want to take that when I knew I was about to get it in the ER and knowing self hadn't progressed that far. Felt chest tightness and shortness of breath. Voice started becoming hoarse. -0800 EMS arrived (delay as team didn't know if they were supposed to call 911 or a Code--they chose EMS even though in hospital). Then staff at COVID vaccine clinic kept emphasizing need to go in ambulance while EMS and self fought to go through hospital (much quicker route). Finally cleared to go through hospital to ER. To get some air via breathing in had to sit up leaning forward. Voice completely hoarse by this time. -About 0817 arrived to ER bay. At this time, frequently coughing and cough started to sound stridorous. Difficulty getting breaths in. Had chest pain near heart. Greeted by MD, 2 RNS, and technician. -0819 received IM epinephrine. Attached to 5 lead EKG monitoring and O2 monitoring. Blood pressure done again. Higher than previous. -About 0821 had working IV (previous two attempts failed as veins were constricting). Given IV Solumderol. Started bolus of 1L Normal Saline. -Not sure how long after by cough subsided, increased mucous production subsided, as well as hoarseness decreased. -Held for observation for 2hours (would be longer if not resolved). - Discharged around 1015. At this time, hoarseness almost all gone. Minimal throat clearing. Cough resolved. -Prescribed</p>	Life Threatening	30-39 years

epipen inhalers (mine expired) and Prednisone. Prednisone is PRN for mild breathing difficulties if it starts again tomorrow 1/13/21. -At 1400 took 50mg Benadryl and 20mg Famotidine as previously prescribed for anaphylaxis maintenance. Will continue this as previously prescribed every 6 hours until symptoms stay resolved. -Made follow up appointment with Primary Care Physician per protocol

COVID19 VACCINE (COVID19)

Life Threatening 30-39 years

Started to feel lightheaded, weak, faint like I was going to pass out, heart rate increased, confusion, trouble speaking, brought to the ED, throat started to swell and started having thick spit and clearing my throat excessively. Diagnosed as anaphylaxis.

COVID19 VACCINE (COVID19)

Life Threatening 30-39 years

within 1 hr post-vaccine on 1/7 I had a mild headache that resolved with Tylenol. At about 12 hours post-vaccine I developed nausea, fever (100.4) and chills and secondary to this had poor sleep. The next day I took scheduled alternating Tylenol & ibuprofen during the day and then overnight 1 episode of chills that woke me up. no events Saturday or Sunday. Then Monday 1/11 in the early morning I started to develop a rash on my b/l elbow and right foot 3rd toe. I applied mometasone topical cream to these locations. while at work the rash extended down both forearms then by 5pm it was on both hips and extending along both legs. I applied Benadryl cream to the most irritated sites and took PO Benadryl 50mg at bedtime and again at 1am when the itching woke me up. I repeated Benadryl 25mg at 8am. The rash seems to be getting better on the arms but then by noon I had a new breakout on my neck and face. I took Benadryl 50mg at 1pm. The rash continued to have a rapid progression over the next hour and resulted in angioedema with my throat swelling, lips puffed and numb and eye swelling. I was injected with an epi pen and sent to the ED where I received PO prednisone, famotidine, and Benadryl. The face/neck rash then greatly improved and I was sent home on prednisone 40mg daily for 3 days.

COVID19 VACCINE (COVID19)

Life Threatening 30-39 years

Unprovoked seizure (clonic tonic) 13 days later, requiring hospitalization and testing

COVID19 VACCINE (COVID19)

Life Threatening 30-39 years

Saturday had. Sweating. Chills. Headache. Nausea.; Saturday had. Sweating. Chills. Headache. Nausea.; Saturday had. Sweating. Chills. Headache. Nausea.; Sunday had emergency appendectomy for acute appendicitis.; Friday at 3pm, the patient had numbness and tingling to left hand, lips and throat; Friday at 3pm, the patient had numbness and tingling to left hand, lips and throat; Friday at 3pm, the patient had numbness and tingling to left hand, lips and throat; Friday at 3pm, the patient had numbness and tingling to left hand, lips and throat; Friday at 3pm, the patient had numbness and tingling to left hand, lips and throat; Friday at 3pm, the patient had numbness and tingling to left hand, lips and throat; Post surgery had allergic reaction unknown reason with head to toe rash; Post surgery had allergic reaction unknown reason with head to toe rash; This is a spontaneous report from a contactable nurse (patient). A 34-year-old female patient (pregnant: No) received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via intramuscular (lot number: EL1283) on left arm on 08Jan2021 at 6:30 AM at single dose for covid-19 immunisation. The relevant medical history included celiac, anemia, known allergies: Sulfa and Gluten. Concomitant medications were not reported. The patient received first dose of BNT162B2 via intramuscular (lot number: Ek5730) on left leg on 18Dec2020 at 11:00 AM at single dose for covid-19 immunisation. The patient previously took Codeine, fish oil and experienced allergies. Friday at 3pm, the patient had numbness and tingling to left hand, lips and throat. On Saturday the patient had sweating, chills, headache, nausea. On Sunday had emergency appendectomy for acute appendicitis. Post surgery had allergic reaction unknown reason with head to toe rash. It was also reported that the adverse event started on 08Jan2021 at 03: 15 PM (as reported). The patient had 1-day hospitalization. The patient received treatment for the events. The adverse events resulted in Emergency room/department or urgent care. The events were reported as serious due to life threatening and hospitalization. The most recent COVID-19 vaccine was administered at hospital. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The outcome of the events was recovering.; Sender's Comments: A causal association between BNT162B2 and the reported events cannot be excluded based on a compatible temporal relation between vaccination and onset of events. Medications administered during appendectomy may confound reactions experienced post-surgery. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse

events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate.

COVID19 VACCINE (COVID19)

Life Threatening

30-39 years

Patient developed a hoarseness of voice and tightness of throat and flushed feeling immediately following vaccination. Epi Pen was administered and 50 mg Benadryl given p.o., EMS transport to ED after administration of solumedrol 125 mg - received Pepcid and Zofran and NS IV in the ED. Discharged from ED with prednisone 40 mg daily x 4 day with Epi Pen prescription.

COVID19 VACCINE (COVID19)

Life Threatening

30-39 years

Swollen tongue and SOB with decreased swallow

COVID19 VACCINE (COVID19)

Life Threatening

30-39 years

Day 1-3 after the dose flu like symptoms Day 3-7 swelling in lymph nodes on left side of body (baseball sized) took ibuprofen and Tylenol Day 8 angioedema, anaphylaxis. Received epi subq, IVP 50mg Benadryl, Pepcid 20mg IVP, liter of NS Day 9 raised red rash all over body and face still going on Day 16- present: severe joint pain and fever, unable to obtain any relief

COVID19 VACCINE (COVID19)

Life Threatening

30-39 years

Severe Right sided chest pain, right sided muscle spasms and difficulty breathing two weeks after vaccine was administered Diagnosis of bilateral pulmonary embolism was made on presentation to ER. No personal or family history of clots in arteries or deep veins or any risk factors in patient. Received heparin drip, pain medications, muscle relaxants inpatient. Pain progressively improved over days. Was discharged after 6 days on admission. Was discharged on oral anticoagulant (Rivaroxaban aka xarelto)

COVID19 VACCINE (COVID19)

Life Threatening

30-39 years

Developed dizziness and nausea within 90minutes of vaccine; then developed tingling, and flushing of my skin. Then rapid heart rate and chest tightness by 2.5hrs post vaccine. I went to urgent Care and they thought it was an allergic reaction (BP 182/90, HR 82) and gave me 125mg solumedrol and Benadryl intramuscularly which caused worsened dizziness and a racing heart which caused me to collapse and they gave me a epi pen and called 911. I was transferred to ER and they completed EKG which was normal and monitored vitals for a few hours and I was released. I continue to remain extremely dizzy and nauseated 2days after the vaccine.

COVID19 VACCINE (COVID19)

Life Threatening

30-39 years

"Pt is 33 yo female with h/o multiple drug allergies , including allergy to benadryl. She has received first dose of COVID vaccine made by Phfizer at 3:45. She reports about 10 minutes after the vaccination she started feeling tingling in her lips, throat and prickly sensation on her chest and feeling ""off"". Felt dizzy, developed small hives on her chest. She was attended to immediately at the vaccine site and our team was called to white code. Pt was sitting on the floor, alert , breathing comfortably. Her BP was 151/84, HR 90, O2 Sats 100%. Her lungs were clear the whole time, no wheezing, no difficulty swallowing or talking. Patient received 125 mg of IV solumedrol and 20 mg of pepcid in vaccination room, she felt the same, still breathing comfortably, speaking full sentences, hives fading away. She was transported to Urgent Care clinic on wheelchair. Pt kept her EpiPen by her site the whole time but refused to use it, states she is afraid to use it and wants to hold off or get it in ER if necessary. About 16:30 patient reported her tingling, prickly sensation In her chest is getting worse, developed sensation of lump in her throat, able to swallow and breath without problems, lungs exam clear. Again recommended to give EpiPen but patient again refused as she feels very anxious about getting new medicine. She was able to speak full sentences and breathing well, O2 Sats 100% the whole time, she repetitively refused EpiPen. EMS called and patient transported to ER, ER notified. Pt left in stable condition."

COVID19 VACCINE (COVID19)

Life Threatening

30-39 years

Anaphylaxis (urticaria, tongue swelling, subjective difficulty breathing) starting approx. 24hrs first moderna dose. No prior episodes of anaphylaxis/allergic rxn. Treated with Benadryl 100mg PO (prior to arrival, pt administered), famotidine 20mg IV, Epinephrine 0.3mg IM. Monitored in ED, complete

resolution of symptoms, discharged home.

COVID19 VACCINE (COVID19)

Life Threatening 30-39 years

PVCs with compensatory pauses, postural orthostatic hypotension associated with chest tightness, shortness of breath, dizziness and blurry vision

COVID19 VACCINE (COVID19)

Life Threatening 30-39 years

"Felt tachycardia immediately, thought she was anxious. After 35-45 minutes she felt like she was having a hard time swallowing which progressed to tongue swelling, all taste buds popped up and sore, hives on face & neck, reddened face. Itchy neck and face. Took double dose of Atarax and went to bed. Felt extremely fatigued unsure if double dose of Atarax. Woke with swelling all over body. Woke up feeling heaviness as if she had ""sumo wrestler"" on her body. 24 hours post vaccine heaviness started to lift but felt as if she had a vise on her lungs. Continuing to take Atarax every 6 hours per MD order."

COVID19 VACCINE (COVID19)

Life Threatening 30-39 years

Anaphylaxis less than two hours after vaccination. I had no symptoms immediately after vaccine however did develop symptoms within one minute of completing a run. Developed b/l hand swelling and tingling, diffuse hives and itching, tachycardia, elevated blood pressure, lips tingling and swelling which required emergency room visit and EpiPen, IV fluids, Benadryl and IV steroids. This is similar to previous reactions I have had to running previously. Symptoms resolved within one hour after treatment in ED.

COVID19 VACCINE (COVID19)

Life Threatening 30-39 years

"Patient called this nurse stating she had an allergic reaction to COVID vaccination given on Friday 1/15/21. States she felt fine for the 15 minutes post immunization, was on her way home and started feeling dizzy, short of breath, chest heavy, throat felt full ""like a ball in it"". She came back to clinic which was closed but sat in the parking lot for a while. While in parking lot trying to figure out what to do, her symptoms lessened. She got home safely but started to feel jittery/shaky and her BP was very high (couldnt remember exact number). She then went to urgent care where they told her she was having an allergic reaction and given a pill of something and steroid for 6 days. Went home from urgent care and BP still high but got better at bedtime. Saturday she had a ""really bad headache and just layed around all day. I was not able to function at all."" Sunday she still had a headache and added muscle aches. Monday she started feeling ""a lot better"" until 8 PM when she was walking around doing her nightly routine and started to feel a wave of dizziness, throat felt funny so she sat down and took her BP with result of 207/131. Says this reaction felt worse than Friday's reaction so she went to ER where she was again told she was having an allergic reaction and the steroid given to her at Urgent Care was not helping and to stop taking them. Given Benadryl in the waiting room, had labs and EKG which came back ""normal"", and given a different med Vistaril to take with any future symptoms. Was also told to NOT take the second dose of COVID vaccination. Says she has not had to take the Vistaril yet and has not had any sign of reaction today so far. Said she did report the initial headache on the V-safe app."

COVID19 VACCINE (COVID19)

Life Threatening 30-39 years

I am a registered nurse at hospital. On 12/25, seven days after receiving the shot I started to get right lower leg pain and I kept complaining about it till New Years Day. I had no symptoms of a DVT. I triaged on 1/1/21 and the doctors ordered labs/imaging and the results were as followed: D-Dimer biomarker (+) , Ultrasound of the Rt lower leg (-) , CTA showed a PE (segmental right upper lobe pulmonary artery consistent with pulmonary embolus). I was discharged on Xarelto and advised to follow up with a hematologist. On 1/5/2021, I went to hematology and they did a whole bunch of labs. I was sent to get a ultrasound of the leg because the pain persist and they found a clot hidden by my soleus. The plan is to continue on the Xarelto for 6 months. Come back in 3 weeks to scan my leg again and get my lab results. On 1/12/2021, I received the 2nd shot of the Pfizer vaccination.

COVID19 VACCINE (COVID19)

Life Threatening 30-39 years

12 hours after vaccination began experiencing fever, chills, body aches, slight head ache - lasted around 12 hours Had slight pain above eye prior to getting vaccination Saw PCP on 01/08/2021 due to eye pain - had CT scan for possible aneurysm, found 2 spots on brain, thought patient had

shingles On 01/10/2021 shingles rash appeared

COVID19 VACCINE (COVID19)	Life Threatening	30-39 years
I was having episodes of dyspnea and non productive cough starting from 1/1/2021. On 1/13/2021 I experienced severe dyspnea and had loss of consciousness for 5 seconds and was found down. I was rushed to the hospital and diagnosed with multiple pulmonary embolus (about 9) which was treated with direct TPA via catheterization. I then recovered in the ICU and transitioned to oral anticoagulation and discharged home on 1/15/2021.		
COVID19 VACCINE (COVID19)	Life Threatening	30-39 years
Began itching and wheezing approximately 5 minutes after the injection. Gave first epi dose. Throat started tightening, and nausea presented. Gave second epi 5 min after the first. Gave third epi 5 min after the second. EMS arrived, gave 4th epi in ambulance. ER treated with breathing treatment, IV steroids, IV Benadryl, IV Pepcid and IV zofran. Was observed for 6.5 hours.		
COVID19 VACCINE (COVID19)	Life Threatening	40-49 years
40 year female received Pfizer-BioNTech COVID-19 Vaccine today Patient reported prior h/o severe allergic reaction to influenza vaccine with eggs preservative. She has received flu vaccine w/o egg w/o problem. Due to her prior history of severe allergic reaction/ anaphylaxis to another vaccine, in this case flu vaccine with eggs, we should proceed with caution. She was told we could defer vaccination until more information becomes available. She opted to proceed with receiving Pfizer-BioNTech COVID-19 Vaccine and be observed for 30 minute observation period. Patient developed throat tightening approximately 20 minutes after vaccination. She received EpiPen within 1 minute of symptoms and was sent to ER immediately in wheelchair by nursing staff. Patient was evaluated in ED and was hemodynamically stable. She was given IV benadryl and was stable throughout observation		
COVID19 VACCINE (COVID19)	Life Threatening	40-49 years
12 minutes after injection, I felt flushed and dizzy. They hooked me up to a vital sign monitor which showed my heart increasing to 133 bpm, SaO2 98%. A manual blood pressure check was 168/110. My heart felt like it was pounding, I was hot and sweating. After 10 minutes or so, I felt increasingly dizzy and my vision started fading. VS still showed tachycardia and hypertension. It became difficult to swallow and my tongue was feeling fat. A Rapid Response Team was alerted, they started an IV, and took me to the Emergency Department. I became very cold and shaky. My hands and feet became a little mottled. They gave me 50 mg IV benedryl, 20 mg IV pepcid, a dose of solumedrol, and IM epinephrine 0.3mg, and 1 Liter of fluid. My symptoms resolved and I was discharged home a couple hours later.		
COVID19 VACCINE (COVID19)	Life Threatening	40-49 years
The patient was well prior to vaccination (12/17). The day after, he felt mildly unwell and had a low grade fever. The following day, he had a fever of 102. He received 1L of fluid at Urgent Care and had a BP in the 80s. Shortly thereafter, he felt palpitations and developed AF. He came to the hospital where he was tachycardia to 200 bpm and hypotensive to SBP70s. He received aggressive fluid resuscitation (4L), IV metoprolol and was started on empiric Abx. Within several hours, the HR lowered, BP increased, and AF spontaneously converted to sinus. He had no dysuria. Cultures so far have not shown growth at our hospital. Urinary culture from urgent care has reportedly shows 20k gram positive cocci.		
COVID19 VACCINE (COVID19)	Life Threatening	40-49 years
Ventricular tachycardia. Defibrillator paced me out of rhythm. I have had my ICD for 3 years. This is the first abnormal rhythm I have had where it delivered a therapy to abort it.		
COVID19 VACCINE (COVID19)	Life Threatening	40-49 years
Anaphylaxis/Angioedema Patient was given EpiPen 0.3 mg IM; Methylprednisolone 125 mg once; Diphenhydramine 25 mg IV push once; Famotidine 20 mg IV push once; Dexamethasone 10 mg IV push once Patient was intubated and put on propofol and midazolam drips for sedation		
COVID19 VACCINE (COVID19)	Life Threatening	40-49 years

years

Received vaccine around 10:40 am, by 10:50 started to feel dizzy, eyes felt full, dry, tingly, swollen, voice became raspy and throat itched. Received 25 mg Benadryl PO at around 10:55. Face, arms, chest and abdomen developed a fine red itchy rash, tongue swollen and itchy, lips tingling, wheezing, blood pressure elevated, pulse thready given 25 mg PO Benadryl, taken to the Emergency Room, symptoms persisted, stomach hurt became nauseated, received IV solumedrol, Pepcid, IV fluids, nebulized albuterol. Sent home once stable after 3 hours, with instruction to take Benadryl every 4-6 hours for the next 2 days, albuterol as needed, and prednisone for the next 5 days.

COVID19 VACCINE (COVID19)

Life Threatening

40-49 years

Patient experienced bronchospasm with coughing and tongue itching approximately 10 minutes after the injection.

COVID19 VACCINE (COVID19)

Life Threatening

40-49 years

patient felt slightly nauseated at 10 minutes after injection, then developed slight sweating; BP 160/81; 83 at 5:45 and then 158/87 with HR 82 at 5: 52 pm. Her lungs were clear, she was speaking in full sentences and was denying any chest pressure, her usual sense of asthma exacerbation. At 6:05 it was 164/83 with HR 79 and patient developed a dry cough; we decided to have her wait just a bit longer, then cough worsened, so at 6:25, decision was made to have patient seen in ER for further assessment, and en route in wheelchair to ER the dry cough became persistent, spasmodic and patient was unable to speak. Epi-Pen was injected in right mid thigh, and patient transported to ED urgent eval. She noted immediate palpitations, and slight improvement of breathing, was able to speak in four word sentences. On arrival to the ED, patient was administered Duonebs, Albuterol neb, IV Benedryl, IV Solumedrol; CXR was obtained, with results pending. Patient was sent to observation for ongoing monitoring and assessment of breathing. at 6:30 PM in the ER, she

COVID19 VACCINE (COVID19)

Life Threatening

40-49 years

ANAPHYLACTIC REACTION, SOB, CHEST PRESSURE, TIGHTNESS IN THROAT, TACHYCARDIA

COVID19 VACCINE (COVID19)

Life Threatening

40-49 years

Initially started with nausea around min 5, shortly after then itching on arms. Around min 15 ? lump? sensation in throat. Around min 20 swelling of tongue, worsening feeling in throat, wheezing, itching around mouth. Sent to ER, received IM Epi, IV: Steroids, Benadryl, Zofran, Pepcid, Albuterol inhaler.

COVID19 VACCINE (COVID19)

Life Threatening

40-49 years

15 min after receiving Covid 19 vaccine patient started to feel like her heart was racing / felt faint. Burning feeling in upper thigh and pelvic area. BP 180/100 HR 130. Rapid Response called / transported to ER. Admitted for 24 hr observation.. Solu-medrol, Benadryl and Ativan given in ER. Released home the next day. 72 hrs later patient states she has numbness and tingling in hands and feet. 12/24/2020 patient reports she is feeling better today / no symptoms noted.

COVID19 VACCINE (COVID19)

Life Threatening

40-49 years

listed before

COVID19 VACCINE (COVID19)

Life Threatening

40-49 years

Fever, muscle aches, hypertension, rapid heart heart

COVID19 VACCINE (COVID19)

Life Threatening

40-49 years

Palpitations, shortness of breath, chest tightness, presyncope, which led to New onset atrial fibrillation with rapid ventricular response and required synchronized cardioversion and hospitalization. Discharged on anticoagulation and beta-blocker.

COVID19 VACCINE (COVID19)

Life Threatening

40-49 years

12/23- began to experience intermittent right lower quadrant pain in the morning, fever of 100.4 F in the evening which subsided with ibuprofen. 12/24- no fever noted but intermittent right lower quadrant pain continued, seen at the Health Clinic, sent to Hospital ER for CT scan, diagnosed with appendicitis, appendectomy performed.

COVID19 VACCINE (COVID19)

Life Threatening

40-49 years

years

right after the vaccine she felt light headed felt better in observation after about 7 minutes employee c/o heart racing, Chest pressure, feeling light headed, throat scratchy and tight. allergy to MRI contrast dye only - Gadolinium. Has had lots of vaccines in the past without problems. Taken to ED via W/C was talking all the way not SOB admitted to ED. 12-28 States she was admitted to the hospital overnight for anaphalaxis on a second trip to ED. She will not be able to get her second dose of the vaccine. this should be entered into the VAERS reporting system. She is till using the benedryl.

COVID19 VACCINE (COVID19)

Life Threatening

**40-49
years**

Adverse reaction post Covid vaccine. Waited for 20 min post vaccine. Experienced S/S Heart palpitations, shortness of breath, tingling in extremities, diaphoretic after leaving clinic observation. Drove back to hospital, escorted by pre surgical testing hospital staff and taken by wheelchair to ED.

