The Vaccine Adverse Event Reporting System (VAERS) Results

Symptoms	Vaccine	Vaccine Manufacturer	VAERS ID	Adverse Event Description
RESPIRATORY FAILURE	COVID19 (COVID19 (JANSSEN)) (1203)	JANSSEN	1111699-1	Patient developed symptomatic COVID infection with symptoms starting 3/13, was admitted to the hospital for respiratory failure on 3/16 and expired on 3/18/21
RESPIRATORY FAILURE	COVID19 (COVID19 (JANSSEN)) (1203)	JANSSEN	1144220-1	Bacteremia - strep epidermidis, developed respiratory distress required intubation for hypercapnic respiratory failure. Developed PEA on 3/28 died.
RESPIRATORY FAILURE	COVID19 (COVID19 (JANSSEN)) (1203)	JANSSEN	1198107-1	53 y.o. female with a PMhx of asthma, CHF, CKD (not on HD), DM, HTN, hypothyroidism, methadone dependence for back pain, chronic bilateral foot ulcers presents with c/o one day of fever and admitted for sepsis of unknown origin on 3/9. Patient tested negative for SARSCOV2 on admission on 3/9. She was deemed a candidate for the vaccine and it was administered on 3/10 (Janssen Lot 1805031). On 3/19, she tested positive for SARSCOV2. She developed worsening respiratory failure and required oxygen supplementation with gradual escalation until she was intubated on 3/29. She received 5 days of remdesivir and steroid therapy. She developed DIC for which she received supportive care (vitamin K, transfusions, etc) and an HLH-type picture for which the steroids treatment was prolonged. She was not a candidate for tocilizumab given the elevated LFTs > 5x the upper limit of normal. During the ICU course patient was started on hemodialysis. Patient gradually started improving around 4/5 with planning for spontaneous breathing trials in attempts to extubate after weaning of sedatives. On 4/8, during a dialysis session patient became hypotensive and bradycardic. After this episode, patient's mental status worsened and developed worsening metabolic acidosis and worsening shock refractory to vasopressors. Family decided for DNR and transition to comfort care. Patient expired on 4/12.
RESPIRATORY FAILURE	COVID19 (COVID19 (JANSSEN)) (1203)	JANSSEN	1214724-1	Emergency Department Note (Verified) Visit Date: 04/13/2021 CHIEF COMPLAINT: Shortness of breath. HISTORY OF PRESENT ILLNESS: The patient is a 65-year-old male with a history of hypertension and congestive heart failure, presents with shortness of breath that started on Friday and worsened significantly this morning. He does have some chest discomfort with this. No fevers, chills, or other complaints. Discharge Diagnoses 1. Hypertensive emergency, 04/13/2021 2. Chest discomfort, 04/14/2021 3. Heart failure, systolic, 04/13/2021 Assessment and Plan 65M w/ HTN and HFrEF p/w hypoxic respiratory failure i/s/o a hypertensive emergency. BP and respiratory status much improved, admitted to CCU for acute BP management and medication titration. #HTN Emergency Likely precipitated by lack of medication non-adherence since 04/11, when he ran out of his medications. SBP approx 220 at time of presentation, good response to enalapril and nitro gtt. Decreased work of breathing with Bi-pap. MAP 130-140 on presentation, will attempt to lower by 20-25% in first 2-6hrs w/ MAP goal of approx 100, while aiming towards normotensive in next 24-48 hrs while transitioning from IV to PO meds. -TTE ordered -cont incremental BP mgmt: -goal MAP < 110 -prn hydralazine -gradual goal towards normotensive over next 24-48hrs thereafter -cardiac monitor -will ensure that patient has anti-hypertensives prior to DC -q4hr neuro checks #Acute Hypoxic and Hypercapnic respiratory failure Decreased work of breathing with Bi-pap. Likely related to HTN emergency as above in addition to moderate-severe volume overload as seen on CXR. VBG in am of 4/13 showed pH 7.17, pCO2 64, pO2 58, bicarb 24. -cont Bi-pap, will