COVID19 VACCINE (COVID19)

Life Threatening

**40-49
years**

10 MINUTES FOLLOWING VACCINE - SOB, COUGH, TIGHTNESS IN CHEST, THRAOT SWELLING, DIFFICULTY SWALLOWING, LIGHT HEADEDNESS, AND ELEVATED HEART RATE. ORAL AND IM BENADRYL ADMINISTERED, 2 DOSE OF EPINEPHRINE, 2 NEB TREATMENTS, O2 PLACED. 911 CALLED AND TRANSPORTED TO EMERGENCY FOR FURTHER TREATMENT AND MONITORING. AT HOSPITAL IV STEROID ADMINISTERED. SYMPTOMS SUBSIDED WITH SECOND DOSE OF EPINEPHRINE, HOWEVER RETURNED 3 HOURS LATER AND ANOTHER DOSE OF BENADRYL ADMINISTERED. ELEVATED HEART RATE CONTINUED AND IV FLUIDS ADMINISTERED TO ATTEMPT IN BRINGING DOWN HEART RATE. IV FLUIDS WERE NOT EFFECTIVE. HEART RATE (118-120) REMAINED ELEVATED INTO THE OVERNIGHT HOURS AND SUBSIDED AROUND 1:30A ON 12/29/2020. CONTINUED HEADACHE, NAUSEA ONSET, FATIGUE, DIFFICULTY SWALLOWING AND COUGH ON 12/29/2020.

COVID19 VACCINE (COVID19)

Life Threatening

**40-49
years**

Pt. began to feel weak with palpitations about 8-10 minutes after vaccination, her pulse was extremely fast, she then began to complain of lower mid-esophageal burning

COVID19 VACCINE (COVID19)

Life Threatening

**40-49
years**

anxiety, tachycardia, flushing, diaphoresis, HTN, SOB

COVID19 VACCINE (COVID19)

Life Threatening

40-49 years

Within 3 minutes of vaccination patient became fully flushed head and neck, with rapid heart rate (112), and feeling like her airways were tightening.. Nurse immediately called for response, administered Epipen, when response arrived applied oxygen and transported to ED. Solumedrol 125 mg, Bendadryl 25 mg, and Famotidine 20 mg, she responded well and was released home with Rx Prednisone 40 mg x 3 days. Only residual effect was a dry/sore throat.

COVID19 VACCINE (COVID19)

Life Threatening

**40-49
years**

Near syncopal episode approximately 2.5 hours after vaccination. Sudden onset of dizziness, nausea, and diaphoresis. Was admitted to ED and observed overnight. Full cardiac work up was done and shown to be within normal limits. I have no pre-existing conditions and considered to be a healthy adult.

COVID19 VACCINE (COVID19)

Life Threatening

**40-49
years**

Rash, Itching and swelling of left arm. Progressed to tachycardia in the 150's, hypertension 200/114. Tingling of lips, dizziness

COVID19 VACCINE (COVID19)

Life Threatening

40-49 years

Patient had an anaphylactic reaction to the vaccine the day after it was given and went to the nearest ER.

COVID19 VACCINE (COVID19)

Life Threatening

40-49 years

Anaphylaxis. Immediately experienced shortness of breath, rapid heart rate, and rash. I am a Nurse Practitioner in the emergency department. Had went down to the temporary vaccine station to receive my vaccine, immediately returned to the ER and began to experience symptoms of

anaphylaxis. Was immediately placed in a treatment room and received treatment by the ER physician, which included oxygen, intravenous Benadryl, Solumedrol, and Normal Saline. Was observed for several hours and then eventually sent home with prescription for Prednisone and Pepcid. I do have a allergy to shellfish, was never asked about my allergies and nothing on the paperwork I was given prior to the injection noted a concern for shellfish allergies.

COVID19 VACCINE (COVID19)

Life Threatening

40-49 years

Anaphylactic Reaction, facial swelling, facial Redness, Face felt like it was burning, face flushing, throat swelling, heart palpitations, trouble swallowing , feet swelling, light headed, anxiety. Hospitalized from the 12/23/20 to 12/26/2020 . Medications now on Epinephrine, diphenhydramine, cetirizine, famotidine, prednisone, lorazepam, cephalexin. on 1/1/2021 was taken to E.R. by ambulance around 11:00 am left hand was tingle started to go numb traveled up my arm into left side of my face ,ear, tongue, and then down to the left side of my leg and into left foot, could not move left side of body for a good 7 to 8 mins then went away transferred to ambulance enroute to ER blood pressure was high and and started having right ear pain and right side frontal severe headache, arrived to ER and was given diphenhydramine ,ketorolac, metoclopramide HCl, lorazepam. MRI was ordered and Neurologist found two small lesions on right side of frontal brain, following up now with neurologist. added more meds naproxen

COVID19 VACCINE (COVID19)

Life Threatening

40-49 years

Anaphylactic reaction (swelling and redness of face and torso, shortness of breath, constriction of airway and dizziness)

COVID19 VACCINE (COVID19)

Life Threatening

40-49 years

Patient presented to receive COVID-19 vaccine, received vaccine at approximately 10 am. Patient waited 15 minutes for observation and left observation area without complaining of any sx. Patient returned a few minutes after reporting tongue tingling which eventually got to her lips. . No difficulty breathing or any other sx. No history of allergies. NP/RN administered PO Benadryl 25 mg. As of report of this iReport no additional symptoms or intervention needed. Last vitals: 131/83 75spo2. BP higher than usual per patient, spO2 normal.

COVID19 VACCINE (COVID19)

Life Threatening

40-49 years

Developed shortness of breath, swelling of tongue, persistent cough within 5 minutes of vaccination. Was treated with EpiPen and kept in ER for observation overnight. Symptoms resolved.

COVID19 VACCINE (COVID19)

Life Threatening

40-49 years

Swollen lips/tongue, shortness of breath, cough, hives, nausea, headache Epi shot, Benadryl, Pepcid, prednisone

COVID19 VACCINE (COVID19)

Life Threatening

40-49 years

ITP Plt 2

COVID19 VACCINE (COVID19)

Life Threatening

40-49 years

Initial itching at injection site, observed and returned to work. Came back ~30-40 minutes later with itchiness in throat and hives to arm. Given Benadryl PO and observed for extended period of time. Symptoms not resolving. Patient transferred to Emergency Department for further care. At that point observed to have full body rash, SOB. Given Epi while in ED. Developed tachycardia, hypotension. Treatment continued.

COVID19 VACCINE (COVID19)

Life Threatening

40-49 years

I had a myocardial infarction on December 27, 2020. I had received my first vaccination for COVID-19 on December 22, 2020. Not sure if these are related but I felt I should report it.

COVID19 VACCINE (COVID19)

Life Threatening

40-49 years

Shortness of breath, cough, rash on face and neck, arthralgia

COVID19 VACCINE (COVID19)

Life Threatening

40-49 years

7 day after site itching, hot swelling. Unsure if related 9 day after suffered CVA and have

hyper coagulation

COVID19 VACCINE (COVID19)

Life Threatening 40-49 years

I am not sure if related or not. This event was 13 days after my COVID-19 1/2 immunization. Otherwise, I am a very healthy physician, normal BMI, I have also been tested 5-6 times negative for COVID. I do get exposed in my job, but wear proper PPE. Viral infection in FEB that was like COVID-19 sx, I did AB test as soon as it was available, and negative. ---The Event: Monday morning (1/4/21), after getting out of shower, I was talking to my husband (who is MD) and started having BROCA's aphasia sx (could not get words out coherently), then fell into bed and started right wrist and right foot posturing. This lasted 10 min. I have non-memory of it, but my MD husband witnessed it. After 10 minutes, I was back to normal, except shaky and some word finding difficulties. After 30 min, totally back to normal.

COVID19 VACCINE (COVID19)

Life Threatening 40-49 years

Throat closing Pruritic throat and tongue Tingling lips and tongue Throat clearing Hoarse voice

COVID19 VACCINE (COVID19)

Life Threatening 40-49 years

Pain at site of injection, eyes, throat, face swelling. Unclear thinking, hoarse speech, headache, hives, swelling. Intervention taken immediately. Ongoing 11 days: SOB, headaches, nose bleeds, coughing, blood sugars triple, hair falling out, major swelling, dizziness.

COVID19 VACCINE (COVID19)

Life Threatening 40-49 years

Sever thrombocytopenia (platelet count 2,000) 8 days following Moderna COVID vaccine. Clinically suspicious for ITP.

COVID19 VACCINE (COVID19)

Life Threatening 40-49 years

Anaphylactic reaction; Flushed; Diaphoretic; redness and rash; hives on chest; Tachycardia; shortness of breath; Chest tightness; Dizziness; Headache; This is a spontaneous report from a contactable nurse, the patient. A 47-year-old female patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE; Lot Number: EL1283), via an unspecified route of administration on 08Jan2021 at 08:49 (at the age of 47-years-old) as a single dose for COVID-19 immunization. There were no known medical history or concomitant medications. The patient previously received the first dose of BNT162B2 on 18Dec2020 (Lot Number: EK5730) for COVID-19 immunization and experienced nausea, headache, and fatigue. On 08Jan2021, about 5-10 minutes after the second dose, the patient experienced anaphylactic reaction, flushed, diaphoretic, redness and rash, hives on chest, tachycardia, shortness of breath, and chest tightness, reported as life-threatening. She reported that these events occurred within less than 10 minutes of receiving the vaccine. She went to the emergency room and was treated with methylprednisolone (SOLUMEDROL), diphenhydramine hydrochloride (BENADRYL), famotidine (PEPCID), and epinephrine (MANUFACTURER UNKNOWN). She was sent home and prescribed methylprednisolone and epinephrine (EPI-PEN). Later on 08Jan2021, she experienced dizziness and headache, which were consistent. She stated she would most likely take ibuprofen (MOTRIN) as treatment (not specified if taken). The clinical outcomes of the flushed, diaphoretic, redness and rash, hives on chest, tachycardia, shortness of breath, and chest tightness were recovered on 08Jan2021; while the outcomes of the dizziness and headache were not recovered and that of the anaphylaxis was reported as recovering.; Sender's Comments: The reported information is limited. Based on the close temporal relationship and the description of the events, there is a reasonable possibility that the events are related to BNT162 vaccine. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

COVID19 VACCINE (COVID19)

Life Threatening 40-49 years

Woke up on 1/6/2021 with hot flashes, palpitations, dizziness and heart racing. Went to urgent care and they did an EKG which showed A-Fib, so I was sent to the ER and from there, I was transferred to an ICU at a different facility. I stayed until 1/8/2021. No cause was found and no history of A-Fib or family history.

COVID19 VACCINE (COVID19)

Life Threatening 40-49 years

first day after shot, nausea, body aches, 2nd day Sunday headache, Monday 5 am woke up itching, then 9 am hives everywhere, trouble breathing, anaphylaxis, went to ER, got epi X 2, solumedrol, benadryl, pepcid, then still with hives, tachycardia, dyspnea, iv fluids were infusing and epi drip started, went to ICU

COVID19 VACCINE (COVID19)

Life Threatening

**40-49
years**

First Day after the injection I had a headache and nausea the entire day into the next day. The second day I still had the headache and the nausea. I work overnights. When I awoke in the afternoon, my throat was closing up. It was hard to swallow and I struggled to breath. I immediately drank liquid Benadryl and called my doctor in the morning.

COVID19 VACCINE (COVID19)

Life Threatening

**40-49
years**

2230 feeling of unease, body aches, site arm tingling, general mild aches 0220 awoke from sleep choking, having difficulty breathing, felt very SOB, worse with exertion or trying to speak, great difficulty swallowing and speaking even in brief words. Took 50mg of Benadryl PO and went to the ED, about a 15 minute car ride. Had tingling and numbness of the tongue and back of throat by arrival but still able to breath with focus. Exertion of just walking into the ED greatly increased the SOB. Was triaged, Benadryl starting to help, was able to speak a little better, 3-4 words without too much SOB caused. Was walked to a room, SOB milder with that exertion. Seen by Dr. Given IV Sol-u-Medrol and 50mg Benadryl. Was observed on cardiac monitor/Q15VS for a few hours and discharged home around 5:30. Given Rx of Prednisone 20mg -3tabs x2 days, 2tabs x5 days all once a days and told to take 50mg of Benadryl Q4H for the next 24 hours at least and to return prn. I did need to stay on Benadryl, as the Sol-u-Medrol wore off some of the swelling in thr throat did return but not severe, Benadryl did help, along with taking my Asthmnex I already had. I also continued my normal HS antihistamines. I had SOB on exertion, progressively better from the 6th-10th with it mostly resolved to yesterday. Body aches have continued but also progressively better. Yeasterday1/12/21 the Rx of prednisone was completed and I did have some mild swelling /tingling in the throat/face/mouth return in the evening, took Benadryl 50mg again and inhaler used. I have an appointment today to seek further care at my primary doctor's office. Asthmmax used again this morning as well, only mild tightness in the throat currently with mild body aches this whole time.

COVID19 VACCINE (COVID19)

Life Threatening

**40-49
years**

Patient received vaccine in afternoon of 12/28. She works in ER as housekeeper 7pm-7am. The day she received the vaccine she became ill with fever chills and nausea and left work at 2am. On 12/31 she developed hemianopia. She went to ER and they did CT scan. She was told it was complex migraine. She left and came Home. On 1/1/21 her vision was back to normal. On 1/3 she suffered bilateral cerebellum ischemic stroke. She is currently in medical center. In Trauma.

COVID19 VACCINE (COVID19)

Life Threatening

**40-49
years**

Patient received COVID-19 Vaccine at 0956 and reported symptoms of itchy face and chest pressure at approximately 1008 during observation period. Pt vital signs were 133/86, HR 130 and oxygen saturation 100% on room air. Pt reported worsening symptoms of chest pressure and itchiness to face. Provider instructed Epi Pen be given and pt to be transported to ED for further evaluation. EKG obtained and showed sinus tachycardia. Nonrebreather oxygen mask applied with 2L/min and oxygen saturation remained at 100%. Pt was transported via ambulance to at 1038 and pt reported feeling improved symptoms prior to leaving the clinic at approximately 1034. Pt stable at time of transfer.

COVID19 VACCINE (COVID19)

Life Threatening

**40-49
years**

severe angioedema, hives, tachycardia, hypertension, pruritus, chest tightness and shortness of breath.; severe angioedema, hives, tachycardia, hypertension, pruritus, chest tightness and shortness of breath.; severe angioedema, hives, tachycardia, hypertension, pruritus, chest tightness and shortness of breath.; severe angioedema, hives, tachycardia, hypertension, pruritus, chest tightness and shortness of breath.; severe angioedema, hives, tachycardia, hypertension, pruritus, chest tightness and shortness of breath.; severe angioedema, hives, tachycardia, hypertension, pruritus, chest tightness and shortness of breath.; severe angioedema, hives, tachycardia, hypertension, pruritus, chest tightness and shortness of breath; This is a spontaneous report from a contactable nurse (reporting for herself). A 41-year-old non-pregnant female patient received two doses of BNT162B2

(PFIZER-BIONTECH COVID-19 MRNA VACCINE), both via an unspecified route of administration in the left arm, the first dose on 16Dec2020 09:00 (lot number: EH9899) and the second dose on 08Jan2021 07:15 (lot number: EL0140), both at a single dose for COVID-19 immunization. Medical history included ongoing anxiety, from an unspecified date. The patient had no known allergies. Concomitant medication included escitalopram oxalate (LEXAPRO), acetaminophen (MANUFACTURER UNKNOWN), naproxen sodium (MANUFACTURER UNKNOWN), ibuprofen (MANUFACTURER UNKNOWN). The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, the patient was not diagnosed with COVID-19 and since the vaccination, has not been tested for COVID-19. On 09Jan2021 at 01:30 AM, the patient experienced severe angioedema, hives, tachycardia, hypertension, pruritus, chest tightness and shortness of breath, all of which were reported as being life-threatening. The patient went to the Emergency room due to the events. Therapeutic measures were taken as a result of the events and included: methylprednisolone sodium succinate (SOLUMEDROL) 125 mg, famotidine (MANUFACTURER UNKNOWN) 20 mg and diphenhydramine hydrochloride (BENADRYL) 50 mg. The clinical outcome of severe angioedema, hives, tachycardia, hypertension, pruritus, chest tightness and shortness of breath was recovering.; Sender's Comments: A possible causal association between administration of BNT162B2 and the onset severe angioedema, hives, tachycardia, hypertension, pruritus, chest tightness and shortness of breath cannot be excluded, considering the plausible temporal relationship and the known adverse event profile of the suspect product. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

COVID19 VACCINE (COVID19)

Life Threatening 40-49 years

Began with tingling/itching to tongue and roof of mouth approx 15 minutes after administration, progressed to tingling of lips, was sent to the ED for observation. Within 20-30 minutes developed cough, throat tightness, difficulty swallowing, breathing, vomiting, shortness of breath. Noted to have uvular swelling and wheezing on examination. Given Benadryl, Pepcid, Solumedrol, Zofran, Albuterol MDI, Epi IM. within a few minutes symptoms returned and were worse where I felt like I could not breathe, throat was closing, could not talk. Noted to be pale, HR in 140's. Given second dose of epi IM and symptoms improved. Was transferred to Obs Unit., within 2 hours (approx 6 hours after administration), developed SOB, throat tightness, cough, vomiting, difficulty breathing. Again noted to have swelling of uvula, wheezing on exam. Given Solumedrol, Benadryl, SQ epi, Albuterol, Racemic Epi nebulizer. Was transferred to ICU, all meds held except Pepcid. Day #2 ~10 am (25 hours from administration) developed throat tightness, diffuse red rash to arms, difficulty breathing, vomiting. Again noted to have uvular swelling and wheezing. Given Solumedrol, Benadryl, Pepcid, Albuterol MDI, Racemic Epi neb. Solumedrol started q12hour dosing. Strange feeling/fullness in throat continued all day, got additional racemic Epi neb that night with improvement of symptoms. Following morning (day#2 after vaccine) noted to have diffuse red rash to chest and face, spread to arms, then began coughing. Given Solumedrol, Pepcid, Benadryl, Advair, Racemic Epi nebulizer. Solumedrol changed to q8 dosing. Approx 4 hrs later nurse noted rash worse on face, associated with itching, throat tightness. Given additional Benadryl, Racemic Epi neb with improvement. Rash continued that night with throat tightness, got additional Benadryl and Racemic Neb that night (total of 3 Racemic nebulizer on Day#2 post vaccine). Transferred to telemetry floor. Day#3 post vaccine rash improved, but still present to chest and face. Throat fullness present, especially after drinking. Am still hospitalized while writing this report

COVID19 VACCINE (COVID19)

Life Threatening 40-49 years

Systemic: Anaphylaxis-Medium; symptoms lasted 1 day

COVID19 VACCINE (COVID19)

Life Threatening 40-49 years

Vaccination given 1314 and sent to waiting room for monitoring. Began to have itching at 1325. PO benadryl administered. Then with throat swelling. Epinephrine administered by EMS/Fire at 1:32pm: 0.5mg IM right arm. 1342 improving 1350 itching/throat swelling returning while EMS/Fire on phone with medical director. 1352 second dose of epinephrine administered by De Pere EMS/Fire: 0.5mg IM left arm Medical Director on site for evaluation. Client given option to transport to hospital or stay for monitoring with EMS/Dr. Condition improving, chose to stay for monitoring. Client improved and up walking halls 1513 Client cleared to be released home via private transport

COVID19 VACCINE (COVID19)

Life Threatening

40-49 years

Anaphylaxis- throat tightness , nausea , rash , pruritis , chest tightness, wheezing . 9-11 called epinephrine x 2 , decade on , IV Benadryl , duo-nebs, famotidine, admission to icu high dose prednisone , nebulizers , zofran , duo-neb nebulizers

COVID19 VACCINE (COVID19)

Life Threatening

40-49 years

throat closing up; struggled the breath; This is a spontaneous report from a contactable consumer (patient). A 44-year-old female patient (non-pregnant) received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: Pfizer EL 3302), via an unspecified route of administration on 09Jan2021 07:30 am at single dose at left arm for covid-19 immunization. Medical history included diabetes, high blood pressure, allergies. The patient's concomitant medications were not reported. Patient didn't receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient was not diagnosed with COVID-19 prior to vaccination. Since the vaccination, patient has not been tested for COVID-19. On 10Jan2021 14:30, patient woke up with throat closing up and struggled the breath. Patient immediately drank a dose of diphenhydramine hydrochloride (BENADRYL). Patient did that two more time in the evening of 10Jan2021. Patient called the doctor in the morning. Events were considered serious per life-threatening. The adverse events resulted in doctor or other healthcare professional office/clinic visit, life threatening illness (immediate risk of death from the event). Patient received treatment liquid diphenhydramine hydrochloride, epinephrine (EPI-PEN) for events. Outcome of events was recovered in Jan2021.

COVID19 VACCINE (COVID19)

Life Threatening

40-49 years

Onset of shortness of breath and cough on 1/3 that progressively got worse. Clinical diagnosis of pneumonia without fever was made, patient started azithromycin on 1/5 and albuterol treatments every 4-6 hrs. Initially he improved, but then worsened. chest xray on 1/6 was negative for pneumonia, PCR covid test was negative, albuterol treatment did not bring much relief. He started respiratory distress on 1/10 and was taken by car to the local ER where another covid test was negative and chest CT revealed multiple bilateral pulmonary emboli. The leg US revealed blood clots in both of his legs. He had an emergency catheter-delivered thrombolysis and was discharged home from the ICU on 1/12 on oral anticoagulants. He is gradually improving, but very weak. He tires easily and gets a drop in oxygen to 90- 93%, as well as an increase in the heart rate to 120 when walking less than half a mile. He runs out of breath with exertion.

COVID19 VACCINE (COVID19)

Life Threatening

40-49 years

About 10 minutes after getting my vaccine I noticed the roof of my mouth itching as well as my tongue and back of my throat. I waited to see if it would go away and then a couple minutes later noticed my lips started itching and swelling and from there it just got worse. I told the nurse practitioner that I think I was having a reaction, she had me take a seat told her my entire mouth throat & lips felt swollen and itching and she looked and said it was full blown anaphylaxis reaction. Administered EpiPen, benadryl and called ambulance where they took me to medial emergency department.

COVID19 VACCINE (COVID19)

Life Threatening

40-49 years

At 6 days after my second COVID-19 Pfizer vaccine (first dose given 12/17/20), I had acute onset of chest pain and shortness of breath prompting a trip to the Emergency Department. A chest CT Angio to rule out pulmonary embolus was done and negative for pulmonary embolus. My EKG showed some mild ST changes and a troponin I level was elevated at 0.08 (normal 0.04). Subsequent troponin levels 90 minutes apart showed a rising troponin at 0.18 and 0.38. An echocardiogram was performed which showed regional wall motion abnormalities consistent with Takotsubo cardiomyopathy and an ejection fraction of 45%. I was then taken to cardiac catheterization lab for coronary angiograms which were normal. My LV angiogram was consistent with Takotsubo cardiomyopathy and my LVEDP was elevated. I was started on a beta blocker and sent home the following day.

COVID19 VACCINE (COVID19)

Life Threatening

40-49 years

The day after receiving the second vaccination, I began to have mild intermittent abdominal pain2-3/10. The pain gradually increased, became more intense, and more constant. Mild fever and chills

started happening, and I took Ibuprofen. By about 4 days after the vaccine, the abdominal pain was severe enough that I had some difficulty walking and I couldn't sleep at night. Pain was 6-8/10. I went to the ER, and CT scan with IV contrast showed 18 mm appendicitis. I underwent laparoscopic surgery and it was found to be perforated. It was removed. I am currently recovering in the hospital. I received the vaccine as a health care provider at my hospital, specifically I am a practicing pediatrician physician for over 10 years.

COVID19 VACCINE (COVID19)

Life Threatening

40-49 years

I was vaccinated at 3:30pm . At 5:27pm while driving home i felt a cold sensation in the back of my neck and back of my throat which began spreading to the back of my head . My heart felt as if I was startled by something. I looked at my smart watch and my heart rate was 145. I began trembling and having abdominal cramping . The back of my head felt like I had swelling or collection of fluid. I opened my windows and began taking slow deep breaths to bring down my heart rate . It took quite a while to get it below 100. I felt as if I was going to pass out. After deep breathing for what felt like atleast 15 to 20 minutes , my pulse came down and I closed my windows . As soon as my body warmed back up in the car , the symptoms returned and my heart rate went back up to 130s , 140s . I had to keep my windows down and deep breathe the entire way home which took an hour . My body was trembling. When I got home I felt as if I was too weak to get out of the car . I still felt that startled feeling in my heart and was afraid of what could happen next . My lips and face were swollen. My lips were also slightly itchy. I called 911 for help . By the time they arrived my vital signs had stabilized but I still had swelling in my face and lips . My EKG , vital signs and oxygen levels checked out normal so I did not go to the ER. That night I took benadryl and Tylenol. Day 2 post vaccine the collection of fluid or swelling in the back of my head had now spread to the top . That night I had the feeling that my throat was swelling do I took benadryl and Tylenol and my face and lips were still slightly swollen . Day 3 post vaccine I woke up with slightly blurry vision. The swelling in my head now feels like it has encompassed my entire head and have a slight headache. I went to the urgent care requesting an MRI of the head and an epi pen . I was given Medrol dose pack , an RX for epi pen for emergencies and advised to continue benadryl and Tylenol. Day 4 post vaccine, slight headache continues. Slightly blurry vision

COVID19 VACCINE (COVID19)

Life Threatening

40-49 years

Was feeling anxious right after vaccine given. Laid in cot for a short time, then stated her throat felt like it was closing.

COVID19 VACCINE (COVID19)

Life Threatening

40-49 years

1) Skin rash over 80% of my body including, face and lips; started to change my voice sound and started to compromise my airways. 2) Uncontrollable shakes, but not sure if this was related to Covid-19 itself. Was given steroids via injection into my blood stream, within minutes the shakes stopped and within 2 hours the rash was gone.

COVID19 VACCINE (COVID19)

Life Threatening

40-49 years

8 hours after vaccine severe injection site pain/swelling, severe body aches, 101.0 temp. 16 hours after vaccine woke up from sleeping with flushed skin, facial swelling, and throat swelling. I immediately took 100mg of Benadryl and went to hospital emergency room. Approximately 30-40 minutes later symptoms started to lessen. Once at the ER, at the same time symptoms began to resolve, I was given PO Solumedrol and Pepcid. I was monitored and then discharged with RX for prednisone, and EPIPEN (to use if needed). No other issues with allergic reaction. Mild injection site soreness, mild body aches, 99.3 temp persist at 36 hours post injection.

COVID19 VACCINE (COVID19)

Life Threatening

40-49 years

Developed chest tightness around right side of chest into back and SOB 50.5 hours after vaccination. Went to local ER and found to have a right lower lobe pulmonary embolism. Treated with Xarelto and sent home with outpatient follow up.

COVID19 VACCINE (COVID19)

Life Threatening

40-49 years

1/16/21, Covid vaccine injection at 12:09 PM Minute 1: dizzy and light headed (like drinking a beer on an empty stomach) Minute 10: Nausea Minutes 23-25: Neck tightness (like doing unsupported crunches and holding my head up) Minute 27: Inability to swallow and inability to speak EMS on site administered EpiPen auto-injection to left thigh, immediate improvement in symptoms Transport to

hospital via ambulance Hospital monitored me for several hours and discharged same day

COVID19 VACCINE (COVID19)

Life Threatening 40-49 years

Started with severe chills, body aches and feverish. The. Slight leg pain which worsened with time , swelling on the right leg calf, warm to touch and difficulty breathing. Got hospitalized on 1/16 21 with multiple clots in my right leg and clot in the lung. Still in the hospital now.

COVID19 VACCINE (COVID19)

Life Threatening 40-49 years

Systemic: Anaphylaxis-Severe, Systemic: Seizure-Severe

COVID19 VACCINE (COVID19)

Life Threatening 40-49 years

Visited Provider appx 500 pm 1.14.2021 DVT - left calf - 2 clots via ultrasound on Eliquis now

COVID19 VACCINE (COVID19)

Life Threatening 40-49 years

Patient developed symptoms of Guillain-Barre syndrome on January 15, 2021 and was admitted the Hospital. She was diagnosed and eventually required ICU level care and has been treated with plasmapheresis. She is currently still in the ICU but is stable.

COVID19 VACCINE (COVID19)

Life Threatening 40-49 years

Tachycardia, Shortness of breath, headache, dizziness, weakness, chills, nausea, fever

COVID19 VACCINE (COVID19)

Life Threatening 40-49 years

Dizziness, Headache, Myalgia, Tachypnea, CoughWheeze, NauseaVomiting, Palpitations & Tachycardia & Narrative: Patient stated that after receiving injection on 01/06/2021, tasted metal in her mouth. No reaction noted in clinic after vaccine administered. Patient states that after returning home, she began to have chills, headache, and muscle aches. Could not sleep. On 01/07/2021. Patient continued to experience above symptoms. Approx. 13:50 on 01/07/2021. Patient presented with respiratory difficult, tachypnea stridor, and stated she felt as if her airway was closing. Patient was vomiting and was tachycardic. Epi-pen administered via left lateral thigh. Patient administered 50mg of PO Benadryl, and 2 puffs of albuterol inhaler. Continuous V/S initiated. Patient began to experience relief of symptoms. HR and blood pressure remained elevated, but this was expected side effect of epi. SpO2 stabilized around 99% on room air. Patient was monitored for 60 minutes. Transportation home was arranged and family was present to observe overnight.

COVID19 VACCINE (COVID19)

Life Threatening 40-49 years

Fainting, dizziness and weakness, trembling, BP 168/129. HR 145

COVID19 VACCINE (COVID19)

Life Threatening 40-49 years

Pt was 18 weeks pregnant at the time of the vaccine. Second pregnancy. Pt is a physician. Pregnancy was entirely normal up to that time. On 1/18/2021, she began to have heavy vaginal bleeding probably due to a placental abruption and subsequently delivered at 18 weeks. Baby was stillborn. Ultrasound done 1/15/2021 normal. Lethal event for the fetus. The patient did well.

COVID19 VACCINE (COVID19)

Life Threatening 40-49 years

The patient was seen in my office on 1/19/21 with complaint of heavy vaginal bleeding. A CBC was obtained which revealed an H/H of 12.2/36.1 and a platelet count of 1 (not 1K, but 1 platelet!) and this was confirmed on smear review. She was immediately sent to the Hospital ED and repeat CBC confirmed the critically low platelet count. She is currently hospitalized and she has received platelet transfusions but her platelet count is still critically low. She is also receiving steroids and immunoglobulin and is under the care of MD (Heme/Onc)

COVID19 VACCINE (COVID19)

Life Threatening 40-49 years

Patient got her 2nd dose of Pfizer covid vaccine on 1/8. On 1/11 she had intermittent chest pain that lasted a few days and started to notice small purpura rash on left breast. She didn't think much of it but noticed the same type of rash on her pant line and then right thigh. On 1/15 she called Occupational Health who advised her to go straight to the ED.

COVID19 VACCINE (COVID19)

Life Threatening 40-49 years

Started itching within (left arm) 15 minutes. They said I was fine and to go back to work. About an

hour later, I started breaking out in hives and whole body itching. I went back in and they gave me to full strength Benadryl and it was not helping and my BP was 190/140 (stroke level) and they tried to bring that down. About 10:15 my face was starting to swell and I was short of breath and 10:30 they took me to ER - and gave me Cortisol shot. And IV fluids. And I was in ER for two hours. They wrote me a prescription for six days for 2 prednisone for every day for one week. The PA saw me at the ER and he prescribed. I went home but couldn't drive home because I couldn't see straight so got a ride home. They tested my O2 levels before they left me. Oxygen was 96. My blood pressure was down to 140/95 - so it was down but still elevated. I still had facial swelling for 3 days. But after three or four days it resolved the face swelling. Had a weakness from the shot and still itching but nothing like it was that day still after the four days. Dr. told me I couldn't get second dose. It was an anaphalactic reaction. Dr - prescribed me an EpiPen in case I have another bad reaction to anything.

COVID19 VACCINE (COVID19)

Life Threatening

50-59 years

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

COVID19 VACCINE (COVID19)

Life Threatening

50-59 years

Pt expressed feeling tachycardic, jittery, shaky, site edema, shortness of breath and dizziness. Pt received epipen 0.3 mg IM injection x1 dose and benadryl PO, responded favorably and transported to ED for follow up care.

COVID19 VACCINE (COVID19)

Life Threatening

50-59 years

PT WAS OBSERVED IN HOLDING AREA LEANING FORWARD IN HER CHAIR ABOUT 7 MINUTES AFTER RECEIVING THE VACCINE. RN ASSESSED AND NOTED: AUDIBLE WHEEZE, RESP 40/MIN, LIP SWELLING AND PT COMPLAINED OF NAUSEA. PT WAS ESCORTED TO ER IN WHEELCHAIR ACCOMPANIED BY 2 RN'S (2 MINUTE WALK) ONE HOUR LATER - AS REPORTED BY DR (ER) WORKING DIAGNOSIS - ANAPHYLAXIS / STATUS ASTHMATICUS MEDS RECEIVED: SOLUMEDROL 125, DIPHENHYDRAMINE 50MG, FAMOTIDINE 20MG --ALL IV EPINEPHRINE 0.3MG IM X1 FOLLOWED BY 0.3MG IV X 1 FOLLOWED BY 0.1MG IV X1 PT IS RECEIVING O2 - AND PROGRESSING TO BIPAP

COVID19 VACCINE (COVID19)

Life Threatening

50-59 years

Acute NSTEMI with symptom onset 4 days after vaccination

COVID19 VACCINE (COVID19)

Life Threatening

50-59 years

Subject received vaccination Wednesday Dec 16th in the afternoon. He became symptomatic (shortness of breath, low grade fever) the next day. Went to the Emergency room on Saturday Dec. 26th, 2020 due to shortness of breath, had an O2 Sat of 60%, and was hospitalized in the ICU at another hospital (due to bed unavailability).

COVID19 VACCINE (COVID19)

Life Threatening

50-59 years

Itching, cough. Given benadryl 50mg and epinephrine 0.3 in vaccine clinic, and taken to ED for further tx.

COVID19 VACCINE (COVID19)

Life Threatening

50-59 years

Pt. developed tachycardia, hypertension and felt weak with decreased verbal responsiveness, alert but lethargic. She complained of dry throat, took a sip of water then began persistent coughing and writhing also C/O itching of her throat. She denied difficulty breathing, there were no cutaneous signs of edema, tongue enlargement, etc.

COVID19 VACCINE (COVID19)

Life Threatening

50-59 years

years

12/30 9:30 am developed angioedema. Swelling of face, lips, tight throat. Also had bright red rash over body trunk and arms. Both palms were red, hot and painful.

COVID19 VACCINE (COVID19)

Life Threatening 50-59 years

On Dec. 20, 2020 around 11:30 PM, 2 days after patient received her COVID-19 vaccination, she was found on the bathroom floor, obtunded, very pale, diaphoretic, nauseous, and complaining of severe chest pain. Paramedics was called and patient was transported to the nearest emergency room.

According to paramedics, on the way to the ER while patient was in the ambulance, she was noted with a sudden drop in heart rate about 19 beats/minute and have to be given Atropine IV Push, oxygen and was connected to transcutaneous pacing which improves her heart rate. In the ER patient continued to have chest pain and she was given Morphine, Oxygen, Nitroglycerine and Aspirin. IM had an EKG which showed Sinus Bradycardia with a Right Bundle Branch Block. She had serial ekgs, a chest x-ray, laboratory testing which included Troponin. Her first Troponin level came back elevated prompting her hospital admission to Telemetry. Her next 2 Troponin level improved and return to normal range and her chest pain has resolved.. She underwent a Stress Test which came back negative. Patient was admitted for a total of 20 hours in the Telemetry unit with Cardiology consultation before being discharged home last . She was re-evaluated by the cardiologist yesterday which diagnosed her a chest pain of unknown origin.

COVID19 VACCINE (COVID19)

Life Threatening 50-59 years

Shortly after receiving the vaccine (within 10 minutes) the patient's tongue swelled, facial redness, gasping for air. This resident was marked for a 30 minute observation due to previous anaphylaxis type reaction. Immediately administered 0.3mg epinephrine x 1 dose. Then administered 50mg IM Diphenhydramine. This treatment course resolved the adverse reaction. Patient was monitored onsite at facility. Her husband came to pick her up and take her home. Tried to reach patient several hours after but was unable to at this time.

COVID19 VACCINE (COVID19)

Life Threatening 50-59 years

Flushing, sweating, increased heart rate proceeded to feel difficulty swallowing and clearing my throat. I was taken to the ER. The symptoms progressed to feeling dizziness, difficulty speaking, and chest pressure with increased SBP/DBP. General nausea and feeling very unwell.

COVID19 VACCINE (COVID19)

Life Threatening 50-59 years

Acute Pericarditis. Patient was admitted from 12/27-12/28/2020 at hospital by cardiology team who strongly felt the acute pericarditis was due to the Pfizer Vaccine (Dr. was senior cardiologist).

COVID19 VACCINE (COVID19)

Life Threatening 50-59 years

thrombotic stroke -necessitating hospitalization; and craniotomy; required mechanical ventilator for 2 days. Patient now extubated, breathing on her own. Patient remains hospitalized with marked deficits (aphasic)

COVID19 VACCINE (COVID19)

Life Threatening 50-59 years

20 minutes after receiving the vaccination the resident started to not feel well. She said she felt very far away and just kept repeating I don't feel well. She was diaphoretic and her chest was very red and she kept scratching and rubbing it at it. I asked if she wanted IM Benadryl or epipen and she at first denied. She also said she felt like she needed to focus on her breathing. At this time we decided it was best to administer Epipen x 1 dose. Immediately after she felt better. She was observed for another 30 minutes and then went home. at 7:17pm I called and spoke with her. She said her arm was sore and that her oxygen levels were about 88-89% which is low for her but she said she felt fine and is currently working right now.

COVID19 VACCINE (COVID19)

Life Threatening 50-59 years

2 minutes after vaccine was administered, noticed swelling back of tongue, progressed to posterior 2/3 of tongue, tachycardia, elevated BP. Progressive angioedema involving larynx, cough, shortness of breath. No wheezing. Physical exam did not show any obvious swelling. O2 sat decreased to 80, 1st epinephrine IM administered, 50mg benadryl IV and Famotidine administered. some improvement in

symptoms. In 30mins, reoccurrence of angioedema and second epinephrine vaccine administered. Monitored for 2 hours without reoccurrence of symptoms and discharged from ER.

COVID19 VACCINE (COVID19)

Life Threatening

50-59 years

PATIENT VACCINATED AROUND 9AM. SHE REPORTS SHE FELT WARM/FLUSHING, FAINT AND STOMACH SPASMS WITHIN ABOUT 4-5 MINS. SHE FELT BETTER AND GOT UP TO WALK ABOUT 30 MINS LATER. SYMPTOMS WORSENER AFTER WALKING ~9:45AM: FAINT AGAIN, SEVERE RETCHING, BP196/140 TO 199/164, TROUBLE SWALLOWING, SOB, WHEEZING. AT 9:58AM, EPI PEN 0.3MG ADMINISTERED AND EMS ACTIVATED. SYMPTOMS REPORTED IMPROVED FOLLOWING EPI. EMS ARRIVED 10:05AM. PATIENT REPORTED RECEIVING 2 BAGS OF PEPCID, STEROIDS, AND ZOFRAN AT HOSPITAL. WAS RELEASED BETWEEN 11:30AM-12PM ON 1/4/21, BP 140/90 AND ACUTE SYMPTOMS RESOLVED. FOLLOW UP WITH PATIENT 1/5/21: NO PRIOR HX OF HTN, BP 120/60, NO SOB/ BREATHING DIFFICULTY. C/O SEVERE HEADACHE, LOW TEMP, FATIGUE, MUSCLE ACHES, SORE THROAT.

COVID19 VACCINE (COVID19)

Life Threatening

50-59 years

Severe right lower quadrant pain, anorexia over 12 hours. Went to the emergency department. Lab results showed elevated WBC and CT scan showed acute appendicitis. Admitted for urgent surgery: laparoscopic appendectomy. Was hospitalized from 12/26/20-12/28/20.

COVID19 VACCINE (COVID19)

Life Threatening

50-59 years

Rapid heart rate, shakiness, headache, rash, scratchy throat, raspy voice, dizziness, extreme weakness

COVID19 VACCINE (COVID19)

Life Threatening

50-59 years

anaphylaxis, dyspnea

COVID19 VACCINE (COVID19)

Life Threatening

50-59 years

Resident had the COVID vaccine 12/30/2020. 12/31/20, resident has been in bed all shift. Staff became concerned when resident was not easily aroused. Resident displayed signs of tremors, twitching, confusion, in and out of consciousness, low O2 sats, elevated pulse and fever, fatigue and weakness. Writer called NP. NP stated this is most likely a reaction d/t the COVID vaccine. She gave orders for Benadryl 25mg IM x1 now and Tylenol 1000 mg now. NP also stated resident will not be getting the second dose of vaccine. Will continue to monitor and update NP if worsening symptoms. After receiving Benadryl and Tylenol at 145pm, resident began to appear as though she was feeling better and was talking to talk, fever had gone down. Tonight resident is not easily aroused, lethargic, continues to have tremors and twitches, almost appearing as convulsions. When asked if she knows where she is or what day it is, resident can properly answer. Resident denies SOB but staff has noted loud squeals while breathing. NP was updated and gave new orders to give Benadryl 25 mg IM x1 if needed and Ok to send resident to ED. Resident currently refuses to go to the hospital. Will continue to monitor. BP 152/112, P 116, T 99.1, O2 87-91. Resident's O2 at 1205am was 80% on 3LPM. Resident unable to be aroused from sleep by writer. NAR called to assist. NAR could not arouse resident. Writer and NAR attempted to reposition resident and resident's breathing became more labored. Resident turned back to previous position and writer called on call MD at approx. 1220am. MD returned call approx. 1235am with orders to send resident to ED. 911 called and ambulance arrived about 1245am. History of present condition given to EMTs and they stated resident would be going to Hospital. Writer has attempted to contact Hospital ED x3 but have been unable to get through. An EMT did just call to clarify when vaccine was given, what symptoms have been present and when they started. She said she has everything she should need and she will let Hospital ED staff know to call if they need anything else. Writer will again attempt to contact them though. Resident's temp was 97.5 and BG 128. When EMTs arrived they got an O2 reading of 60%. Resident did open her eyes a couple times during transfer from bed to stretcher and while stretcher was going outside but no responses from resident were made.

COVID19 VACCINE (COVID19)

Life Threatening

50-59 years

Swelling of lips & tongue, tightening of throat. Quivering of arms & legs. Tightening of chest. Dizziness lightheaded.