wean as tolerable -repeat VBG this am for resp acidosis #HFrEF w/ acute exacerbation Last echo 04/14/2017, LVEF 38%, cxr on admission shows moderate-severe volume overload. -TTE ordered on 4/13 -may consider additional diuresis, given furosemide in ED on presentation, mindful of BP -goal net negative 1-2L/24hrs as pressures permit -daily standing weights -fluid and sodium restriction when off Bi-Pap #NSTEMI Likely type II given HTN emergency, did have chest pain on presentation which was relieved with BP control. -trend trops until flat, next at 08:00 #type II DM Hgb A1c 7.5% on 4/13, mild hyperglycemia on presentation -SSI #polycythemia Could be indicative of undiagnosed OSA vs manifestation of heart failure. Additionally, hemoconcentration from CHF i/s/o HTN emergency is another possibility. -TTE as above -ctm w/ am labs #lymphocytosis Afebrile, no urinary symptoms. Hypoxic on presentation, likely related to edema i/s/o HTN emergency as above. No suspicion for infectious etiology at this time, no white count. -ctm w/ am labs #HLD -cont statin #QTC prolongation 561 on 4/13/2021 -avoid QTc prolonging medications
RESPIRATORY FAILURE	COVID19 (COVID19 (JANSSEN)) (1203)	JANSSEN	1226027-1	Diagnosed with COVID infection on 4/13/2021. in ICU on 4/18 with severe hypoxemic respiratory failure
RESPIRATORY FAILURE	COVID19 (COVID19 (JANSSEN)) (1203)	JANSSEN	1231142-1	COVID-19 infection confirmed 4/19/2020 with hospital admission for acute hypoxic respiratory failure

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RESPIRATORY FAILURE	COVID19 (COVID19 (JANSSEN)) (1203)	JANSSEN	1237947-1	Patient admitted 4/12/21 with fatigue and abdominal pain. Found to have UTI but no definite sepsis, and acute renal failure. Treated with iv antibiotics and iv fluids. Over next 48 hours developed worsening encephalopathy and thrombocytopenia. MRI/MRA/MRV showed no acute findings. Hyperammonemia noted, with no known Hx of cirrhosis; US did not show portal vein or hepatic vein thrombosis. Encephalopathy worsened, no clear etiology; EEG just showed generalized encephalopathy. Renal function worsened. Patient became obtunded and was intubated 4/16/19. Platelet nadir of 31k. Dialysis started. Left common femoral DVT developed. Patient had DIC type picture. Respiratory failure worsened, hypotension developed, patient passed away 4/20/21. No clear etiology of encephalopathy and thrombocytopenia identified, unclear if related to J&J vaccine received 2 weeks prior.
RESPIRATORY FAILURE	COVID19 (COVID19 (JANSSEN)) (1203)	JANSSEN	1266405-1	Patient received J&J COVID vaccine on 4/10/2021. She underwent elective R total knee arthroplasty on 4/20/2021. On 4/21, patient developed chest pain and was found to have a STEMI (large embolus in the posterolateral branch of the right coronary artery). She underwent thrombectomy and angioplasty on 4/21 with no evidence of CAD elsewhere. She developed hypoxic respiratory failure evening of 4/21 and was found to have bilateral pulmonary embolus with saddle type emboli and distal emboli throughout both lungs. She underwent IR guided thrombectomy on4/22 and had a cardiac arrest intra-operatively. Given timing of onset and recent J&J COVID vaccination, the patient was treated with IVIG, steroids, and placed argatroban. She continued to have multiorgan failure requiring mechanical ventilation and hemodialysis. On 4/26, CT head was positive for small area of subarachnoid hemorrhage. Patient was transitioned to comfort care measures and palliatively extubated on 4/26.
RESPIRATORY FAILURE	COVID19 (COVID19 (JANSSEN)) (1203)	JANSSEN	1270480-1	March 25 - loss of taste - March 30 - shortness of breath - resp failure - March 31 - transferred to ER - intubated for three days. Transferred to hospital - March 5 - transferred to Rehab - 4/15; released to home 4/24.