COVID19 VACCINE (COVID19)

Life Threatening

50-59 years

Facial (cheek) numbness and swelling with slight face droop Swelling continued on 1/7/2021 On

1/8/2021, lip swelling and numbness and tongue numbness By 1/9/2021 4pm, swelling and numbness resolved but chills and muscle aches began

	COVID19 VACCINE (COVID19)	Life Threatening	50-59 years
Anaphylactic reaction			
	COVID19 VACCINE (COVID19)	Life Threatening	50-59 years
Chills Hip pain			
	COVID19 VACCINE (COVID19)	Life Threatening	50-59 years
anaphylaxis; throat tightening; throat tightening/tingling; throat tightening/tingling/soreness; dry wheezy cough a little dizziness; dizziness; tachycardia; Itching; chills; numb R foot; Low grade temp; h/a today; This is a spontaneous report from a contactable Nurse (patient). A 51-years-old female patient (no pregnant) started to receive bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number e13248), via an unspecified route of administration on 06Jan2021 11:00 at the first single dose at left arm for covid-19 immunisation. Medical history included supraventricular tachycardia, adrenal insufficiency, hypothyroidism, attention deficit hyperactivity disorder, hypermobility syndrome, developmental hip. Concomitant medication included hydrocortisone, trazodone, levothyroxine sodium (LEVOTHROID), bupropion hydrochloride (WELLBUTRIN). The patient previously took erythromycin, morphine and experienced drug hypersensitivity. The patient experienced anaphylaxis, throat tightening/tingling/soreness, dry wheezy cough a little dizziness and tachycardia. Itching, numb R foot, Low grade temp and chills and headache on 06Jan2021 11:15. Seriousness criteria reported as life threatening. Taken to ER had IV benadryl, solumedrol, pepcid for anaphylaxis. Placed on O2 and given albuterol nebulizer. Had IV fluid bolus. Now on benadryl and 5 days of prednisone. The patient felt completely fine prior to vaccine. The patient underwent lab tests and procedures which included sars-cov-2 test: negative on 06Jan2021. The outcome of events was recovering. No other vaccine in four weeks; No covid prior vaccination.; Sender's Comments: A possible causal association between administration of BNT162B2 and the onset of anaphylaxis presented as throat tightening/tingling/soreness, dry wheezy cough a little dizziness and tachycardia. Itching, numb R foot, Low grade temp and chills and headache cannot be excluded, considering the plausible temporal relationship and the known adverse event profile of the suspect product. The underlying predisposing condition of drug allergies may put the patient at high risk of anaphylactic reactions. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.			
	COVID19 VACCINE (COVID19)	Life Threatening	50-59 years
on 1/8/2021 17:30 patient taken to ER, cerebellar hemorrhage, stroke, aneurysm			
	COVID19 VACCINE (COVID19)	Life Threatening	50-59 years
immediate tingling of lips, followed by fullness of posterior oropharynx, hoarseness and pruritus			
	COVID19 VACCINE (COVID19)	Life Threatening	50-59 years
At first I has some injection site pain and soreness nothing too bad. But around 01:30 I awoke with a really high fever. My fever was 102.8 when I first woke up. I was very nauseous and my fever felt worse. My thermometer would not read any more until my temp came down. I can only guess how high it got but at least 103 degrees. I took Advil Liquid Gells and then my fever broke. I was actually scare for my life. In March I actually caught coronavirus and developed anti bodies for Covid. I can only guess my body was fighting for it's life.			
	COVID19 VACCINE (COVID19)	Life Threatening	50-59 years
I was short of breath and went to emergency room on 1/5/2021. I was diagnosed with bilateral pulmonary embolisms. I was Covid negative and had no other symptoms.			
	COVID19 VACCINE (COVID19)	Life Threatening	50-59 years
altered mental status, hypoxic, fever 39.3, agitated			
	COVID19 VACCINE (COVID19)	Life Threatening	50-59 years
He collapsed with left sided hemiparesis; Stroke; Rt basal ganglia hemorrhage w/ edema and mass			

effect.; Rt basal ganglia hemorrhage w/ edema and mass effect.; Low platelets, 114; His bp as high as 200s/100; Hand weakness; Myalgia; Fever; Severe fatigue; This is a spontaneous report from a contactable physician. A 58-year-old male patient received first dose of bnt162b2 (Pfizer BioNTech COVID vaccine), intramuscularly on 16Dec2020 at a single dose for COVID-19 immunization. Medical history included hypertension with reported med noncompliance in the last few months due to stress. Concomitant medication included hypertension medications in two weeks. The patient was presumed neg covid status prior to vaccine. He worked as a Pulm/critical care physician. He reported fever, myalgia, fatigue on 16Dec2020. Next day (17Dec2020), he took off from work due to his symptoms. The following day (18Dec2020), he came to work. He c/o ongoing severe fatigue & hand weakness in am. Staff noted him to be evaluating his hands during clinic. At 12:15, he collapsed with left sided hemiparesis. The reporter had suspicion for stroke. He was transported to the Emergency Room (ER), head CT showed Rt basal ganglia hemorrhage w/ edema and mass effect. Labs notable for Low platelets, 114 (unknown baseline) on 18Dec2020, normal coags on an unspecified date. BP recorded as 179/101, but it was noted in trauma room his bp as high as 200s/100. He had a history of hypertension with reported med noncompliance in the last few months due to stress. Patient was transferred for further care. Full course was unknown but had rebleed there with low plts. Adverse event (he collapsed with left sided hemiparesis) resulted in hospitalization (22 days), life threatening illness (immediate risk of death from the event), disability/incapacitating or permanent damage. Treatment was received for adverse events. Results of tests and procedures for investigation of the patient: on 18Dec2020, Nasal Swab test: negative. The outcome of events was not recovered. Unknown if any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient was not tested for COVID-19. Information on the lot/batch number has been requested.; Sender's Comments: Collapsed with left sided hemiparesis/suspicion for stroke are as consequences of basal ganglia hemorrhage with edema, which is caused by worsening of hypertension. Low platelet also contributes to brain hemorrhage. All these serious events are unrelated to the vaccine use. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

COVID19 VACCINE (COVID19)

Life Threatening 50-59 years

Pt. with dizziness, then Afib with RVR, then massive cerebral hemorrhage Pt. non oriented & unable to give history - History provided by S.O and daughter

COVID19 VACCINE (COVID19)

Life Threatening 50-59 years

I had no side effects after my vaccine on 12/24/20 until 1/8/21. On Friday, 1/8/21 at 830pm I began with severe abdominal pain, low grade fever, nausea and loss of appetite. My abdominal pain persisted and worsened over the next 24-36hours. I presented to the ER on Sunday, January 10, 2021 at 8am with severe right lower quadrant pain, pelvic pain, nausea and low grade fever. I was promptly diagnosed with appendicitis and taken to the OR at approximately 2pm on the same day. In the OR my appendix was gangrenous, there was pus in the pelvic area and fluid in my peritoneum. My appendix was not ruptured. My appendix was removed as well as part of the omentum. I remained in the hospital on IV Metronidazole and Ciprofloxacin for 2 days and was discharged on 1/13/21 at 9pm. I am continuing to recover at home on the same 2 antibiotics in oral form. I have a JP drain that is still in place. Of note I had two negative COVID 19 tests on 1/9/21 and 1/10/21. Both were PCR tests.

COVID19 VACCINE (COVID19)

Life Threatening 50-59 years

We (myself and 2 other pharmacists) were conducting a COVID-19 vaccine clinic. The patient is on staff at the clinic and came in for her 1st dose of the Pfizer/BioNTech COVID vaccine. 10 minutes post-vaccination, patient started experiencing SOB, tingling fingers and face, and swelling of her lips and tongue. She moved herself outside to cooler air and then sent someone back inside to ask us for help. I ran outside with an EpiPen and immediately noted her pulse of 158 on her watch and she appeared to be experiencing an anaphylactic reaction. Patient stated she did not want to use the EpiPen but wanted to try chewing Benadryl instead first. I asked the staff for a blood pressure monitor and pulse oximeter. The 1st readings, approximately 12 minutes after vaccination, were HR 158, BP 155/105, and pulse ox 97%. Patient stated the Benadryl was working and her swelling was decreasing. The patient was not having trouble breathing at the time. I continued monitoring vitals and talking with the patient and approximately 20 minutes post-vaccination, she was improving (BP down to 134/80 and HR

120) but agreed we should call 911. She decided she wanted to move inside and lie down. I escorted her with support to a bed. Her vitals then increased again to BP 152/95 and HR 133 and her lips and tongue started swelling again. The patient appeared to be more labored in breathing then but still refused the EpiPen. Roughly 5 minutes after lying down, the medics showed up and took over and I went back to the vaccination area. I learned later that the patient refused to go to the hospital and after more observation was eventually allowed to leave with a friend/coworker driving her home.

COVID19 VACCINE (COVID19)

Life Threatening 50-59 years

5-6 HOURS AFTER VACCINATION. CONVULSIONS/SEIZURE, HIGH BLOOD PRESSURE, INCREASED HEART RATE,

COVID19 VACCINE (COVID19)

Life Threatening 50-59 years

"Per husband, was in usual state of health on the AM of 1/10/20, AOx3 able to perform all I/ADLs. At around 2:30pm that day was complaining of chills and generalized malaise. Then at ~9:30pm when husband returned home from work found patient diaphoretic, confused (stating things like ""not now, I want to go to lake""), and complaining of chills and weakness. Unable to provide any additional hx regarding other sx. Initially presented to ED, where mental status had deteriorated to AOx0, unable to respond to verbal commands. Initial vitals notable for T102.6F (unclear other vitals). Patient is now AOx0 most concerning for encephalopathy."

COVID19 VACCINE (COVID19)

Life Threatening 50-59 years

anaphalactic shock reaction, epi injection by hospital emergency staff at vaccine site, emergency room admission . We were very lucky vaccine site was Hospital was concerned that this might happen as patient had a previous anaphalactic shock by antibiotic injection few years ago

COVID19 VACCINE (COVID19)

Life Threatening 50-59 years

On January 14, 2021, I noticed generalized petechiae all over my body. I went to seek medical care and was found to have platelet count of 2. I was hospitalized for idiopathic thrombocytopenic purapura. I was given platelets which increased my platelets to 4. Next day, given IVIG dose. Also receiving 4 doses of decadron. Day after IVIG, platelets to 20. I am still in the hospital getting treatment today.

COVID19 VACCINE (COVID19)

Life Threatening 50-59 years

The patient received her first Moderna COVID-19 vaccination on 12/29/2020. However the patient was diagnosed with a positive COVID-19 test on January 4, 2021. Patient complained of nausea, vomiting, back pain, and sharp chest pain. On January 13, the patient presented to the emergency department again with shortness of breath and sharp, stabbing left-sided chest pain radiating to her back and right side. Initial work up ruled out cardiac etiologies. CTA chest demonstrated COVID-19 pneumonia. The patient complained of bilateral lower extremity weakness which had been progressing since her COVID-19 vaccination, per patient report. However, during her hospitalization the patient's bilateral lower extremity weakness began to accelerate. On the 13th, the patient was able to ambulate to and from the bathroom herself. Then on January 14 the patient required maximum assistance. Neurology was consulted and work up initiated for suspected possible Guillain-BarrT syndrome (GBS) secondary to recent COVID-19 infection. On January 15, 2021, the patient became obtunded and unable to protect airway. She was emergently intubated for acute hypercapnic respiratory failure secondary to GBS. Neurology started GBS treatment with IVIG. Patient also developed NSTEMI and Takotsubo cardiomyopathy. Patient remains critically ill requiring mechanical ventilation.

COVID19 VACCINE (COVID19)

Life Threatening 50-59 years

0900 IM Covid 19 vaccine 0905 Sore throat 0920 Dizzy episode followed by headache 0945 Stridor upon deep breath 1000 Facial tingling, top lip and eye swelling 1015 Present to Emergency Services 1040 IV benadryl - Tingling throughout body, stridor worsening, , visible facial swelling 1045 IV Decadron - Throat swelling worsening, chest heaviness, wheezing 1050 IM Epinephrine 1055 Racemic Epi nebulizer treatment 1100 Facial and throat Swelling reducing, breathing easier, 1105 Breathing back to normal 1430 Discharged from Emergency Services with prescription for Dexamethasone 4Mg for 3 days, 2 allegra 2x daily, famotidine 2 x daily

COVID19 VACCINE (COVID19)

Life Threatening 50-59 years

On 01/13/2021 at about 11pm I began having pain in both arms and across my chest. Also nausea and vomiting. At midnight I went to the Emergency room and was diagnosed with a heart attack, underwent emergency catheterization and stent placement. I had complete occlusion of the right coronary artery

COVID19 VACCINE (COVID19)

Life Threatening

50-59 years

itching, hives, short of breath, numbness and tingling to lips with hives to bottom. headache.

COVID19 VACCINE (COVID19)

Life Threatening

50-59 years

Acute liver injury requiring transplant evaluation and acute kidney injury

COVID19 VACCINE (COVID19)

Life Threatening

50-59 years

a couple hours after the vaccine, I experienced a bit of rapid heart rate, which resolved after a few minutes. The following day around 3 pm I began to have chills and felt like I had the raid heart rate again. By 5 pm I was beginning to feel really bad, I was freezing, chills and my heart rate was now extremely fast, I was having trouble speaking complete sentences, my husband drove me to the emergency department. I had a very high heart rate and high fever, I was admitted and in the hospital until Sunday afternoon. The diagnosis was pneumonia, I don't really believe this, as I felt fine and had no symptoms prior to the onset of the fever.

COVID19 VACCINE (COVID19)

Life Threatening

50-59 years

Pt found unresponsive at home, respiratory distress. Had reported nausea and vomiting for two days prior to admit which started 1/15. Acute metabolic encephalopathy and acute renal failure Currently at time of this report still in critical care

COVID19 VACCINE (COVID19)

Life Threatening

50-59 years

1/4/21- Patient stated she had tenderness on the back of her left lower leg with redness then 1/8/21 started to have shortness of breath and made a doctor's appointment for 1/13/21. Seen by provider on 1/13/21 and was sent to ED and admitted to the hospital [ICU] with NSTEMI, acute deep, occlusive venous thrombosis left femoral vein and saddle embolus of pulmonary artery. Transferred to another acute care hospital for removal of thrombosis. Patient started on Eliquis and no intervention for removal of the thrombosis.

COVID19 VACCINE (COVID19)

Life Threatening

60-64 years

Throat closure (angioedema/anaphylaxis) requiring ambulance transport to Hospital emergency room and stay IV infusion of Benedryl, solumedrol, and Pepcid with excellent results. Observed twelve hours, then discharged.

COVID19 VACCINE (COVID19)

Life Threatening

60-64 years

Dizziness, dyspnea, neck swelling

COVID19 VACCINE (COVID19)

Life Threatening

60-64 years

she is better but still not good; not to be able to breath; sore right arm; This is a spontaneous report from a contactable nurse (patient herself). A 62-year-old female patient received bnt162b2 (BNT162B2, lot EK5730), intramuscular on 18Dec2020 at single dose for immunisation. Medical history included asthma (hospitalized on Jan2020 and has not had any issues since that time, referring to her asthma) diabetes, high blood pressure, swelling, sciatica, blood cholesterol abnormal, rosacea, reflux, allergies, sinus congestion, shingles and post carpal tunnel surgery. Concomitant medications included lisinopril, hydrochlorothiazide, gabapentin, rosuvastatin, metformin, glipizide, doxycycline, sucralfate, cetirizine hydrochloride (ZYRTEC), pseudoephedrine, ascorbic acid, ergocalciferol, nicotinamide, retinol, riboflavin, thiamine hydrochloride (VITAMINS) and tramadol. The patient reported that she not to be able to breath (seriousness criteria-life threatening) on 22Dec2020. She woke up this morning and could not breathe and there was no reason for her to not be able to breath. She thought she may have had a reaction to the COVID vaccine. It was the only thing she could think of that might have caused her not to be able to breathe this morning. As treatment for not to be able to breath, she used Budesonide and Levosalbutamol in her nebulizer. She had sore right arm on 18Dec2020. She informed that she had done everything she can and she was better but still not good. She planned to take the second dose of the COVID Vaccine because she thought it was more important to be protected. She

suspected that the vaccine was related to the events sore right arm and could not breathe. The outcome of the event not to be able to breath was recovering; for sore right arm was recovered on unknown date in Dec2020; for she is better but still not good was unknown.; Sender's Comments: Severe allergic reaction including anaphylaxis is the known risk factor; a possible causal association between administration of BNT162B2 and the onset of not being able to breath cannot be excluded, considering the plausible temporal relationship and the known adverse event profile of the suspect product. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

COVID19 VACCINE (COVID19)

Life Threatening 60-64 years

Patient stated he stopped his blood pressure medications 3 days prior to vaccination due to a previous reaction to losartan, a medication he was no longer taking. Patient took aspirin and a MVI on day of vaccination and drank lemon water. Patient developed tingling sensation in his mouth after eating dinner around 18:00. Patient stated he ate tacos with apple cider and noticed tingling after dinner. Patient stated he took two benadryl with no relief. His tongue continued to swell and he took two additional benadryl at 22:00. Once he developed difficulty swallowing he went to the emergency department. Patient presented to the ED with tongue swelling and difficulty swallowing. At 23:57 he was administered 0.3mg of epinephrine IM, diphenhydramine 25mg IV, famotidine 40mg IV, dexamethasone 10mg IV at 0114, methylprednisolone 60mg q6hrs started at 0417, diphenhydramine 25mg q6hrs IV started at 0416, albuterol 2.5mg via neb q6hrs started at 0710

COVID19 VACCINE (COVID19)

Life Threatening 60-64 years

approximately 30 minutes after receiving vaccination i began to develop tongue and lip swelling as well as difficulty swallowing and breathing , i then proceeded immediately to the nearest er

COVID19 VACCINE (COVID19)

Life Threatening 60-64 years

Patient developed a septic knee (history of arthroplasty) need for immediate surgery, hospitalization and months to years of antibiotics in his future now.

COVID19 VACCINE (COVID19)

Life Threatening 60-64 years

6-7 hours after the vaccine she developed arm pain, fever and chills. About an hour later she started to have abdominal pain which worsened over the course of the day to excruciating. She went to the Emergency Room where a CT scan revealed a perforation of her sigmoid colon and had a resection of the area of the colon and a diverting colostomy surgery done the evening of 1/3/2021.

COVID19 VACCINE (COVID19)

Life Threatening 60-64 years

"Client received vaccine at approximately 3:50pm, waited in observational area x30min. Left with husband, stated that she got a few miles down the road and starting experiencing tightness in her chest and flushing. She took 50 mg of Benadryl, 30mg of prednisone and two puffs on her inhaler. She returned to the clinic, upon assessment from nursing she looked extremely flushed and anxious, she stated that she still felt tightness and that she had a history of anaphylaxis once before and had used an epi pen in the past. She had an epi pen with her and questioned whether or not she should give it to herself. BP was 190/68, pulse was normal, respirations normal, she continued to experience tightness and ""not able to catch my breath"", encouraged to use epi pen. She administered epi pen to right thigh at approximately 4:45PM, 911 called. Within a few minutes, she stated she was feeling better, less tightness in the chest, flushing was subsiding. BP at 190/70 at 4:52. EMS on scene at 5:03pm. Vitals normal , EKG normal. Client decided not to transport with EMS."

COVID19 VACCINE (COVID19)

Life Threatening 60-64 years

Fever to 103.7F, respiratory rate 36. Was transferred from facility to hospital. Since then has been found to have gram-negative rod bacteremia, although urinalysis was negative, urine culture pending. Patient has since defervesced after receiving 1 dose of cefepime. Overall the most likely cause of fever seems to be urosepsis w/ bacteremia, pending confirmation with urine & blood cultures.

COVID19 VACCINE (COVID19)

Life Threatening 60-64

years

"Myocardial Infarction: patient began to complain of severe chest pain 3 hours after the vaccine was given .. Vaccine NDC # 59267-1000-1. 0.3 ml given by RN. Patient called his PCP: "" ... I had very bad chest and shoulder pains, neck pains and slight fever from 9 pm until early this morning (Jan 8). My blood pressure was 155/95 mmHg. Should I see you today? Still feel sore all upper body. Above message received at 0720 am (Jan 8) and the patient was called back at 0757 am (Jan 8): patient was told that many of the side effects above were related to the vaccine but the chest pain was worrisome and the provider requested the patient go to the emergency room. Patient understood the importance to seek medical attention..... Emergency Room notes: seen by MD on Jan 9. Note at 0749: patient complained of chest pain on/off since received COVID vaccine on Jan 7. Pain was substernal and radiated to the left shoulder, assoc with some SOB. EKG obtained and revealed ST segment elevation and a ""cardiac alert"" was called."

COVID19 VACCINE (COVID19)

Life Threatening

60-64 years

01/06/21 at 6 pm, body aches, and chills 01/07/21 at 12am T102.2, SPO2 62% on room air. Was sent to ER and returned. 01/08/21 at SPO@ less then 60% on room air, non responsive to verbal tactile stimuli. Responsive to sternal rub only. Was sent to ER and admitted to ICU.

COVID19 VACCINE (COVID19)

Life Threatening

60-64 years

SOB, Sleeplessness,

COVID19 VACCINE (COVID19)

Life Threatening

60-64 years

about 14 hours after vaccination I experienced what appeared to be a severe case of Cytokine storm. I had a moderate case of COVID in May 2020 and had positive IgG AB in August. The symptoms started with heavy shaking chills, lasting 1 1/2 hours , fever and most concerning sustained tachycardia with heart rate of 180' to 200' over hours, which then destabilized into runs of Vtach and complex ventricular dysrhythmia, low BP, profound weakness, head aches and joint and muscle pains (similar to the experienced COVID symptoms)

COVID19 VACCINE (COVID19)

Life Threatening

60-64 years

She got the vaccine on Dec 23, and then on Jan 4 she had a mild stroke with left sided arm and face weakness. She did recover fully. She already has known CAD and risk factors for CVD. It is possible, but by no means certain, that the vaccine was an indirect cause of the event. Since the vaccine provoked an immune response, as it was supposed to, it is possible that this inflammation may have set up a metabolic predisposition that may have contributed to the event, which was 12 days later.

COVID19 VACCINE (COVID19)

Life Threatening

60-64 years

Observed in her room having seizure activity and unresponsive to stimuli. BP of 200/120, oxygen level dropped to 86%, HR was 116. She was transferred from Hospital A and later transferred to Hospital B and placed on a ventilator. This remains her current status

COVID19 VACCINE (COVID19)

Life Threatening

60-64 years

Pt had 3 vessel CABG on 1/14/21 after presenting to ED with chest pain on 1/9/21. Pt is critically ill following OR after cardiogenic shock, bleeding. Requiring inotropes and Impella.

COVID19 VACCINE (COVID19)

Life Threatening

60-64 years

Pounding headache, heart racing to over 145 bps, chest burning and tightness and hard to breath. I was taken to the Emergency Room at Hospital immediately. Reaction occurred within 30 minutes of the injection. An EKG was administered. I was prescribed prednisone and Benadryl. I was diagnosed with Anaphylaxis.

COVID19 VACCINE (COVID19)

Life Threatening

60-64 years

DVT in right leg 4 days after injection, severe pain in thigh/calf, difficulty walking Placed on Xarelto 15mg 2X daily for 21 days and then 20mg daily for 9 days. Next Doctor visit is 1/26/2021 at 9:00am Next scheduled Covid 19 vaccine is scheduled for 2/5/2021 at 7:15am

COVID19 VACCINE (COVID19)

Life Threatening

60-64 years

Severe headaches, vomiting, dehydration, shortness of breath ... led to trip to Emergency Room at Hospital on 1/16/21 at 10:45 am; diagnosis for treatment was Diabetic Ketoacidosis (DKA); patient was admitted to ICU to address critical fluid and electrolyte imbalances, headaches, body aches, dehydration, nausea, shortness of breath. DKA is medical emergency.

COVID19 VACCINE (COVID19)

Life Threatening

60-64 years

Appendicitis

COVID19 VACCINE (COVID19)

Life Threatening

60-64 years

Resident became lethargic, general weakness outside baseline, unable to walk, bumbled speech. Elevated HR and Temp of 105.2F

COVID19 VACCINE (COVID19)

Life Threatening

65+ years

12/18/2020: COVID19 vaccine received. 12/19/2020: Patient noticed petechiae/bruising on arms, legs and face. Worsened over next 48 hours. 12/21/2020: Patient had blood drawn (CMP, PT/INR, CBC) at lab. 12/22/2020: Labs resulted; CMP and PT/INR WNL (exceptions: SCr 1.24, TBil 1.7); CBC with platelet count of 1,000 resulting in patient admission to Hospital. At admission he received 80 mg of prednisone, 40 g of IV Ig and a unit of platelets. 12/23/2020: Continued hospitalization. Patient's platelets improved to 20,000 and he received another 35g of IV Ig. 12/24/2020: Patient discharged with platelets of 38,000.

COVID19 VACCINE (COVID19)

Life Threatening

65+ years

Patient presented with signs and symptoms of sepsis, developing over 12 to 24 hours 6 days after vaccination. was hypotensive and confused (beyond baseline)

COVID19 VACCINE (COVID19)

Life Threatening

65+ years

Reported sensation of tongue swelling during post-vaccination observation at 10 minutes. Epinephrine was refused and she was taken to ED for observation where she was given oral dose of Benadryl and Pepcid. Discharged with instructions to return PRN and follow up with PCP. Elevated BP noted.

COVID19 VACCINE (COVID19)

Life Threatening

65+ years

Rushed to ER. Has now been tubed and put into the ICU and has had full-cardiac arrest less than 24 hours after receiving the vaccine.

COVID19 VACCINE (COVID19)

Life Threatening

65+ years

Hospitalized 12/29, has now been tubed and put into the ICU

COVID19 VACCINE (COVID19)

Life Threatening

65+ years

Patient started having myalgia, chills, nausea on the next day of the vaccination. on 2nd day (12/29) patient had chest pressure which made her present to Hospital ED. She had troponin elevation to 1.14. Cardiac Catheterization was done which was negative. On Trans Thoracic Echocardiogram, patient was found to have hypokinesis of the mid and distal segment with some sparing of apex proving Takotsubo (stress induced) cardiomyopathy. Patient did not have any underlying emotional or physical stress going on in her life or family. Till now extensive infectious as well as inflammatory work up is done to rule out any secondary causes of cardiomyopathy which till date have remained negative. As a diagnosis of exclusion, her presentation seems to be COVID-19 vaccine induced Takotsubo Cardiomyopathy

COVID19 VACCINE (COVID19)

Life Threatening

65+ years

Pt had vaccination at city site. Waited 15 min after shot and was cleared to go. Reported to wife that he was very thirsty, so they stopped at a convenience store on the way home. While there, he felt worse and asked to go to the Emergency room. They chose Methodist to enter. Pt went to triage and while at triage, had syncopal episode, then full arrest. After short course of CPR and defib, he had ROSC. Was taken to cath lab for intervention (stents) and is now in ICU.

COVID19 VACCINE (COVID19)

Life Threatening

65+ years

Decompensation and temp 103.6.

COVID19 VACCINE (COVID19)

Life Threatening

65+ years

Patient tolerated the vaccine well with no apparent side effects. Ten days later awoke 12:30 AM with severe chest and upper back pain, presented to Med Center where he was found to have an Acute

Coronary Syndrome. Transferred to Medical Center where he underwent successful PCI with two drug eluting stents for a 99% mid-LAD stenosis

COVID19 VACCINE (COVID19)

Life Threatening 65+ years

5 minutes after injection, my feet and palms itched and I was lightheaded but I tried to shake it off and it faded over the next 10 minutes. I did report it and stayed longer and was ok. Then i went straight home and layed down because i did not sleep well night before (was on call) i awoke 1 hour post injection dry heaving, very nauseated, mild headache, achy, itchy over different parts of my body and weak. Sat up and my face was getting itchier, lips started to swell, tongue started to swell and itch, throat felt like someone was strangling me, had trouble swallowing and trouble breathing. took 2 benadryls immediately and went out into cold air, thought about calling 911 but got better in 10-15 minutes. never have had a reaction like this in my life. have had hives though in the past. If I would have had an epi pen I would have used it (never have had an epi pen) I was frightened but the benadryl worked and I slept due to the benadryl for 5 hours, when I woke up the benadryl wore off and it started again. took more benadryl, and it improved. before bedtime, the benadryl wore off and I had a hard time swallowing my night time meds like my throat was swollen. Took 2 more benadryls, today I am weak and nauseated and ate very little and feel like my face is still red and itchy. I told my sister and she said she is allergic to PEG which i later noted was in the vaccine. i am very disappointed that I had this reaction- I have desparately wanted this vaccine as a medical worker with a lot of covid patients- I onlu hopr this one shot will protect me enough because it is clear to me that i cannot take this vaccine again.

COVID19 VACCINE (COVID19)

Life Threatening 65+ years

Severe Hypotension, Redness, Warmth and sensitivity all over skin surfaces, lack of responsiveness, low oxygen saturation.

COVID19 VACCINE (COVID19)

Life Threatening 65+ years

Congestion Shortness of breath Tachycardia Transferred out 911. Per hospital, patient had a myocardial infarction, is unresponsive, and on hospice services.

COVID19 VACCINE (COVID19)

Life Threatening 65+ years

Anaphylactic reaction, Severe edema and raised red rash entire body, Severe itching ,Soft tissue edema of throat. Swelling of, eyes, lips, face. Multiple trips to ER, treated with steroids, Benadryl, prevacid. , CURRENTLY IN ICU ON EPINEPHRINE DRIP, STEROIDS, MULTIPLE MEDS

COVID19 VACCINE (COVID19)

Life Threatening 65+ years

Developed hypercapnic respiratory failure, CHF exacerbation - readmitted to Hospital. In ICU with BIPAP

COVID19 VACCINE (COVID19)

Life Threatening 65+ years

Low grade Fever, headache needing admission Intracranial hemorrhage with hypertension Medical management for hypertensive emergency Received surgical evacuation admitted in Intensive care,

COVID19 VACCINE (COVID19)

Life Threatening 65+ years

Patient came into the emergency department on 1/8/21 with an acute ischemic stroke with complete occlusion of her left MCA. She had acute and complete flaccid paresis of her right face, arm, and leg, complete aphasia, and neglect of the right side of her body. NIHSS of 27. Onset of deficit was between 6:30pm-7:10pm. She recieved her 1st COVID-19 vaccine dose that morning at 10:31am.

COVID19 VACCINE (COVID19)

Life Threatening 65+ years

Acute ischemic stroke, basilar occlusion

COVID19 VACCINE (COVID19)

Life Threatening 65+ years

Resident had seizure like activity followed by a vagel response with large bowel movement. Resident then began to show signs of blood clot to left lower extremity. No pedal pulse, area on leg warm to touch. Left lower leg now cold to touch, stiff, purple and white in color. No other signs of modeling, body warm to touch, no fever noted. Respirations and pulse increased with low oxygen levels. Resident not responding to stimuli.

COVID19 VACCINE (COVID19)

Life Threatening 65+

years

she was dying as her blood pressure dropped to 70/40 and to come for a last visit; This is a spontaneous report from a contactable consumer. A 100-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 02Jan2021 at single dose for COVID-19 immunization. Medical history included COVID in Dec2020, urinary tract infection (UTI), dehydration and Covid sickness (vomiting) (was treated earlier in month for UTI and dehydration from the Covid sickness (vomiting)). Known allergies: no. The patient's concomitant medications were not reported. After testing positive in mid December to COVID and being declared Covid free on 30Dec by the nursing staff and in good health, with normal vitals and oxygen levels, the patient was given a vaccination on 02Jan2021. In the early evening the patient's blood pressure dropped to 70/40 and the reporter was told to come for a last visit. The patient was sleeping comfortably. She did not wake up when spoke with her. No one expected her to make it through the night. The next morning she work up, ate breakfast, watched TV, got IVs and oxygen and her vitals improved significantly. Lab tests and procedures included blood pressure: 70/40 on 02Jan2021, oxygen levels: normal, COVID test: positive in Dec2020 (testing positive in mid December to COVID and being declare Covid free on 30Dec), vitals: normal; improved significantly. Facility where the most recent COVID-19 vaccine was administered: Nursing Home/Senior Living Facility. If the patient received any other vaccines within 4 weeks prior to the COVID vaccine: No. Prior to vaccination, was the patient diagnosed with COVID-19: Yes. Since the vaccination, has the patient been tested for COVID-19: No. AE resulted in: Life threatening illness (immediate risk of death from the event). Serious: Yes. Seriousness criteria-Results in death: No. Seriousness criteria-Life threatening: Yes. Seriousness criteria-Caused/prolonged hospitalization: No. Seriousness criteria-Disabling/Incapacitating: No. Seriousness criteria-Congenital anomaly/birth defect: No. Information about lot/batch number has been requested.

COVID19 VACCINE (COVID19)

Life Threatening 65+ years

Patient is a 99yr old female who got a covid vaccine in the afternoon of 1/10/21 and woke up in the morning of 1/11/21 with altered mental status, weakness, and dysarthria. She was taken from her assisted living facility to the hospital and MRI showed a small stroke in the right medial thalamus. She was also found to have new onset atrial fibrillation. She was treated appropriately for both conditions and discharged to a skilled nursing facility on 1/13/21.

COVID19 VACCINE (COVID19)

Life Threatening 65+ years

Patient reports no symptoms until 1/8/21 at which time a rash developed along with fatigue and fevers. Patient was seen in ED 1/8 and 1/11/21. Was admitted 1/11/21 with Concern for STEvens Johnson and sepsis. Patient subsequently developed full body macular rash and mucosal lesions. Fevers to 102-104.

COVID19 VACCINE (COVID19)

Life Threatening 65+ years

On 1/12/20 resident woke up and was not able to stand in the E-Z stand. E-Z lift was needed. In addition he needed assistance with eating. At that time VS were stable, equal hand grasp noted, and no further concerns. Around 3pm resident became flaccid on the left side of his face and speech became mumbled. Hand grasp was equal at that time and VS were stable, but B/P was elevated compared to previous recordings earlier in the day. Family did not want him sent to the hospital and asked for comfort cares. Hospice referral obtained and he will be admitted to hospice in the near future. Resident's left side of face has improved within the last 48 hours. He remains total assist with all cares.

COVID19 VACCINE (COVID19)

Life Threatening 65+ years

Resident had been monitored and had shown no signs or symptoms of any kind until 2 pm on 1/14/2021. Resident was found in the floor of her room. She had fallen and was having a seizure, temperature was 99.7F and Oxygen saturation was 82%.

COVID19 VACCINE (COVID19)

Life Threatening 65+ years

Throbbing head ache, difficulty breathing, lips numbness, chest discomfort, upper back, lower legs, fingers tingling/numbness, high blood pressure 148/83, underarm sweating, feels weak

COVID19 VACCINE (COVID19)

Life Threatening 65+ years

Patient had slow progression of kidney disease but since vaccine had unexpected acute kidney

failure. He had to have dialysis and may need biopsy of kidney to confirm if he needs lifelong dialysis. He is still being hospitalized.

COVID19 VACCINE (COVID19)

Life Threatening

65+ years

nausea and vomiting possible cause of diabetic ketoacidosis and svt

COVID19 VACCINE (COVID19)

Life Threatening

65+ years

patient began with vomiting and diarrhea the day after administration, leading to bowel and urine incontinence. patient was hospitalized on 01/16/20 with sepsis. no origin discovered yet. still waiting on blood/urine/stool cultures.

COVID19 VACCINE (COVID19)

Life Threatening

65+ years

Severe rash. Platelets drop to almost needing transfusion

COVID19 VACCINE (COVID19)

Life Threatening

65+ years

Systemic: Anaphylaxis-Severe; symptoms lasted 1 day

COVID19 VACCINE (COVID19)

Life Threatening

65+ years

At approximately 4pm on Jan 11, 2021, I began to have hard chills and fever that reached 104.9. I was admitted to ICU at the Hospital. My blood pressure dropped to dangerous levels. I was diagnosed with sepsis and the doctors determined it was caused by the vaccine.

COVID19 VACCINE (COVID19)

Life Threatening

65+ years

Pulmonary Edema, fever, nausea, vomiting

COVID19 VACCINE (COVID19)

Life Threatening

65+ years

COVID-19 Vaccine

COVID19 VACCINE (COVID19)

Life Threatening

65+ years

Narrative:

COVID19 VACCINE (COVID19)

Life Threatening

Unknown

anaphylaxis; This is a spontaneous report from a contactable physician reporting on behalf of patient. A patient of unspecified age and gender received single dose of BNT162B2 (batch/lot number and exp date not reported), via an unspecified route of administration on an unspecified date for immunisation. The patient's medical history and concomitant medications were not reported. On an unspecified date, the patient experienced anaphylaxis with a very protracted course requiring an epi dose for 4.5 days and was still in the ICU (date/s unspecified) following administration of the COVID vaccine. The physician would like to use a drop of leftover vaccine from one of the vials to do a future skin test after the patient is stable. They were unsure if they needed permission as this was standard practice in allergy to test afterwards but wanted to check in with the company. The outcome of event was unknown. Information about batch/lot number has been requested.; Sender's Comments: A possible causal association between administration of BNT162B2 and the onset of anaphylaxis cannot be excluded, considering the plausible temporal relationship and the known adverse event profile of the suspect product. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

COVID19 VACCINE (COVID19)

Life Threatening

Unknown

anaphylactic reaction/anaphylaxis; This is a spontaneous report from a Pfizer Sponsored Program from a contactable pharmacist. A female patient of an unspecified age received first dose of bnt162b2 (Pfizer BioNTech COVID vaccine, lot number: EK4176), via an unspecified route of administration on 09Jan2021 at 0.3 mL, single (standard like 0.3ml by injection once to deltoid, side unknown) to prevent from getting COVID. The patient's medical history and concomitant medications were not reported. The patient experienced anaphylactic reaction/anaphylaxis on 09Jan2021. Clinical course: The patient got the vaccine while waiting to go into the watch room, to be watched for a few minutes, and she experienced anaphylactic reaction/anaphylaxis, she went down, they gave her an Epinephrine, she didn't respond to the first dose, a second dose was given in the arm where the vaccine was given, then she was picked up by an ambulance. Agent

stated the caller has been on hold for almost an hour. Caller clarifies dose was given in the arm, it occurred on Saturday with the same lot. Saturday and it went away on Saturday, the patient was worried about it coming back, thus why she asked about Epinephrine pen, the patient was taken to the hospital, and given Epinephrine a couple more times, and it resolved eventually, the patient was not admitted, she went to the Emergency Department. It could have required hospitalization but would most likely say life threatening had she not been treated. Reporter seriousness for anaphylaxis is life threatening. The outcome of event was recovered on 09Jan2021. Relatedness of bnt162b2 to reaction anaphylaxis is related for primary source.; Sender's Comments: A possible causal association between administration of BNT162B2 and the onset anaphylactic reaction/anaphylaxis cannot be excluded, considering the plausible temporal relationship and the known adverse event profile of the suspect product. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

COVID19 VACCINE (COVID19)

Life Threatening Unknown

1day after vaccine,developed severe headache & later blister in head officially Shingle . Then decreased platelet count fatally to 29(ITP).now hospitalized getting treatment.

COVID19 VACCINE (COVID19)

Life Threatening Unknown

Anaphylaxis Allergic reaction COVID-19 vaccine: dizziness, vomiting and shortness of breath. Received vaccine and about 5/10 minutes later developed symptoms of chest tightness shortness of breath wheezing. Arrived to ED at 1156 and discharged at 1507. Given epi IM Solu-Medrol, Pepcid, Benadryl, albuterol.

COVID19 VACCINE (COVID19)

Permanent Disability 18-29 years

At about 6am after receiving the shot I felt very tender at the injection site almost as if it was bruised. Then over the course of the day I started to feel very itchy all over my body but mainly on my right side. 10pm I got up for work, and could barely move, I'm feeling intense back pain on my lower back on the right side. I can walk but its all very limited motion, I can really only manage by putting all my weight on my left side.

COVID19 VACCINE (COVID19)

Permanent Disability 18-29 years

Complete loss of vision in the left eye 12 hours after receiving second dose (Moderna mRNA-1273) while having a fever of 102 F for 6 hours. Loss of vision lasted for 1 minute. Loss of vision occurred while standing. Referral to primary care and ophthalmology specialist found normal eye exam and MRI of orbits but presence of tachycardia especially while standing (fluctuations between 60 beats at rest/laying down to 130 beats per minute standing). Postural tachycardia syndrome (POTS) is suspected. Currently pursuing cardiac workup with cardiologist and Covid POTS specialist. POTS specialist believes autoantibody development after vaccination could be suspected as recovering covid patients similarly present to clinic with POTS like symptoms.

COVID19 VACCINE (COVID19)

Permanent Disability 18-29 years

On 12/24 at around 10 PM, circulation to my 4th left digit significantly decreased after being outside of my car for around 15 minutes during a temperature of about 50 degrees. I realized when sharp pain was felt at the digit. After about 5 minutes the digit felt numb. I got in my car, turned on the heater, and massaged my finger. Sharp pain was felt again as circulation returned to the digit. The event last approximately 10 minutes from the moment I realized the finger was pale until color returned. This occurred again on 12/27 at around 2 PM as I walked from my car into a store at a temperature of about 40 degrees. This time, discoloration occurred bilaterally on my left 3rd, 4th, and 5th digits and my right 2nd, 3rd, 4th, and 5th digits. The event lasted more than 15 minutes with constant massaging. This has occurred two more times since then, both times occurring bilaterally with minimal exposure to cold.

COVID19 VACCINE (COVID19)

Permanent Disability 18-29 years

Pt describes falling with onset of weakness below the hip level about 6 inches above the patella with missing clonus reflex. The pt cannot squat down with associated observable loss of strength, pt is not able to stand up. The pt has fallen 7 times since symptom onset around lunchtime between 1200

and 1300. Pt denies LOC.

COVID19 VACCINE (COVID19)

Permanent Disability

18-29 years

sudden sensorineural hearing loss in the right ear, audiology and ENT assessment, currently being treated with steroid medication

COVID19 VACCINE (COVID19)

Permanent Disability 18-29 years

On 01/07/2021 I woke up at 0300am with chills, headache, body aches, joint pain, fever of 101.2 and swollen left axillary lymph nodes. I took Tylenol and Benadryl and it relieved the fever/headache/body aches/joint pain, however the lymph nodes in my left axillary remained swollen. I continue to take Tylenol for the fever/body aches/pains without relief for the swollen and painful axillary lymph nodes. Warm compresses do help to relieve the pain temporarily but they remain painfully swollen. On 01/08/21 I called my doctors office to ask if it was normal to experience such painfully swollen axillary lymph nodes to which they stated "we don't know, it is too soon for us to tell what's normal and what isn't normal right now." They did not offer any suggestions to relieve the pain or swelling. The morning of 01/09/2021 , I called Employee Health at my hospital (my place of work and also where I received the vaccine) and they also stated they didn't know if this was a normal reaction due to the newness of the vaccine. A couple hours later, employee health emailed me a link to the VAERS reporting website and asked me to file a report.

COVID19 VACCINE (COVID19)

Permanent Disability

18-29 years

Moderna vaccine dose #1 received in right shoulder on 12/31/20 at 2:15PM. Injection was uneventful other than sensation of pressure. I did notice at the time, but could not fully see, that the injection appeared to be much higher on the shoulder than normal. I immediately came home afterwards and relaxed. Approximately 2hrs later, I began experiencing extreme pain in my right shoulder. As the night progressed, the pain worsened to 10/10 with inability to move my arm. Later that night after requiring assistance to take off my shirt, I noticed that the bandaid overlying the injection site was very high, immediately below and bordering the acromion process. This was concerning but I was hopeful the pain would go away over the next few days. I took tylenol that night. I woke up multiple times during the night because the pain was so severe. When I woke up, the pain and inability to move my arm were still present. I began taking 800mg ibuprofen and 1000mg tylenol alternating Q4 throughout the next few days. The pain and disability remained so severe that I required assistance performing ADLs for the next 4 days. On day four, with the pain not resolved and still severe despite consistent advil and tylenol use, I began having concern for shoulder injury related to vaccine administration. The next day I decided to seek an evaluation by an orthopedist. I am a physician and was unable to perform basic tasks and ADLs. I happened to have a few days off after the injection but would not have been able to work had I not. After an evaluation by the an orthopedic PA, I obtained an MRI of my right shoulder with results shown below - as I expected evidence of rotator cuff tendinopathy and subdeltoid bursitis consistent with SIRVA. As of now, I still have limited range of motion and shoulder pain on the right which has improved slightly but is far from resolved. I still have difficulty with certain ADLs including putting clothes on and off, lifting items, and tasks that require raising my right arm above my head. I am concerned with the possibility of long term and/or permanent damage after reviewing the literature. I am also concerned about how many other healthcare workers the person who gave me my vaccine may be injuring and/or causing permanent harm to.

COVID19 VACCINE (COVID19)

Permanent Disability

18-29 years

Jan 11-vaccination day. On Jan 14, in afternoon had tinnitus and muffled hearing that went away. The next morning Jan15, complete sudden hearing loss on left ear. Tinnitus and muffled hearing that has not went away.

COVID19 VACCINE (COVID19)

Permanent Disability

18-29 years

Extreme fatigue since getting shot - effecting ability to work

COVID19 VACCINE (COVID19)

Permanent Disability

18-29 years

severe temporary paralysis from the neck down.

COVID19 VACCINE (COVID19)

Permanent Disability

30-39 years

"low grade fever; Her blood pressure was high/ still really high/ blood pressure was up; headache; Fifteen to twenty minutes after she received the vaccine she became light headed and dizzy/ light headedness

and dizziness; This is a spontaneous report from a contactable nurse (patient). A 36-year-old female patient received BNT162B2 (Lot#: EK5730) via an unspecified route of administration on 17Dec2020 afternoon at single dose in the left arm for COVID-19 immunization. Caller was unable to confirm the manufacturer of the vaccine that she received. It is not written on the card, and she didn't see the vial. The patient medical history was not reported. Concomitant medications included oral contraception pill, but the name was unknown. Fifteen to twenty minutes after she received the vaccine on 17Dec2020 she became light headed and dizzy. She had to catch her breath. She couldn't shake it off. The light headedness and dizziness lasted at that intensity for 10 minutes, but it never went away. They encouraged her to be admitted in the emergency room (ER). She would say that the seriousness of being light headed and dizzy was disabling. Caller didn't remember the exact numbers for her blood pressure. It was 160's over 105. Her heart rate was in the low 100's, around 105. She stayed at the first monitoring station in the vaccine area for 2 hours. They were taking her blood pressure every five minutes. She was given diphenhydramine hydrochloride (BENADRYL) there and lots of water. After 3 hours and she was not improving they called a "code medic" that got the medical director and nursing supervisor to come. They encouraged her to go to the ER for continual monitoring. She stayed in the ER for 4 hours and was given meds to help with the blood pressure. She was discharged from the ER home. She was nervous because of all this stemming from the vaccine. She had a low grade fever on 18Dec2020 (Friday) night. Caller stated her work had already reported her reaction. Occupational safety and the medical director are aware. Caller does not have reference number to provide. On 18Dec2020 (Friday) she was not overly concerned because it was the next day. Her blood pressure was high and her heart rate was in the 100's. They monitored her for a couple of hours and she was given a diphenhydramine hydrochloride (BENADRYL). She went to the emergency room (ER) for a few more hours and received additional treatment. They sent her home to be monitored at home. She has been taking her blood pressure every day since and it had not come down. It was still really high. She called her primary care doctor. He was wanting her to start blood pressure medication. She was concerned about starting it with the assumption that it was related to the vaccine. She would like to know the right thing to do. It seems safe to take the medicine, but it was unknown that whether it was going to mask the blood pressure and something else be going on. On 18Dec2020 she still had a headache and didn't feel well, but she thought she needed to give it some time. She had been anticipating not to feel well on 18Dec2020 (Friday). On 19Dec2020 she felt better considering she didn't have a headache. On 19Dec2020 (Saturday) her blood pressure was 138/90 and she felt good. Then on 20Dec2020 she had the bad headache and her blood pressure was up. On 20Dec2020 (Sunday) she had a bad headache and her blood pressure was 156/100. She came to work today and her blood pressure had been high all day. She still had a headache and the light headedness continued. The outcome of the event low grade fever was unknown, of other remain events was not recovered.; Sender's Comments: A causal association between BNT162B2 and the event dizziness cannot be excluded based on a compatible temporal relation. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate."