RESPIRATORY FAILURE	COVID19 (COVID19 (JANSSEN)) (1203)	JANSSEN	1270605-1	His brother reporting that he got the vaccine, the following day he was coughing. The coughing caused him not to be able to sleep and was weak due to that. He could feel his throat closing and he was having a hard time breathing and he called his brother who told him to call 9-1-1. He was taken to Medical Center 4/17/2021, diagnosed with possibly COVID. He was admitted to the COVID ward and he died on 4/26/2021. The doctor that pronounced him was . Cause of death diagnosis. Hypoxic respiratory arrest, COVID 19
RESPIRATORY FAILURE	COVID19 (COVID19 (JANSSEN)) (1203)	JANSSEN	1271189-1	Presented to emergency department at ancillary facility on 3/19/21 with shortness of breath and was admitted at that time. He was transferred to regional medical facility on 3/23/21 for further management due to increasing oxygen requirements and worsening congestion. Patient was discharged on 4/2/21 to rehab facility. Patient presented to emergency department on 4/12/21 from rehab facility for worsening hypoxia and respiratory failure. Chest xray showed new infiltrates and he was started on antibiotics for pneumonia. He was discharged on 4/20/21 to a skilled nursing facility.
RESPIRATORY FAILURE	COVID19 (COVID19 (JANSSEN)) (1203)	JANSSEN	1290291-1	On 5/3/2021 was found to be unresponsive with low BP and slow heart rate. 911 was initiated and CPR started. Resident was admitted to Hospital with diagnosis of respiratory failure
RESPIRATORY FAILURE	COVID19 (COVID19 (JANSSEN)) (1203)	JANSSEN	1295200-1	Pt received Covid-19 vaccine on 3/19 then presented to ED with fever and shortness of breath on 3/23 admitted to the hospital found to be COVID 19+ and requiring 2L oxygen via NC. Treated with dexamethasone, remdesivir and empiric antibiotics. Following admission, O2 requirement increased, received tocilizumab then required transfer to the ICU on 3/29. On 3/31 developed right leg ischemia, underwent thrombectomy and heparin infusion then on 4/1 patient intubated due to increased need for respiratory support and had bilateral chest tubes placed, post-intubation course complicated by shock with AKI requiring pressor support, prolonged encephalolpathy. On 4/24 with worsening shock, hypoxemic resp failure, AKI requiring pressors and CRRT with broad spectrum antibiotics and resumption of stress dose steroids, the family was transitioned to comfort measures and passed away on 4/29.
RESPIRATORY FAILURE	COVID19 (COVID19 (JANSSEN)) (1203)	JANSSEN	1296197-1	"Wife reports patient was vaccinated on 3/30/21. She stated patient only had blurred vision following vaccination which lasted a about 2 days. On 4/4 family members visited and it was noted that 1 member tested positive for Covid on 4/5/21 and her spouse was home sick on 4/4/21 and was later positive on 4/5/21. Around 4/5/21 patient began having more frequent episodes of delusion and confusion. Speech slurred and slouched in chair. Patient would be demanding when asking for water when water was in his hand. Talking to her but looking at the ceiling. She stated she thought he was having ""mini strokes."" Increased weakness with standing. Slid to floor multiple times from chair. She reports loss of appetite and trembling. Saw MD on 4/12. ""Could hardly breathe."" MD ordered doxycycline and an inhaler. Patient to Hospital on 4/13/21. Diagnosed with Covid on 4/13/21 via PCR. Discharged from hospital to Skilled Nursing Facility on 4/16/21. Sent back to Hospital on 4/18/21 and passed away on 5/1/21. Wife states that death certificate indicates ""Utonic Hypercapnic respiratory failure, acute/chronic CHF, hypoxemic respiratory failure and HTN, DM, prostate CA and COVID PNA. No autopsy performed. Medical PCP."