COVID19 VACCINE (COVID19)

Permanent Disability 30-39 years

Received my vaccine on December 22nd, 2020 at around 830 Am. That afternoon, about 3 PM, I started to have a reaction. It started with tingling/numbness in my right hand which progressed up my arm into my elbow. About 10 minutes later, it then progressed into my right foot, and my left foot. About 10 minutes after that, I started to get flushed and a neck rash (diagnosed from Dr.). I took Benadryl and Ibuprofen 800mg PO every 6 hours for the next 24 hours. The numbness in my right foot and left foot along with the flushness went away a couple hours later. Although, the numbness in my right hand never went away. It came and went for the next 4 days until December 27th and 28th when it started getting worse. On December 28th evening, it got so bad that I was debating going to the emergency room around 1 am. The numbness and tingling was in my right hand and started shooting up my arm. The nerve pain around my wrist was unbearable. I finally fell asleep and the next morning, it was not nearly as bad, but was still there. The numbness and tingling moved from my right hand mainly to right hand, right foot, right leg, left foot and left hand today (12-30-2020).

COVID19 VACCINE (COVID19)

Permanent Disability 30-39 years

noticed twitching in L arm shortly after receiving vaccine, numbness, weakness and pain in arm and shoulder girdle, diagnosed with parsonage turner syndrome by neurologist, currently taking neurontin for pain as steroids not tolerated

COVID19 VACCINE (COVID19)

**Permanent
Disability**

**30-39
years**

12/21 had covid vaccine (dose 1). On evening of 12/29 had sudden onset of mild neck pain and significant weakness and numbness of left arm, weak hand grip, clumsiness in hand . Did not improve after trying to shake arm/move around , and took prednisone 40mg oral. Went to ER and had CT C spine which did not show evidence of cervical pathology. Continued with corticosteroids, sought consultation with PMR and neurology specialists, and steroid dose increased to 60mg/day. Some improvement in strength , but still have diminished sensation and strength in left hand/arm. Unable to perform full job tasks as I am left hand dominant. Likely brachial neuritis / parsonage turner syndrome per both specialists seen. Continuing with corticosteroids at this time, pending bloodwork and OT evaluation

COVID19 VACCINE (COVID19)

**Permanent
Disability**

**30-39
years**

Three to four hours after vaccine had bruising, major loss of range of motion, severe sharp pain, elevated temp and chills due to reaction of injection site Treatment given 24 hrs later- strong antibiotics, anti inflammatory, exercise, and three days out of work Due to loss of function of left arm due to inflammation

COVID19 VACCINE (COVID19)

**Permanent
Disability**

**30-39
years**

Moderate to severe headache 24-48 hours post injection. Complete sensorineural hearing loss in left ear 1 week after injection; Moderate to severe headache 24-48 hours post injection. Complete sensorineural hearing loss in left ear 1 week after injection; This is a spontaneous report from a contactable physician (patient). A 37-year-old female non-pregnant patient received her first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 22Dec2020 17:15 at single dose on her left arm for covid-19 immunization. Medical history included known allergies to penicillin. The patient had no other medical history. There were no concomitant medications. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine and the patient was not received list of any other medications within 2 weeks of vaccination. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. The patient experienced moderate to severe headache 24-48 hours post injection. Complete sensorineural hearing loss in left ear 1 week after injection on 23Dec2020. These events resulted in doctor or other healthcare professional office/clinic visit, disability or permanent damage. The patient had received prednisone to treat the events. The outcome of the events was not recovered.; Sender's Comments: A possible contribution role of first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE) to the onset of sensorineural hearing loss in left ear and headache cannot be excluded due to temporal relationship. The case will be reassessed should additional information become available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics committees and Investigators, as appropriate.

COVID19 VACCINE (COVID19)

**Permanent
Disability**

**30-39
years**

numbness and weakness in left arm; numbness and weakness in left arm; had a brachial plexus pathology; her grip and fine motor are affected in her left arm/she could not do her job; This is a spontaneous report from a contactable physician (patient). A 35-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot# EH9899), via an unspecified route of administration in right arm on 21Dec2020 at single dose for Covid-19 immunisation. Medical history included ongoing birth control. No other medical history. Concomitant drug included other medication she took for birth control. On 29Dec2020, the patient experienced numbness and weakness in left arm, had a brachial plexus pathology, went to the emergency department on 30Dec2020 and was seen by one of the facility doctors and stated this doctor had her on steroids for treatment. She got the vaccine in her right arm, stated her grip and fine motor are affected in her left arm. States this was disabling since she could not do her job. She was following up with neurology on Monday (unspecified), that she had a CT scan of her neck and it was normal. Only other medication she was taking was for birth control, but she did not feel like it was relevant. The outcome of events numbness and weakness in left arm was recovering, while outcome of other events was unknown. This case was reported as serious, seriousness criteria was disabling.; Sender's Comments: Based on the information currently provided, the vaccination with BNT162B2 might play a contributory role in triggering the onset of the reported events. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of

Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

COVID19 VACCINE (COVID19)

Permanent Disability 30-39 years

When vaccine was administered, seemed high on my arm. I had immediate soreness and shoulder discomfort, I was told this was normal. It continued to progress and I eventually had decreased ROM, weakness and sharp shooting pain in my shoulder. Working at OI, I consulted provider, xrays were obtained and I was evaluated. He strongly suggested an MRI be obtained as well. That was completed the same day as my evaluation on 12/31/2020 (1 week and 2 days after the vaccine was administered). The provider informed me that they have had patients with similar situations that were evaluated for frozen shoulder after having a vaccine d/t administration site and vaccine going into subacromial space. He does report that this was my case/situation, upon my exam, I had severe inflammation with this as well-he is now having me follow up for a surgical consultation for my shoulder to be repaired. Today's date is 1/7/2021, I have these same ongoing symptoms that have continued since day of administration, without diminishing in severity. He is unable to provide an injection d/t my upcoming second dose of the COVID vaccine this next week, 1/12/2021. He strongly suggests that my 2nd vaccine be administered elsewhere-advised NOT be administered in the same shoulder OR in opposite to cause these symptoms to flare. He advised in gluteus if possible to avoid any further issues if at all possible.

COVID19 VACCINE (COVID19)

Permanent Disability 30-39 years

Guillain Barre syndrome/AIDP event. Paresthesia and nerve pain developed in bilateral legs 4 hours after shot and progressed slowly for 4 days in intensity and area involved. Symptoms progressed distally to superior. On the 5th day symptoms progressed rapidly and involved bilateral legs up to the groin, left arm up to lateral shoulder, and right hand. I went to the hospital and was admitted to start IVIG treatment for Guillain Barre Syndrome/AIDP.

COVID19 VACCINE (COVID19)

Permanent Disability 30-39 years

Immediate pain and loss of range of movement of left shoulder. Physical examination today demonstrates a healing injection site which is fairly superior on the left shoulder, and abduction of the left shoulder which is limited secondary to pain. Patient's physician's impression is that he has a subdeltoid bursitis which was temporally associated to the COVID-19 vaccination. (SIRVA)

COVID19 VACCINE (COVID19)

Permanent Disability 30-39 years

Patient presented to the emergency department with sensory loss and loss of reflexes, evaluated by neurology and diagnosed with Guillain- Barre Syndrome thought to be secondary to the Pfizer Covid Vaccine

COVID19 VACCINE (COVID19)

Permanent Disability 30-39 years

Pt experienced extreme fatigue and sleepiness the day following her second vaccination for Covid 19 and was found by her family after collapsing on 1/6/21 at 05:30. Upon arousal, she experienced headache, vomiting, weakness, difficulty speaking and difficulty walking with lower extremity weakness. She was taken to urgent care and subsequently admitted for evaluation at hospital and found to have a normal chemistry, blood count, normal lumbar puncture and normal imaging of her neck and brain. Discharge summary notes 3/5 strength and hyporeflexia throughout. Pt had televisit consult with psychiatry and neurology. She is subsequently to be discharged to a Facility without explanation for her sudden onset of progressive lower extremity and vocal weakness. She is noted to have a history of shellfish allergy. She experienced mild symptoms after the first vaccination, but no neurologic or vascular symptoms at that time.

COVID19 VACCINE (COVID19)

Permanent Disability 30-39 years

I was injected high on my shoulder, significantly higher than I've ever been injected in my life. I believe I have SIRVA. The pain has become so severe that I cannot use my left arm. The pain is intolerable. I take four Advil every six hours, ice my arm regularly, and keep my arm in a sling. The pain has gotten significantly worse with time (not better). I've never experienced pain like this from a vaccine in my life. No history of bursitis or shoulder injury. Again, the pain gets worse with time. I'm

almost 48 hours post injection

COVID19 VACCINE (COVID19)

Permanent Disability 30-39 years

Complete loss of smell and taste; Complete loss of smell and taste; This is a spontaneous report from a contactable physician reported for herself. A 37-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; brand: PfizerbioNtech, lot number: EH9888) intramuscularly at left arm on 17Dec2020 at 03:00 PM at a single dose (dose number: 1) for COVID-19 immunization. Medical history was reported as none. No known allergies (no allergies to medications, food, or other products). The patient was not pregnant. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. No other medications the patient received within 2 weeks of vaccination. Facility where the most recent COVID-19 vaccine was administered was at hospital. The patient experienced adverse event complete loss of smell and taste on 19Dec2020 at 07:00 AM. The event was considered as serious due to resulted in disability or permanent damage. No treatment received for the event. The outcome of event was not resolved. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19.; Sender's Comments: Based on the current available information and the plausible drug-event temporal association, a possible contributory role of the suspect product BNT162B2 to the development of events complete loss of smell and taste cannot be totally excluded. The case will be reassessed if additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

COVID19 VACCINE (COVID19)

Permanent Disability 30-39 years

Followed by neurological symptoms starting day 4; parasthesias of both upper extremity; progression to muscle weakness of all four extremities/Currently with significant muscle weakness, Left hand weakness leading to dropping of objects and left foot drop; progression to muscle weakness of all four extremities/Currently with significant muscle weakness, Left hand weakness leading to dropping of objects and left foot drop; Flu like symptoms first 3 days; This is a spontaneous report from a contactable physician (patient). A 39-year-old male patient received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number: ek5730) at left arm, via an unspecified route of administration on 16Dec2020 at single dose for covid-19 immunisation. Medical history included hypertension, diabetes, migraines, Eosinophilic granulomatosis with polyangiitis (EGPA) remission. Prior to vaccination, the patient was not diagnosed with COVID-19. The patient did not have any allergies to medications, food, or other products. The patient's concomitant medications were not reported. On 21Dec2020, the patient experienced flu like symptoms first 3 days. Followed by neurological symptoms starting day 4, parasthesias of both upper extremity with progression to muscle weakness of all four extremities. Leading to 2 ER visits and hospital admission. Evaluation by internal medicine, neurology and rheumatology. Currently with significant muscle weakness, Left hand weakness leading to dropping of objects and left foot drop. The events resulted in Doctor or other healthcare professional office/clinic visit, Emergency room/department or urgent care, Hospitalization, Disability or permanent damage. The treatment for events included High dose steroid. Covid test included Nasal Swab: negative on 19Dec2020. The outcome of events was not recovered.; Sender's Comments: Based on temporal association, the causal relationship between bnt162b2 and the events influenza like illness, neurological symptom, paraesthesia, muscular weakness and peroneal nerve palsy cannot be excluded. The information available in this report is limited. This case will be reassessed once additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees, and Investigators, as appropriate.

COVID19 VACCINE (COVID19)

Permanent Disability 30-39 years

Following the first COVID vaccine dose on Dec/18/2020, I had headaches that started on the third day and ended on the tenth day. The headaches were usually light, unilateral, and alternating from one side to the other. I was usually functional except on the fourth and seventh days where the headaches were moderate to severe, and I took naps to help with the headaches for those two days. I have never had an issue with headaches before, and these symptoms were a new experience for me. I did not take any

medications as treatment for the headaches. Following the second COVID vaccine dose on January/7/2021, I felt fatigue and generalized muscle aches within six to twelve hours, and these symptoms lasted for two days. On January/10/2021, when I woke up that morning I again felt light, unilateral, and alternating headaches. In addition, I noticed that I was unable to move the left side of my face. I felt moderate tingling sensations associated with the distribution of the paralysis. When I looked in the mirror, I could quite noticeably see asymmetry in my face. I immediately went to the emergency department at the hospital where my primary care doctor is located. I was kept in the hospital into the next day for observation. After evaluation by a neurology team and an MRI, I was provided with the diagnosis of Bells Palsy. I have never previously been diagnosed with Bells Palsy, and I have never previously had a hospital stay before. The doctors prescribed medications which I am currently taking. As of today January/12/2021, the symptoms have had some improvement, but the symptoms still continue.

COVID19 VACCINE (COVID19)

Permanent Disability 30-39 years

Sudden hearing loss right ear accompanied by tinnitus

COVID19 VACCINE (COVID19)

Permanent Disability

30-39 years

Sudden hearing loss right arm accompanied by tinnitus

COVID19 VACCINE (COVID19)

Permanent Disability

30-39 years

severe stabbing-shooting lower back pain; severe stabbing-shooting lower back pain that radiated to both legs; Pricking, pins and needles sensations in the hands and feet; numbness; weakness to both legs but mostly the right leg; Coordination problems, unsteadiness; Coordination problems, unsteadiness; This is a spontaneous report from a contactable nurse (patient). A 39-year-old male patient received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EL0140), intramuscular on 20Dec2020 08:00 at single dose at left arm for covid-19 immunization. Medical history included hypertension from an unknown date and unknown if ongoing. The patient's concomitant medications in two weeks included multivitamins. Patient didn't receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient was not diagnosed with COVID-19 prior to vaccination. No known allergies to medications, food, or other products. On 22Dec2020 at approximately 19:15, the patient experienced sudden onset of severe stabbing-shooting lower back pain that radiated to both legs. Pricking, pins and needles sensations in the hands and feet. Coordination problems, unsteadiness, numbness, and weakness to both legs but mostly the right leg. The patient underwent lab tests and procedures post-vaccination which included nasal swab for covid test: negative on 30Dec2020 (Antigen Test). Adverse events resulted in doctor or other healthcare professional office/clinic visit, emergency room/department or urgent care, disability or permanent damage. Patient received pain medication, steroid dose pack, MRI (pending), and physical therapy (pending) as treatment. Outcome of all events was not recovered.; Sender's Comments: Based on the compatible temporal association, a contributory role of vaccination with BNT162B2 in the onset of the events cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

COVID19 VACCINE (COVID19)

Permanent Disability 30-39 years

Peripheral neuropathy

COVID19 VACCINE (COVID19)

Permanent Disability

30-39 years

Extreme lockjaw unable to barely talk or chew

COVID19 VACCINE (COVID19)

Permanent Disability

30-39 years

Right thumb joint pain. I can't hold onto things in my right hand that requires me using pressure from my thumb. Pain is a 9/10 when holding, grabbing, or using the thumb in any way. When not using the thumb there is no pain at all. I work out everyday and I am no longer to lift weights using my right hand because of the excruciating pain when I try to.

COVID19 VACCINE (COVID19)

Permanent Disability

30-39 years

I was diagnosed with COVID-19 on 12/7/2020. My course of symptoms lasted 16 days, meaning I started feeling healthy again on 12/23/20. I am a pharmacist with a healthcare system and they have been offering the Pfizer/Biontech COVID-19 vaccine for essential associates. I received by first dose of

vaccine on 12/31/20. On 1/1/20 I woke up with very noticeable muscle aches and fairly profound lethargy, which last 18-20 hours. I was not able to do much on 1/1/21 because of the way I was feeling. I'm not sure if this reaction is normal for patients who receive their COVID-19 vaccine close to their illness/infection with COVID-19, which is why I'm reporting this to the FDA.

COVID19 VACCINE (COVID19)

Permanent Disability 30-39 years

9th: cold (?fever?), restless, body aches (especially headache, neck pain, bilateral knee pain), nausea, vomiting 10th: profound fatigue, hives, intermittent vertigo 11-17th: vertigo, mild headache and neck pain, nausea, vomiting 18th-current: vertigo, nausea, vomiting *Hospitalized from 17-18th, diagnosed with vestibular neuritis secondary to the vaccine

COVID19 VACCINE (COVID19)

Permanent Disability 30-39 years

Tinnitus started in right ear within hour after receiving first vaccination but resolved within a couple of day. Within 24 hours of receiving second vaccination had muffled hearing, Jan 3, 2021. Symptoms were ignored thinking they would resolve. When symptoms persisted and evaluated patient was noted to have a severe right sided low frequency hearing loss with poor word recognition score. Patient was started on high dose steroids with partial recovery of symptoms.

COVID19 VACCINE (COVID19)

Permanent Disability 30-39 years

Vaccine was administered very high, presumably in the joint space, rather than the deltoid. Patient experienced intense pain in the entire shoulder area for 24 hours following administration. After initial 24 hours, pain remained more localized in the joint itself. Pain is intensified when moving out of the neutral position.

COVID19 VACCINE (COVID19)

Permanent Disability 40-49 years

Received COVID-19 vaccine on 12/18/2020 around 1225pm, ten minutes later while being monitored I started to feel hot flash, got dizzy like about to pass out, I asked to let me lay down, I felt the medication bitter taste in the back of my throat, I was clammy pale, I lay on a stretcher and put my feet up elevated, rapid response was called and BP was checked and Spo2, my hands were getting cold and tingling I was talking to RN, another RN, after laying down for ten minutes I sit up I was getting my BP back to normal, I sat down in the chair again for another 10 minutes, I was offered to go to the ER but I decline, I said I was getting better, after 15 minutes I left monitored by my supervisor I felt the medication in my stomach, after the tingling my fingers were numbed for the next days until present.

COVID19 VACCINE (COVID19)

Permanent Disability 40-49 years

positive COVID-19 test with symptoms; positive COVID-19 test with symptoms; Soreness at injection site; This is a spontaneous report from a contactable nurse (patient). A 40-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 18Dec2020 17:30 in the left arm at single dose for COVID-19 immunization. There was no medical history or concomitant medications. The patient experienced soreness at injection site, cough, body aches on 19Dec2020; sore throat, voice changes from coughing on 20Dec2020; tested positive for covid on 21Dec2020; mild low congestion, loss of taste and smell on 22Dec2020. The nurse stated that he got the vaccine on Friday (18Dec2020). The next day (19Dec2020) he had common side effects: Soreness at the injection site and body aches, which were expected. He also had a cough on top of that, which progressed to the next day. His body aches and coughing were infrequent. The afternoon of Sunday (20Dec2020), he developed sore throat. Yesterday(21Dec2020), he said he could not work because he was still coughing and had a sore throat. His voice was also changing due to the coughing. He was getting better now. The doctor from Employee Health said that the cough was concerning so he got a COVID swab test yesterday(21Dec2020), and today (22Dec2020) it came back positive. This morning (22Dec2020) he had loss of taste and smell. He no longer had sore throat or cough. He had the vaccine before the test. He wanted to know where they were at with information on this. Was this being monitored? How did this happen? Was it possible that the test was a false positive because he had the vaccine prior? He would like someone to give him an answer, if the test was a false positive due to the vaccine? His doctor could not tell if the test was legit a positive because of the vaccine. He was not able to work right now. He did not even know if the COVID was from the vaccine or not. Will he get compensation for this? Will his workplace cover his absences? In the case he went to the hospital, will this be considered a work related or vaccine related issue? The outcome of event soreness at injection site was recovered on 21Dec2020.

The outcome of event tested positive for COVID was not recovered. The nurse considered the cough was disabling as this was not part of the symptoms to watch for after getting the vaccine. All of the symptoms currently besides the cough are not serious as of now, but it has put him out of work. The nurse considered all other events as non-serious except for cough (disabling). Information on the lot/batch number has been requested.; Sender's Comments: Based on the information currently available, a lack of efficacy with BNT162B2 in this patient might not be completely excluded.

COVID19 VACCINE (COVID19)

Permanent Disability 40-49 years

Soreness and weakness of left arm for more than 5 days. Intermittent headaches and runny nose

COVID19 VACCINE (COVID19)

Permanent Disability 40-49 years

Approximately 4 days after vaccine I started experiencing sharp lower back and left hip pain. Also my left foot feels like pins and needles.

COVID19 VACCINE (COVID19)

Permanent Disability 40-49 years

Initial event was soreness at site which resolved on its own within a few days. 2 days after receiving vaccine, I began having an allergy reaction to the same brand N95 that I had been utilizing since the beginning of the pandemic. Symptoms are swollen cheeks and welts, sudden itchiness at the site of my mask placement. The reason for this report is a sudden onset of excruciating and debilitating pain throughout my body specifically pain of my right shoulder radiating down my sprightly arm. I have been receiving testing and treatment for ongoing neuropathy due to Longhailer syndrome, however This recent pain is so debilitating, I spend most of my time in bed. I have been experiencing chills then profuse sweating. I also so fatigued, I sleep much of the day. I have been having episodes of tachycardia with chest tightness which has increased since after having the vaccine. I also become short winded on exertion. I've been waking up in a panic and sweating.

COVID19 VACCINE (COVID19)

Permanent Disability 40-49 years

Cp initially that resolved in seconds. Then severe muscle aches, fatigue, temp 1 week, excruciating joint pain continues now. Malaise.

COVID19 VACCINE (COVID19)

Permanent Disability 40-49 years

shoulder joint pain, injection was given in joint.... I am now on prednisone, physical therapy, if this doesnt help will need a MRI .

COVID19 VACCINE (COVID19)

Permanent Disability 40-49 years

I had a myocardial infarction on December 27, 2020. I had received my first vaccination for COVID-19 on December 22, 2020. Not sure if these are related but I felt I should report it.

COVID19 VACCINE (COVID19)

Permanent Disability 40-49 years

7 day after site itching, hot swelling. Unsure if related 9 day after suffered CVA and have hyper coagulation

COVID19 VACCINE (COVID19)

Permanent Disability 40-49 years

After the vaccine was administered I walked away maybe 50' and I started to feel dizzy I felt light headed and as if I was drunk my legs feel real weak they took me outside so I could catch some fridge fresh air and they set me down on a chair I was very dizzy my legs and my knees felt like I couldn't stand up and they were very weak I kept seeing a the rails double vision and I started to have a tightness in the back of my neck I felt they warrant come over my head and my forehead got very very cold And then I felt as I was gonna blackout and pass out and I was gasping for air and suddenly my tongue went into a spasm and it went to the top of my the roof of my mouth and I couldn't breathe and I was able to send a message for someone to come and help me as I was sitting there by myself they rushed over by now looking at my text message it was for 02 which was within 15 minutes of the vaccine when I had my 1st episode and then minutes after that 3 more came with the same oh unable to swallow I lost the ability to swallow and my tongue fell like I had no control it was just automatically stuck to the roof of my mouth.. Upon the arrival of Ems I was told there was no treatment and there was nothing they could do told me to wait 24 to 48 hours in the symptoms should subside it's been over 72 hours in the symptoms are still occurring. I continue to feel dizzy light headed and now have high blood pressure which was not present before visit ER prescriptions for steroids with issued, I Told to go home and rest. Followed up with family doctor in the morning and was told it was not an allergic anaphylactic reaction probably more so neurologically ransom blood tests waiting for results continue to have loss of control

over tongue spasms unable to eat Accompanied by fatigue dizziness and high blood pressure

COVID19 VACCINE (COVID19)

Permanent Disability 40-49 years

Herpatic infection left eye causing a herpatic dendrite

COVID19 VACCINE (COVID19)

Permanent Disability 40-49 years

One week after administration, I had sudden onset inability to move left arm. I was transported to ER immediately. Treated, scanned with CT of brain, MRI of brain, c-spine and brachioplexus. In hospital for 2 days and no answers. Still no answers to left arm paresthesia and proprioceptor deficits. Spreading into left leg and mild systemic symptoms. I have been to the ER, seen by primary physician, Physiatrist and Neurology and Occupational Therapy. I am scheduled for many more appointments and trying to find and answer.

COVID19 VACCINE (COVID19)

Permanent Disability 40-49 years

patient developed acute onset of right-sided facial palsy and pain; patient developed acute onset of right-sided facial palsy and pain; Brain MRI done showing T2 hyperintensity in the brainstem and basal ganglia, suspicious for inflammation; This is a spontaneous report from a contactable physician. A 46-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection), on 18Dec2020 at SINGLE DOSE for COVID-19 immunization. Medical history included psoriasis. No COVID prior vaccination. It was unknown if the patient received any other vaccines within 4 weeks prior to the COVID vaccine.No known allergies. Concomitant medications (received within 2 weeks of vaccination) included fluoxetine. days following vaccination, on 23Dec2020, the patient developed acute onset of right-sided facial palsy and pain. Brain MRI done showing T2 hyperintensity in the brainstem and basal ganglia, suspicious for inflammation. Work-up is ongoing. AE Resulted in: Doctor or other healthcare professional office/clinic visit, Emergency room/department or urgent care, Disability or permanent damage].It was unknown if the event was treated. The event was assessed as serious for Disabling/Incapacitating. The patient had been tested for COVID post vaccination (covid test result-Negative). The outcome of the events were not recovered Information about lot/batch number has been requested.; Sender's Comments: A possible causal relationship between acute onset of right-sided facial palsy and pain with MRI findings suspicious for brain inflammation and BNT162B2 cannot be completely ruled out considering the temporal relationship. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

COVID19 VACCINE (COVID19)

Permanent Disability 40-49 years

Onset of shortness of breath and cough on 1/3 that progressively got worse. Clinical diagnosis of pneumonia without fever was made, patient started azithromycin on 1/5 and albuterol treatments every 4-6 hrs. Initially he improved, but then worsened. chest xray on 1/6 was negative for pneumonia, PCR covid test was negative, albuterol treatment did not bring much relief. He started respiratory distress on 1/10 and was taken by car to the local ER where another covid test was negative and chest CT revealed multiple bilateral pulmonary emboli. The leg US revealed blood clots in both of his legs. He had an emergency catheter-delivered thrombolysis and was discharged home from the ICU on 1/12 on oral anticoagulants. He is gradually improving, but very weak. He tires easily and gets a drop in oxygen to 90- 93%, as well as an increase in the heart rate to 120 when walking less than half a mile. He runs out of breath with exertion.

COVID19 VACCINE (COVID19)

Permanent Disability 40-49 years

Numbness and tingling sensations in both hands and sometimes radiating up my forearms, more severe in right hand and right thumb; these symptoms still didn't go away since 1/11

COVID19 VACCINE (COVID19)

Permanent Disability 40-49 years

Approximately 28 hours after vaccine, I began to feel tingling in my right eye Approximately 12 hours after that, my face started drooping and was numb so I went to ER. Today is Sunday, and the numbness and drooping was called Bells Palsy at the hospital.

COVID19 VACCINE (COVID19)

Permanent Disability 40-49 years

Received Moderna COVID vaccine 12/31/20, 3 days later noticed generalized joint pain all over. Day 4 noticed both knees were red and tender and could palpate pockets of fluid. Had bilateral ankle and foot pain, right ankle swollen. Overnight 1/5-1/6/21 was in severe pain and unable to sleep, very difficult to walk on ankles and feet, stairs were very painful. Motrin relieved symptoms to where able to walk more comfortably but generalized achiness and tenderness to ankles and knees remain.

COVID19 VACCINE (COVID19)

Permanent Disability 40-49 years

Approximately 3 days after my injection I began experience severe tremors lb bilateral arms, bilateral legs, head, and vocal cord tremors as well as blurry vision and memory impairment. Unfortunately, the symptoms don't seem to be improving. My MD prescribed metoprolol, which I will begin today.

COVID19 VACCINE (COVID19)

Permanent Disability 40-49 years

"suddenly lost mobility of left arm; Continue paresthesia and proprioceptive deficits of left arm; Continue paresthesia and proprioceptive deficits of left arm; This is a spontaneous report from a contactable nurse (patient). This 46-year-old female patient received the first single dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot EK5730) intramuscular, in right arm, on 16Dec2020 at 14:00, for COVID-19 immunization. No other vaccine was given in 4 weeks. Medical history included hypothyroidism, migraine headaches, IBS and COVID-19 (on an unspecified date prior to vaccination). Past drug history included allergy to morphine. Concomitant medication included levothyroxine sodium (SYNTHROID). On 23Dec2020 at 09:30 the patient experienced suddenly lost mobility of left arm, continue paresthesia and proprioceptive deficits of left arm. She was transported to the ER and was admitted to hospital for 2 days. CT of brain X3, MRI of brain X2, MRI of C-spine and Brachioplexus were performed with unknown results. The patient was not tested for COVID19 after vaccination. The events resulted in: Doctor or other healthcare professional office/clinic visit, emergency room/department or urgent care, hospitalization, disability or permanent damage. No treatment was administered. The events had not yet resolved.; Sender's Comments: Based on the temporal relationship, the association between the events "" lost mobility of left arm, continue paresthesia and proprioceptive deficits of left arm"" with BNT162b2 can not be fully excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate."

COVID19 VACCINE (COVID19)

Permanent Disability 40-49 years

Patient got her 2nd dose of Pfizer covid vaccine on 1/8. On 1/11 she had intermittent chest pain that lasted a few days and started to notice small purpura rash on left breast. She didn't think much of it but noticed the same type of rash on her pant line and then right thigh. On 1/15 she called Occupational Health who advised her to go straight to the ED.

COVID19 VACCINE (COVID19)

Permanent Disability 50-59 years

decreased range of motion in vaccinated arm: unable to raise left arm above shoulder x 72 hours now due to pain. no associated numbness or swelling. I am a surgeon and this impacts my work and driving. I would not have been able to operate during these last 3 days and while the pain is better 72hrs later, my arm is still out of commission. I think we need to inform healthcare providers who perform procedures that they may want to schedule the vaccine when no planned procedures for at least 72 hrs. Due to this issue I will be unable to proceed with the second dose, unless I can take it a week later than the scheduled January 24, 2021. It is taking too long to regain full function of the arm but i expect it will be back to normal as it is better today 72 hrs later.

COVID19 VACCINE (COVID19)

Permanent Disability 50-59 years

12/18 VACCINATION 12/19 WOKE UP, RINGING IN BOTH EARS. CALLED PCP, CONSULTED ENT ABNORMALITY - L INNER EAR; HIGH DOSE STEROIDS, 10 DAYS, 60 MG/DAY. WEEK 2; TINNITUS GOT WORSE. DR. PRIMARY CARE PHYSICIAN MEDICAL EXAM ON 1/6/2021 INJECTION OF STEROIDS.

COVID19 VACCINE (COVID19)

Permanent Disability 50-59 years

thrombotic stroke -necessitating hospitalization; and craniotomy; required mechanical ventilator

for 2 days. Patient now extubated, breathing on her own. Patient remains hospitalized with marked deficits (aphasic)

COVID19 VACCINE (COVID19)

Permanent Disability

50-59 years

felt like she had a stroke; fell down; Pain in leg; itchiness in her head; left leg not functioning normally; This is a spontaneous report from a contactable nurse (reporting for herself). A 51-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot number: EH9899), via an unspecified route of administration in the left deltoid on 21Dec2020 at 10:00 (at the age of 51-years-old) as a single dose for COVID-19 immunization. Medical history was none. There were no concomitant medications. There were no prior vaccinations within 4 weeks prior to the first administration of the suspect vaccine. On 21Dec2020, the patient experienced left leg not functioning normally, which was reported with the seriousness criteria of disability. On 21Dec2020, the patient had itchiness in her head. The patient felt like she had a stroke, fell down and pain in leg on 22Dec2020, which were all reported with the seriousness criteria of disability. The patient called the doctor office and spoke with the doctor on call and was told to use diphenhydramine hydrochloride (BENADRYL). No further details provided. The patient was sent home for 10 days and she was sent back to work. The patient underwent lab tests and procedures which included COVID: negative in Dec2020. The outcome of the events was not recovered. The reported assessed the events related to the suspect product, BNT162B2.; Sender's Comments: The reported events leg dragging, leg pain and fall and suspected stroke were possibly related to the use of first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), due to temporal relationship. However, stroke was not diagnosed. The case will be reassessed should additional information become available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

COVID19 VACCINE (COVID19)

Permanent Disability

50-59 years

Bell's palsy

COVID19 VACCINE (COVID19)

Permanent Disability

50-59 years

headache, sore throat, runny nose, arm pain that migrated to the axilla and down the side of the body, joint pain (hands, wrist, feet, hips, knees, spine, neck), insomnia, general malaise, fatigue, and lower grade fever. Most symptoms lasted about 7 -10 days. However, it is now day 20 after the initial vaccine and I still have joint pain that has not gone away. esp in hands, wrists, and feet. When I sleep I still wake up with all my joints hurting it gets better as I start moving but the wrist, hands, and feet pain has not gone away. This pain will wake me in the night when I change positions. I called my doctor today to inquire if it is a good idea if I should take the second dose because the first dose made me so debilitated. Awaiting for a response. I am due to take the second vaccine on 2/9/21.

COVID19 VACCINE (COVID19)

Permanent Disability

50-59 years

Approximately 1 - 2 hours after receiving I had numbness and soreness to my neck. A few days later started experiencing tingling, buzzing, weakness and heaviness to my right arm and leg. I reported this to my MS doctor who ordered an MRI of the brain and told me to report to you

COVID19 VACCINE (COVID19)

Permanent Disability

50-59 years

GIVEN ON 12/23. SORENESS FELT ON LEFT ARM SITE THE NEXT DAY, WITH DECREASED MOBILITY AND STRENGTH DUE TO SEVERE SORENESS AND PAIN. PAIN PROGRESSIVELY LESSENER BUT THE SORENESS STILL VERY APPARENT. ON 1/5, SPOKE TO PRIMARY MD, XRAY ON LEFT SHOULDER DONE ON 1/6. ON 1/7, STIFFNESS WITH SEVERE PAIN UPON MOVEMENT NOTED ESP IN THE MORNING. ULTRASOUND WAS DONE ON 1/8, NOTED BICEPS TENOSYNOVITIS. ORTHOPEDIC SURGEON SEEN ON 1/11, W DX OF ADHESIVE CAPSULITIS, SUGGESTED FOR PT FOR NOW, AND OFF WORK, AND TO BE FOLLOWED UP ON 2/1 BY SAME ORTHO SURGEON. WILL NOT OFFER CORTISONE SHOT FOR NOW AS IT MAY COMPROMISED OR WEAKEN IMMUNE RESPONSE, IN WHICH MY SECOND COVID SHOT DUE ON THE 15TH OF JANUARY. FIRST APPT FOR PT ON 1/15

COVID19 VACCINE (COVID19)

Permanent Disability

50-59 years

I had a mild headache the evening of the shot, I had a headache the next two days that was relieved by

Advil. I had a very sore arm at the injection site Friday and Saturday after the shot was given. The arm pain was gone Sunday morning. I was very tired on Saturday especially and slept through the morning and early afternoon on and off until about 3:00 pm. On Friday during the day, I noticed my right ear starting to feel unusual and uncomfortable. On Saturday, the ear issue continued, I felt like I had some hearing loss and a constant buzzing and ear fullness feeling. On Sunday, the ear issued continued with the hearing loss, buzzing and fullness and has through today and hasn't stopped. I tried some nasal decongestant on Sunday afternoon, but it didn't have any effect. I made an appointment with the ENT doctor on Monday morning for Tuesday. I had a hearing test on Tuesday and saw the ENT doctor on Wednesday. He prescribed prednisone and ordered an MRI. I will be starting the prednisone later today (Wednesday) when the pharmacy has the prescription ready.

COVID19 VACCINE (COVID19)

Permanent
Disability

50-59
years

Headache; migraine; tenderness at injection site; Ten hours after injection he had shaking, sweats, hot and cold flashes, and augmentation of myalgias; Ten hours after injection he had shaking, sweats, hot and cold flashes, and augmentation of myalgias; Ten hours after injection he had shaking, sweats, hot and cold flashes, and augmentation of myalgias; Ten hours after injection he had shaking, sweats, hot and cold flashes, and augmentation of myalgias; Ten hours after injection he had shaking, sweats, hot and cold flashes, and augmentation of myalgias; Fatigue; This is a spontaneous report from a contactable physician (patient). A 53-year-old male patient received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EK9231), via an unspecified route of administration on right deltoid on 05Jan2021 07:45 at single dose for covid-19 immunization. Family history included migraine (other family members). Medical history included mild blood pressure and kidney stones, reactive airway disease. Concomitant medication included colecalciferol (VITAMIN D), potassium, allopurinol and hydrochlorothiazide/valsartan for mild blood pressure and kidney stones, fluticasone propionate, salmeterol xinafoate (ADV AIR) for reactive airway disease, atorvastatin, and multivitamins. The patient previously took fluticasone propionate, salmeterol xinafoate (ADV AIR) and experienced dry mouth and lost sense of taste. The patient also previously took Tdap booster on Aug2020, Shingrix on 10Aug2020, and influenza on 12Oct2020; all for immunization; and tetanus injections for immunization and experienced localized tenderness. The patient had the first dose of BNT162B2 (lot number: EH9899) for COVID-19 immunization on 15Dec2020 and experienced localized tenderness at injection point. The received his second dose of COVID vaccine on 05Jan2021. With the first dose he had increased localized tenderness at injection site on 15Dec2020, and he rated it mild to moderate. He would say it was 80% resolved in 24 hours. It had completely resolved in 36 hours. He would say that he has recovered completely from the localized tenderness with the first dose. Then he noted his second dose was yesterday, in the context of not having much sleep the night before. The actual injection was uncommonly eerily painless. The other folks in his department had similar experience. Maybe it was the nurse who gave the injection. Maybe it was because it was the same area and sensitivity was decreased. They had to check the Band-Aid to make sure blood was there. The administration was painless. He was relieved when the arm started getting sore to know he actually received it. He had increased arm tenderness at injection site which he rated as moderate which has now resolved. It got to moderate where lifting the arm up was sore. He definitely knew that he had been vaccinated. He got the vaccine at 7:45AM and now it is 16 to 17 hours later and he would say the pain is mild now. It did persist. The first vaccine hurt a little more. He expects this to go away. Ten hours after injection he had shaking, sweats, hot and cold flashes, and augmentation of myalgias. He had unrelenting headache over night that was moderate to severe. He said it kept him awake. It was exacerbated by lying down. Sitting up helped him. It became a migraine which is something he doesn't often experience. Migraines are pretty rare for him. He took 800mg of Advil at 6AM that helped for headache and migraine. The weight of the patient was 250 to 255 pounds. Shaking, sweats, hot and cold flashes, and augmentation of myalgias have resolved. Everything has resolved except for a little headache. In the background he literally had one or two hours of sleep. He thinks that likely precipitated a migraine was increased. Last night he slept literally an hour. He took 800mg of Advil and fell asleep. He is operating on 2 hours of sleep in 48 hours. Most of the stuff is gone except a little headache and expected fatigue. Headache Seriousness Criteria: he would say that it was relatively disabling. He would not have been able to carry on. He wouldn't have been able to operate last night. It would have interfered. It was dissimilar to others. He gets rare migraines. Everything was amplified with a migraine. He certainly felt that. It was fair to say the vaccine precipitated the migraine that was mild or severe. He doesn't want to falsely attribute these things to the vaccine. Causality Headache: precipitated by the vaccine. In the context that he had not slept the night before. He had a nasopharyngeal COVID test and it was negative. He has been in a COVID study where they are looking at combination. They developed a saliva test at (Name). There is a combination of

saliva oropharyngeal and immunoglobins. He has been negative multiple times. The outcome of the events headache and fatigue was not recovered and recovered for the rest of the events.; Sender's Comments: A causal association between BNT162B2 and the reported event headache cannot be excluded based on a compatible temporal relation between vaccination and onset of events. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate.

COVID19 VACCINE (COVID19)

Permanent Disability 50-59 years

He collapsed with left sided hemiparesis; Stroke; Rt basal ganglia hemorrhage w/ edema and mass effect.; Rt basal ganglia hemorrhage w/ edema and mass effect.; Low platelets, 114; His bp as high as 200s/100; Hand weakness; Myalgia; Fever; Severe fatigue; This is a spontaneous report from a contactable physician. A 58-year-old male patient received first dose of bnt162b2 (Pfizer BioNTech COVID vaccine), intramuscularly on 16Dec2020 at a single dose for COVID-19 immunization. Medical history included hypertension with reported med noncompliance in the last few months due to stress. Concomitant medication included hypertension medications in two weeks. The patient was presumed neg covid status prior to vaccine. He worked as a Pulm/critical care physician. He reported fever, myalgia, fatigue on 16Dec2020. Next day (17Dec2020), he took off from work due to his symptoms. The following day (18Dec2020), he came to work. He c/o ongoing severe fatigue & hand weakness in am. Staff noted him to be evaluating his hands during clinic. At 12:15, he collapsed with left sided hemiparesis. The reporter had suspicion for stroke. He was transported to the Emergency Room (ER), head CT showed Rt basal ganglia hemorrhage w/ edema and mass effect. Labs notable for Low platelets, 114 (unknown baseline) on 18Dec2020, normal coags on an unspecified date. BP recorded as 179/101, but it was noted in trauma room his bp as high as 200s/100. He had a history of hypertension with reported med noncompliance in the last few months due to stress. Patient was transferred for further care. Full course was unknown but had rebleed there with low plts. Adverse event (he collapsed with left sided hemiparesis) resulted in hospitalization (22 days), life threatening illness (immediate risk of death from the event), disability/incapacitating or permanent damage. Treatment was received for adverse events. Results of tests and procedures for investigation of the patient: on 18Dec2020, Nasal Swab test: negative. The outcome of events was not recovered. Unknown if any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient was not tested for COVID-19. Information on the lot/batch number has been requested.; Sender's Comments: Collapsed with left sided hemiparesis/suspicion for stroke are as consequences of basal ganglia hemorrhage with edema, which is caused by worsening of hypertension. Low platelet also contributes to brain hemorrhage. All these serious events are unrelated to the vaccine use. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

COVID19 VACCINE (COVID19)

Permanent Disability 50-59 years

Fever, joint pain, weakness. Pain at the injection site.

COVID19 VACCINE (COVID19)

Permanent Disability

50-59 years

Pt. with dizziness, then Afib with RVR, then massive cerebral hemorrhage Pt. non oriented & unable to give history - History provided by S.O and daughter

COVID19 VACCINE (COVID19)

Permanent Disability 50-59 years

Severe fatigue, Headache frontal and temporal, dizziness/vertigo, tinnitus,

COVID19 VACCINE (COVID19)

Permanent Disability

50-59 years

9 to 36 hours. Lymphnode swelling , pain left axilla. Fever, chills ,muscle aches, brain fog. 1 week post Facial paralysis, fatigue, vocal cord weakness, feeling of unwell.

COVID19 VACCINE (COVID19)

Permanent Disability

50-59 years

Excruciating abdominal pain, left arm pain, chest pain. Gangrenous appendicitis requiring emergency surgery and followed by admission for complicated acute abdomen.

COVID19 VACCINE (COVID19)

Permanent

60-64

Arm weakness increased each day by post vaccine day 4 arm weak and unable to raise arm, conduct ADLs, painful interrupting sleep. Unable to initiate movement in arm. Use other arm to help move arm. Went to ED on post vaccine day 4. Wbc 12. Crp 4. CT no abscess. Mri on 1/4 shows bursitis. DX SIRVA. Bursa aspirated. Pending cultures. PO MEDROL DOSEPAK.