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RESPIRATORY FAILURE	COVID19 (COVID19 (JANSSEN)) (1203)	JANSSEN	1323176-1	J&J Dose 4/10/21 (1808980) COVID Positive 4/27/21 4/29/21: Presented to ED and admitted. 4/30/21: Pt. is a 49-year-old female with history of persistent asthma who was diagnosed with COVID-19- 5 days ago. The patient tested positive for COVID-19 infection on 04/25/2021. Since then she had dry cough, on and off wheezing, worsening shortness of breath. Since yesterday she became extremely short of breath for which she decided to come to the emergency room. Earlier yesterday she was evaluated by an ED physician and she was advised to be admitted because of hypoxemia and pulse oximetry of 87%. Patient declined admission and went home. She came back with worsening shortness of breath. On exam patient was comfortably breathing on 2 L with oxygen saturation 95% ; chest examination was significant for bilateral extensive rhonchi with good air entry and no wheezing. Blood work shows sodium 133, potassium 2.4, BUN 5, creatinine 0.5, albumin 3.4, D-dimer was elevated at and follow-up with CT of the chest with contrast was done. It showed bilateral extensive multilobar pneumonia . There was no pulmonary thromboembolic disease. 5/4/21: Patient is a 49-year-old female who was diagnosed COVID positive on 4/25/2021. She presented to the emergency department on 4/30/2021 with worsening shortness of breath and was noted to be hypoxic. She was admitted to the medical floor with acute hypoxic respiratory failure, secondary to bilateral COVID-19 pneumonia. She received 1 unit of convalescent plasma. She was started on Rocephin, Zithromax, dexamethasone, and Remdesivir therapies. She had a persistent dry cough for which codeine/guaifenesin was effective. Her potassium was also noted to be low, and it was supplemented. She was started on oral therapy and this has maintained it. She is no longer requiring supplemental oxygen. She reports she is feeling much better. She has completed her Remdesivir therapy today and is requesting to go home.
RESPIRATORY FAILURE	COVID19 (COVID19 (JANSSEN)) (1203)	JANSSEN	1337780-1	Person died on 5/7/2021 with death note stating acute respiratory failure with hypoxia, thrombocytopenia.
RESPIRATORY FAILURE	COVID19 (COVID19 (JANSSEN)) (1203)	JANSSEN	1350611-1	Patient admitted to hospital 5/15/2021 with acute toxic encephalopathy due to disseminated varicella zoster virus and acute hypercapneic respiratory failure. Patient remains hospitalized as of date of this report. Encephalopathy is resolving and patient has been extubated but remains on 4 liters of oxygen via nasal canula.
RESPIRATORY FAILURE	COVID19 (COVID19 (JANSSEN)) (1203)	JANSSEN	1378066-1	Resident went into respiratory distress during early am of 6/7/2021. Pulse ox dropped to 56%. Resident sent to Medical Center and admitted with Respiratory Failure.
RESPIRATORY FAILURE	COVID19 (COVID19 (MODERNA)) (1201)	MODERNA	0910059-1	Numbness in sole of feet. Unable to walk, develop high fever, resp failure resulting in intubation, acute kidney injury
RESPIRATORY FAILURE	COVID19 (COVID19 (MODERNA)) (1201)	MODERNA	0924410-1	Adult failure to thrive; Chronic hypoxemic respiratory failure; Generalized weakness
RESPIRATORY FAILURE	COVID19 (COVID19 (MODERNA)) (1201)	MODERNA	0930611-1	Developed hypercapnic respiratory failure, CHF exacerbation - readmitted to Hospital. In ICU with BIPAP
RESPIRATORY FAILURE	COVID19 (COVID19 (MODERNA)) (1201)	MODERNA	0939050-1	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.
RESPIRATORY FAILURE	COVID19 (COVID19 (MODERNA)) (1201)	MODERNA	0941811-1	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.
RESPIRATORY FAILURE	COVID19 (COVID19 (MODERNA)) (1201)	MODERNA	0951799-1	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.

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RESPIRATORY FAILURE	COVID19 (COVID19 (MODERNA)) (1201)	MODERNA	0966449-1	hypoxia to 30%, only improved to 82% on Nonrebreather at 100%, intubated for hypoxic respiratory failure
RESPIRATORY FAILURE	COVID19 (COVID19 (MODERNA)) (1201)	MODERNA	0976019-1	Per summary of primary hospitalist. Pt admitted for acute hypoxic respiratory failure requiring mechanical ventilation secondary to angioedema from Moderna COVID-19 vaccination. Pt presented with a chief complaint of tongue and facial swelling approximately 10 minutes after receiving first dose of the vaccination. She did not respond to Benadryl or IM epinephrine. She was admitted to ICU and intubated. She was started on IVsteroids, famotidine and diphenhydramine. Swelling gradually improved and she was successfully extubated. Her hospital course was complicated by steroid-induced hyperglycemia requiring insulin.
RESPIRATORY FAILURE	COVID19 (COVID19 (MODERNA)) (1201)	MODERNA	0981928-1	Sepsis, Acute Pancreatitis, Respiratory Failure on Mechanical Ventilation, Disseminated Intravascular Coagulation, Pneumonia, Acute Kidney Injury. Refractory Hypoglycemia
RESPIRATORY FAILURE	COVID19 (COVID19 (MODERNA)) (1201)	MODERNA	0982472-1	Worsening respiratory failure 1/20/2021 death 1/27/2021
RESPIRATORY FAILURE	COVID19 (COVID19 (MODERNA)) (1201)	MODERNA	0987080-1	Client developed a mild covid infection 12/8/21 and recovered. He was admitted 12/25 with hypogycemia and mild weakness and sent home He was given his first dose of the Moderna vaccine 1/4/21 at approximately 9AM covid vaccine clinic He developed weakness the next day (1/5) prompting admission to a hospital and then transition to subacute rehabilitation briefly Work up at hospital revealed progressive respiratory failure and pneumonia requiring intubation and progressive ascending weakness and sensory loss without upper motor neuron changes. MRI : nerve root enhancement LP : protein 40, +/- 80 lymphocytes, cultures negative B 12 and B6 normal extensive CSF testing still pending campylobacter and Musk antibodies negative Neurology diagnosed likely AIDP (Guillain-Barre) and an EMG is planned for the near future. Neurology felt the cause of his GBS was likely his covid infection verses his Moderna vaccination He was treated with plasmapheresis. Client received dexamethasone, remdesivir, and zosyn and doxycycline when progressive leukocytosis and procalcitonin elevation was noted. Candida was cultured from tracheal aspirates but felt most likely d/t colonization with an option to treat further if he did not continue to improve. He is now extubated, unable to swallow and has profound weakness and distal sensory loss. He will transition to Acute rehab in the near future. Comorbidities:as described in the above section and... DM2, CKD3, HTN, DJD, BPH (h/o prostate surgery), h/o Lumbar surgery and hernia repair, GERD, hypothyroidism, hyperlipidemia. Possible etiologies of his AIDP (GBS) would include his recent covid infection, the Moderna Vaccine, or other undiagnosed infection. He got his flu shot 9/25 (fluzone sanofi) so this is not likely to be the culprit
RESPIRATORY FAILURE	COVID19 (COVID19 (MODERNA)) (1201)	MODERNA	0998463-1	Resident passed away unexpectedly on 01/19/21 after developing acute hypoxic respiratory failure on morning of 01/19/21. She was transferred to hospital via EMS where she was intubated, coded, and ultimately expired with uncertain underlying cause, potentially ACS.