Disability **years**

COVID19 VACCINE (COVID19)

Permanent Disability **60-64 years**

I immediately felt dizzy, and there was ringing in my ears, I felt faint. I also felt shakey. I have had these symptoms for 12 days, unchanged. I cannot work because of these symptoms. I have been to urgent care and have had lab work and an EKG

COVID19 VACCINE (COVID19)

Permanent Disability **60-64 years**

blasting headaches; chills all night; dry heaving all night; Nausea; no fever but her skin felt hot; sore left arm; This is a spontaneous report from a contactable nurse for herself. This 64-year-old female patient started to receive BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), intramuscular on 18Dec2020 at single dose on left upper arm (lot: EKS730), via an unspecified route of administration on 05Jan2021 14:30 at single dose (lot: EL1284 or EK1284) for COVID-19 immunisation. Medical history and concomitant medications were none. The patient did not have anything with the first shot except a sore left arm on 18Dec2020. She stated that if she lays on left side it is sore. The patient had the sore left arm both times that she got the vaccine. She got second dose of vaccine on 05Jan2021 at 2:30pm and had a blasting headache and just had chills that went away about hour ago on 05Jan2021. She did not have a fever but her skin felt hot on 05Jan2021. She stated that she had dry heaves on 05Jan2021. The patient started that she had a blasting headache within a few hours of the vaccine and it gradually got worst by the time she went to bed. Stated that the chills and dry heaves started then and throughout the night. The chills stopped an hour before she got up. Stated that she went to check her temperature and did not have a fever despite having chills and her skin feeling hot. Stated that nausea started about 10 at night on 05Jan2021. Seriousness for blasting headache, chills and dry heaves was disabling, for nausea was medically significant, for other events was non-serious. The patient took Ibuprofen for the headache. Stated that she was going to try to drink something. The outcome of sore left arm was not recovered; of chills was recovered on 06Jan2021. The outcome of other events was recovering. The causality for blasting headache, chills, dry heaves, nausea and skin felt hot was related (Source of assessment: Primary Source Reporter, Method of assessment: Agency Information on the batch number has been requested.; Sender's Comments: Based on available information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the headache, chills, dry heaves and other reported events due to temporal relationship. There is limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, diagnostics, counteractive treatment measures and concomitant medications. This case will be reassessed once additional information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

COVID19 VACCINE (COVID19)

Permanent Disability **60-64 years**

Woke up 1/4/21 with right sided facial weakness consistent with Bell's Palsy. Started high dose Prednisone and Valtex. Received IVIG infusion on 1/6/21 and 1/7/21. Mild improvement 1/11/21.

COVID19 VACCINE (COVID19)

Permanent Disability **60-64 years**

left side will blur; Left side of face was sagging/ water leaking out of mouth/Progressive weakness on left side of face/ Swelling on lower left mandible/ diagnosed with Bell's Palsy.; Eye tearing; This is a spontaneous report from a contactable nurse who reported for himself. A 61-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Batch/lot number: EK5780) in left arm on 26Dec2020 at 08:30 at single dose for covid-19 immunisation (worked in surgical ICU and was over 61 years old). Medical history included Pre-diabetic. Family history included: mother died; mother's side had colon cancer and grandparents and uncles had cardiovascular diseases. Concomitant medication included exenatide (BYDUREON), amlodipine besilate (NORVASC), omeprazole (PROTONIX), hydrochlorothiazide, lisinopril and pneumococcal vaccine on 08Dec2020 and tetanus vaccine on 08Dec2020. It was reported that on 31Dec2020 at 07:30, the patient had eye tearing and water leaking

out of mouth, left side of face was sagging, swelling on lower left mandible (eye tearing was first, as reported); on 31Dec2020 he also experienced progressive weakness on left side of face; on 02Jan2021 the patient was diagnosed with Bell's Palsy. Then on an unknown date, left side will blur occurred. All events required emergency room visit and physician office visit. Diagnosis of Bell's Palsy and event eye tearing were serious per disability; left side will blur was non serious. Patient described the events as follows: on 31Dec2020 he was brushing teeth and noticed the water was going everywhere. Left side of face was sagging, noticed some swelling and thought it was from a bug bite. He wasn't sure if it was a stroke or not. In the morning of 01Jan2021 noticed it was progressively causing a problem. Days before noticed tearing of left eye (as reported). On 31Dec2020 before midnight, something felt wrong. He saw four cases on clinical trial with similar side effects (he clarified he had no patient information for the four patients mentioned with similar side effects from Pfizer Clinical trial. He saw this information from a article; stated four from Pfizer and Moderna). In the morning of 02Jan202, he went to Emergency Room (ER) and was diagnosed with Bells Palsy. He was given prednisone 20mg to take 3 times by mouth every day for 5 days, tetracycline 100mg, at 1 capsule by mouth twice a day for 10 days and methylprednisolone (SOLU MEDROL; Lot: 9945776;Exp: Nov2021) 4mg dose pack, started with 6 tablets first day. It was told by doctor it might cause tick problems. He was waiting for results. On 04Jan2021 went to family doctor and more blood work was taken. Because he was taking prednisone, noticed his sugar was up a little bit (date unspecified). It was prescribed Glitizide extended release, 2.5mg one tablet twice a day with breakfast. Patient was checking sugar every 6 hours. It was also prescribed Acyclovir 400mg one tablet orally five times per day for 10 days. 08Jan2021 is last day of prednisone 5 day dose and will follow up with methylprednisolone tablets. Patient had an appointment with a neurologist on 13Jan2021. Patient was still having symptoms. It was really hard for him. Not hard to swallow. Face was still drooping. Eyes were still tearing. Could not work with eyes tearing all of the time. Needed to be alert. When driving, had to focus on the right side because his left side will blur. He had to chew only on the right side because food will be left behind in between his cheeks and gums. If he drank through a straw, he had to cover the left side of his lips so he was able to suck out fluids. He thought symptoms were progressively getting worse, he didn't see much improvement. He clarified swelling was on lower part of mandible on left side. It was slightly bigger than right. When looking at face, the lines on his forehead on the left side were down. If he smiled he cannot raise his left eye brow, when before the COVID-19 vaccine he could. Noticed left side of nose was lower than the right. Cannot raise left side of lips. Outcome of the event Eyes tearing and Bell's Palsy was not recovered; outcome of the other event was unknown. Information on the batch number has been requested.; Sender's Comments: Based on available information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the reported events of Bell's palsy, Lacrimation increased and vision blurred due to temporal relationship. However, the Bell's palsy may likely possibly represent concurrent medical condition in this patient. There is limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, diagnostics including head CT/MRI and viral serologies, counteractive treatment measures and concomitant medications. This case will be reassessed once additional information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

COVID19 VACCINE (COVID19)

Permanent Disability 60-64 years

Received the 2nd vaccine at 10am on 1/11/21 intramuscular in the right arm. At 3pm on the same day, I had a painful swolle lymph node on left side of neck. That same evening I developed pain, swelling, in my right armpit radiating to the right upper breast and down my right arm with a swollen lymph node under the right arm pit. The pain was about a number 7 on a scale of 1 to 10. The pain and swelling still persist today on 1/15/2021 Still painful, especially to touch. Still radiating down the arm. Lymph node still swollen The pain is about a 2 on a scale of 1 to 10

COVID19 VACCINE (COVID19)

Permanent Disability 60-64 years

Injection given without unusual pain, but appeared to be at higher site than usual for other vaccinations patient has received. No immediate reactions. No redness or swelling at injection site. Approximately 3 hours later with restriction of abduction of left arm, which became worse over 24 hours. No numbness, pain 4-5/10 diffusely over deltoid and in acromium, posterior suprascapular area.. Able to passively move arm, treated with topical Voltaren gel, Naproxyn 500 x 1 dose. D2 with increased ROM, but still restricted.

COVID19 VACCINE (COVID19)

Permanent Disability

60-64 years

Doesn't feel like eating; Fever; Chills/ Chilled; Nausea; Severe Headache/Dull headache/Frontal headache; Fatigue; Body aches; This is a spontaneous report from a contactable Nurse (patient). This 61-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number EJ1686), via intramuscular, on 06Jan2021 (at 14:30) at single dose at left deltoid for COVID-19 immunisation, administered at hospital. Age at vaccination is 61-year-old. Historical vaccine included Diphtheria and Tetanus vaccine (intramuscular, at single dose) on 15Dec2020 for immunization; and Shingles vaccine (intramuscular, at single dose) on 15Dec2020 for varicella immunization. Relevant medical history included usual tenderness. No relevant concomitant medications were provided. On 07Jan2021, she woke up at 2:00 in the morning, she had a high temperature, she was chilled, she had a severe headache, nausea, fatigue, and body aches. She got up and took ibuprofen (ADVIL). She was basically in bed, she had to cancel all her appointments in the morning, she just laid in bed and the following afternoon her fever broke at about 4:30 in the afternoon then she just had a low grade temperature and a dull headache, nausea through the next day, Friday the 08Jan2021. She still has a very dull headache and just not right, kind of like a flu bug. She had no fever; she had not had any fever after Friday afternoon or Saturday. Fever started at 2 in the morning 07Jan2021 and she experienced the chills until after fever broke. Fever went above 102 degrees. She still had a little of the nausea, she just didn't feel like eating. She still had the dull headache. The nausea and headache have improved when compared to how it was on the 07Jan2021. She was back to work now she just has a dull frontal headache. The reporting nurse assessed all the events, except of 'Doesn't feel like eating', serious for disability. She stated she may have had usual tenderness but nothing like this. The patient had recovered from the event fever on 08Jan2021 and from the event 'chills/chilled' on 07Jan2021; the patient was recovering from 'nausea' and 'severe Headache/Dull headache/Frontal headache', while the outcome of the remaining events was unknown.; Sender's Comments: A possible contribution role of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) to the onset of the reported events cannot be excluded due to temporal relationship. It is worth noting that patient had other vaccines not far ago, including Diphtheria and Tetanus vaccine and Shingles vaccine on 15Dec2020 for immunization. The case will be reassessed should additional information become available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics committees and Investigators, as appropriate.

COVID19 VACCINE (COVID19)

Permanent Disability

65+ years

Patient is a pleasant 83 y.o. female pediatrician with history of Sjogren's, hypothyroidism, hyperlipidemia, hypertension who had been at Hospital to get her Covid vaccine. 30 minutes after doing so she reports being in the lobby and about to walk upstairs and feeling fine. The next thing she knows she wakes up on the stairs with her nose and face bleeding surrounded by healthcare team. She denies any precipitating symptoms such as chest pain, shortness of breath, fevers dizziness, headache. She reports feeling well otherwise in the last few days. I did a thorough bony palpation exam including spine and he only point of tenderness besides on her face was the area above her right ankle. She does not have a history of syncope or collapse

COVID19 VACCINE (COVID19)

Permanent Disability

65+ years

Chest pressure, dizziness, increased troponin lab value.

COVID19 VACCINE (COVID19)

Permanent Disability

65+ years

I received the vaccine shot on 12/23/20 at 3 pm. By 12/24/20, I had pain in my left arm that radiated to my neck and back on the left side. Over the past 4/5 days, I continue to have pain in my left arm, back and neck

COVID19 VACCINE (COVID19)

Permanent Disability

65+ years

Shortness of breath Hives, Fever, chills joint pains. I was Tx in the ER with Pepcid IV Solumedrol IV, Benadryl IV ,Tylenol and IV fluids. I was discharged on prednisone , Benadryl and Tylenol.

COVID19 VACCINE (COVID19)

Permanent Disability

65+ years

Weakness, fatigue, decreased appetite, upper extremity shaking, sternal red blotchy rash, decreased mental status, non-verbal, decreased level of conscious, mottling, left side facial droop,

hypertensive, fever, unable to follow commands

COVID19 VACCINE (COVID19)

Permanent Disability 65+ years

on dec 22 I felt some myalgias, chills, fatigue, HA --quite normal. That evening, noted small amount swelling R hand --I iced and took acetaminophen. By Dec 25, hand very swollen and painful with decreased ROM all fingers

COVID19 VACCINE (COVID19)

Permanent Disability 65+ years

Woke up Thursday am with hives on right lower abdomen and leg getting progressively worse throughout the day. By that afternoon had back pain in right back and continuing hives. Woke up Friday with numbness to right leg, hives, and back pain all on right side of body. Had numbness to foot, face but especially thigh, back and across upper buttocks. Saturday hives subsiding, numbness receding to face, upper thigh and foot only on right side of body. Sunday, back pain some improved, no hives or hives minimal, numbness persists upper thigh face and foot on right side of body. Monday, Tuesday and Wednesday the same. Woke up Thursday with shingles rash to upper thigh back, numbness to foot face and upper thigh persist only on right side of body. Darn!!!

COVID19 VACCINE (COVID19)

Permanent Disability 65+ years

Hemorrhagic Stroke. Began with vision difficulty in the morning. Then I noticed she had left sided neglect. Went to ER. Treated with Andresxa (to counteract Elaquis). In SICU for 2 nights then telemetry unit for 3 nights. Currently in Rehab.

COVID19 VACCINE (COVID19)

Permanent Disability 65+ years

Patient came into the emergency department on 1/8/21 with an acute ischemic stroke with complete occlusion of her left MCA. She had acute and complete flaccid paresis of her right face, arm, and leg, complete aphasia, and neglect of the right side of her body. NIHSS of 27. Onset of deficit was between 6:30pm-7:10pm. She received her 1st COVID-19 vaccine dose that morning at 10:31am.

COVID19 VACCINE (COVID19)

Permanent Disability 65+ years

Joint pain /felt like it was worsening joint pain; just severe pain to where she couldn't walk; This is a spontaneous report from a contactable Other HCP. A 70-year-old female patient received BNT162B2(Lot Number: ET1685), via an unspecified route of administration at Deltoid Left on 23Dec2020 08:00 at the 70 years old at single dose for COVID-19 immunization. The medical history included rheumatoid arthritis. The concomitant medications were none. The patient received the shot on 23Dec2020 and experienced Joint pain afterward on 02Jan2021. The patient did have rheumatoid arthritis so there was that. The patient felt like it was worsening joint pain on 02Jan2021. She has had no fever, just severe pain to where she couldn't walk on 02Jan2021. The joint pain has gotten worse and it has gotten to where she is going to advise her not to take the second shot. The Reporter assessed the seriousness for the events was Disabling. The events did not require a visit to Emergency Room but required a Physician Office visit on 06Jan2021. The patient received a steroid injection on 06Jan2021. There was none History of all previous immunization with the Pfizer vaccine considered as suspect. There was none Additional Vaccines Administered on Same Date of the Pfizer Suspect. There was no Prior Vaccinations within 4 weeks. The patient underwent lab tests and procedures, which included x-rays on 06Jan2021: unknown results (they were awaiting the X-rays). The outcome of the events was not recovered. The information on the batch number has been requested.; Sender's Comments: Based on the available information the events worsening joint pain and walking difficulty are attributed to underlying Rheumatoid arthritis; however, based on a compatible temporal association, contributory role of BNT162B2 vaccine to events occurrence cannot be completely excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

COVID19 VACCINE (COVID19)

Permanent Disability 65+ years

Tested positive for COVID-19; CT showed increased infiltrates 10-15%; Dehydration/Dehydrated; Chills; Tested positive for COVID-19; Hypotensive; Achy; Severe achy cramps/Severe cramps all over body; This is a spontaneous report from a contactable nephrologist (patient himself). This 78-year-old male patient

received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number EK5730), via an unknown route, on 17Dec2020 at single dose for COVID-19 immunisation. Age at vaccination was 78-year-old. The patient was diabetic and hypertensive. Additional medical history included hyperlipidaemia. No relevant concomitant medications were provided. On 18Dec2020, the patient developed severe achy cramps/severe cramps all over body. On 19Dec2020, the patient developed achy. On 20Dec2020, the patient was dehydrated and hypotensive, he had also chills. On unknown date, blood pressure was down to 76/50. His symptoms for COVID were severe achy cramps, hypotension, and dehydration. On 20Dec2020, COVID-19 test was positive. On 21Dec2020, the patient was given monoclonal antibodies. A computerized tomogram (CT) of the lungs was performed on 21Dec2020 and it was ok. A week later (Dec2020), he had a repeat CT which showed increased infiltrates of 10 to 15%. He then started on dexamethasone, apixaban (ELIQUIS) and the rest of the things. He had a repeat CT on 05Jan2021 which showed resolution of the infiltrates; most of the lesions went gone. CT results had improved significantly. The patient underwent a second COVID test a week ago which was still positive. He had a third COVID on 06Jan2021, but results were not available yet. The patient queried if he can proceed with second dose planned on 07Jan2021 or if he should wait. The clinical outcome was recovered for the event 'severe achy cramps/severe cramps all over body' on 19Dec2020, for 'dehydration/dehydrated' on 20Dec2020, for 'chills' on unknown date in Dec2020, for 'achy' on 30Dec2020, for 'hypotensive' on 20Dec2020; the outcome of the event 'CT showed increased infiltrates 10-15%' was recovering; the outcome for 'Tested positive for COVID-19' was unknown. The reporter considered the events 'achy' and 'severe achy cramps/severe cramps all over body' serious because causing disability; the events 'tested positive for COVID-19', 'dehydration/dehydrated', 'chills' and 'hypotensive' were considered medically significant. The reporter considered the events 'Tested positive for COVID-19', 'CT showed increased infiltrates 10-15%' and 'dehydrated/dehydration' unrelated to BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE).; Sender's Comments: A possible contributory effect of suspect BNT162B2 on reported events cannot be excluded. Case will be reassessed when new information is received. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

COVID19 VACCINE (COVID19)

Permanent Disability 65+ years

5 days after Moderna vaccine, developed severe abd pain, mid epigastrium. No Nausea or vomiting. No fever. Mild diarrhea. after 48 hrs with no improvement went to ED

COVID19 VACCINE (COVID19)

Permanent Disability 65+ years

Tufts of my hair came out by the handful - first time in my life I have experienced ANY hair loss! It is still ongoing and I am worried it will result in permanent baldness.

COVID19 VACCINE (COVID19)

Permanent Disability 65+ years

Moderna COVID-19 Vaccine At 2 PM I went blind in my left eye. Went to emergency room at Hospital Was told I have Blood clot in my eye causing the blindness and Ophthalmologist says it will probably be permanent

COVID19 VACCINE (COVID19)

Permanent Disability 65+ years

Received Pfizer vaccine, first dose on Wed. 01/13/21 between 12 and 1 P.M. Thurs. 01/14/21 in the afternoon he began to note that he had difficulty walking. Went to bed when he woke up at 5:48 A.M. he reported he had ataxia. Patient reported having to walk in tiny steps to stay upright. He went to the emergency room. Had CT scan of head and found blood clots. MRI performed. Stroke found in right PCA territory, but no loss in strength in left lower extremity. Sensation and vision intact. Strength in all four extremities is 5 out of 5.

COVID19 VACCINE (COVID19)

Permanent Disability 65+ years

Right arm weakness 2 hrs after vaccine and then right leg weakness later that evening

COVID19 VACCINE (COVID19)

Permanent Disability 65+ years

Remarkable Myalgia of extremities and back, interfering with rolling or sitting. Spasmodic twitching of upper extremities, These resulted in Hospitalization.

COVID19 VACCINE (COVID19)

Permanent Disability 65+ years

Aphasia, ,right-sided weakness and garbled speech

COVID19 VACCINE (COVID19)

Permanent Disability

65+ years

Two days after her shot, she was sitting down working on her computer paying bills. She became nauseas and dizzy and then fainted. She hit the tile floor.

COVID19 VACCINE (COVID19)

Permanent Disability

65+ years

Sudden Sensorineural Hearing Loss in left ear. Symptoms began Friday evening Jan. 8, 2021. Sounded like muffled sound in my ear, water running, ringing. Then on Saturday Jan.9, 2021 my left ear felt like it had to pop and I felt my hearing was impaired. By Sunday evening Jan. 10, 2021, I could barely hear out of my left ear. I called MD immediately Monday morning, Jan. 11, 2021 and was seen that afternoon. I was examined and had a hearing test. I was diagnosed with SSHL and started treatment of a series of steroid injections directly into my eardrum to save my hearing immediately. I have had 2 injections and hearing test since then. The doctors feel this was a side effect of the COVID vaccine due to my compromised immune system, but not an allergic reaction, but a side effect. I had the same condition about 15 years ago from a virus.

COVID19 VACCINE (COVID19)

Permanent Disability

65+ years

Noticed small area of burning sensation at right side of wrist and the vein there was very enlarged and sticking out.

COVID19 VACCINE (COVID19)

Permanent Disability

Unknown

First dose on 16Dec2020, second dose on 05Jan2021; Tinnitus; constant ringing in ears; louder this time; This is a spontaneous report from a contactable nurse (patient). A 51-year-old female patient (no pregnancy) received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), with first dose (lot number: EH9899) on 16Dec2020 via intramuscular route, with second dose (lot number: EK4176) on 05Jan2021 via an unspecified route of administration, both at single dose for covid-19 immunization. Medical history included allergies: penicillin. Concomitant medication included famotidine, ibuprofen (DUEXIS), iron (IRON) and multivitamins, all received within two weeks of vaccination. On 17Dec2020, the patient experienced tinnitus, constant ringing in ears that started 24 hours after first vaccine, lasted about 2-3 days and went away. Ringing in ears started again and is louder this time on 06Jan2021. Facility where the most recent COVID-19 vaccine was administered was in hospital. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. No treatment received for the adverse event. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. The event was identified as serious and resulted in disability or permanent damage. The outcome of event tinnitus was not recovered. The outcome of the other event was unknown.; Sender's Comments: Based on the compatible temporal association with positive rechallenge result, the Company considers the event tinnitus is possibly related to vaccination with BNT162B2. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

COVID19 VACCINE (COVID19)

Permanent Disability

Unknown

I received the Pfizer vaccine on 12/21/20 without adverse events other than soreness in deltoid. On 12/31/20 I began to notice pain, redness and swelling in second toe on R foot from base of toe to base of nail. I initially thought it was gout and self medicated with ibuprofen 400 mg BID x 1 day on 01/01/21 with some improvement. I did not take anything on 01/02/21 and woke up on 01/03/21 with return of swelling, redness and pain. I took another 400 mg of ibuprofen and it felt better but after examining the toe, I questioned whether I had developed pernio (COVID toe).

COVID19 VACCINE (COVID19)

Permanent Disability

Unknown

Several back operations of stimulator in the back and in pain management; This is a spontaneous report from a contactable Consumer. This adult female Consumer(patient) reported that: An adult female patient received bnt162b2 (BNT162B2) at single dose on an unspecified date for Covid-19 immunisation. Medical history was none. No known allergies. The patient's concomitant medications were not reported. Patient was not pregnant a time of vaccination. The patient had not received any other vaccines within 4 weeks prior to the BNT162B2 vaccine. The patient had not experienced Covid-19 prior to

vaccination. The patient experienced several back operations of stimulator in the back and in pain management on an unspecified date, resulted in disability or permanent damage. Post the vaccination, the patient has not been tested for COVID-19. The outcome of events was unknown. Information on the lot/batch number has been requested.

Note:

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Notes:

VAERS accepts reports of adverse events and reactions that occur following vaccination. Healthcare providers, vaccine manufacturers, and the public can submit reports to VAERS. While very important in monitoring vaccine safety, VAERS reports alone cannot be used to determine if a vaccine caused or contributed to an adverse event or illness. The reports may contain information that is incomplete, inaccurate, coincidental, or unverifiable. Most reports to VAERS are voluntary, which means they are subject to biases. This creates specific limitations on how the data can be used scientifically. Data from VAERS reports should always be interpreted with these limitations in mind.

Caveats:

The strengths of VAERS are that it is national in scope and can quickly provide an early warning of a safety problem with a vaccine.