RESPIRATORY FAILURE	COVID19 (COVID19 (MODERNA)) (1201)	MODERNA	1000849-1	Narrative: Respiratory failure / respiratory depression went to ED / ICU 2/1/2021. Frail patient. 1st vaccine 12/23/2020 Moderna Lot 039K20A exp 6/20/2021, 2nd vaccine 1/20/2020 Moderna Lot 013L20A exp 7/8/2021
RESPIRATORY FAILURE	COVID19 (COVID19 (MODERNA)) (1201)	MODERNA	1002461-1	10 minutes after vaccine--throat became tight, some scattered itching, O2 sat to 93%, lungs mild-moderate decreased air movement. Took Proair inhaler, 10 mg Prednisone, 25 mg Benadryl. 1 hour after injection symptoms resolved and sat up to 98+% and lung clear moving better air per the RN monitoring for reactions. 1 day post injection-- exhausted, spordaic and severe muscle cramps, chills 2 day post injection, chills better, muscle cramps stronger, abdominal muscles and intestines cramping
RESPIRATORY FAILURE	COVID19 (COVID19 (MODERNA)) (1201)	MODERNA	1004952-1	Patient reported following his immunization he became short of breath, tired, weak, joint pain, headache, recommended go to emergency room, resulting Hospitalization 1/20-22/2021 dx Acute Hypoxic Respiratory Failure secondary to Acute on Chronic Diastolic Heart Failure exacerbation, currently patient remains on home oxygen
RESPIRATORY FAILURE	COVID19 (COVID19 (MODERNA)) (1201)	MODERNA	1016709-1	ON 02/08/2021 AROUND 0600 RESIDENTCOMPLAINED OF MOUTH PAIN AND RECEIVED OXYCODONE. DURING THE COURSE OF THE MORNING, RESIDENT EXHIBITED A FEW EPISODES OF LABORED/SHALLOW BREATHING AND SOB AT RESTING. 0XYGEN SATURATION RATE WAS 93-98% ON ROOM AIR, LUNG SOUNDS CLEAR IN ALL LOBES AND PULSE AND TEMPERATURE WITHIN NORMAL RANGE. AS THE DAY PROGRESSED, VITAL SIGNS REMAINED STABLE BUT RESIDENT CONTINUED TO HAVE PERIODS OF SOB/LABORED BREATHING.FAMILY AND NURSE PRACTIONER UPDATED AND THE ORDER WAS RECEIVED TO SEND PATIENT TO MEDICAL CENTER ER FOR EVALUATION PER AMBULANCE. RESIDENT TRANSPORTED AT 1425. RESIDENT RETURNED FROM THE ER AT 1830 ON HOSPICE CARE WITH THE DIAGNOSIS OF: ACURE RESPIRATORY FAILURE WITH HYPOXIA AND END OF LIFE DECISION MAKING. RESIDENT WAS MADE COMFORTABLE AND MONITORED DURING THE NIGHT AND EXPIRED AT 0630 ON 02/09/2021.
RESPIRATORY FAILURE	COVID19 (COVID19 (MODERNA)) (1201)	MODERNA	1017660-1	Patient contracted COVID and was hospitalized. He later died- respiratory failure secondary to COVID-19 pneumonia. This was not related to a vaccine adverse event, but reporting based on requirements.

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RESPIRATORY FAILURE	COVID19 (COVID19 (MODERNA)) (1201)	MODERNA	1023673-1	Patient was vaccinated on 1/14/2021. On 1/22/2021, patient tested positive for COVID-19 and admitted to the hospital for acute hypoxemic respiratory failure, COVID-19 pneumonia, and severe ARDS. Patient was intubated on 1/23/2021 and later died on 2/10/2021 after being extubated and placed on comfort measures.
RESPIRATORY FAILURE	COVID19 (COVID19 (MODERNA)) (1201)	MODERNA	1036463-1	FEVER, FATIGUE, SHORTNESS OF BREATH, ACUTE CYANOSIS WITH RESPIRATORY FAILURE REQUIRING INTUBATION (SUCCESSFULLY EXTUBATED 2/17)
RESPIRATORY FAILURE	COVID19 (COVID19 (MODERNA)) (1201)	MODERNA	1036591-1	Patient received vaccine on 2/8 at 2:50pm. On 2/9 at 10am, patient was found unresponsive. EMS noted R gaze preference and L sided contracture. Patient was intubated and symptoms resolved when given Versed. Concern for seizure activity.
RESPIRATORY FAILURE	COVID19 (COVID19 (MODERNA)) (1201)	MODERNA	1040919-1	Hypoxic failure secondary to acute on chronic diastolic heart failure; Shortness of breath; Weak; Tired; A spontaneous report was received from a healthcare professional concerning a 90-year-old, male patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced hypoxic failure secondary to acute on chronic diastolic heart failure, shortness of breath, tired, and weak. The patient's medical history, as provided by the reporter, included chronic diastolic heart failure. Concomitant product use was not provided. On 15 Jan 2021, the patient received their first of two planned doses of mRNA-1273 (Lot number: 012L20A), intramuscularly for prophylaxis of COVD-19 infection. On 16 Jan 2021, the patient had shortness of breath, was tired and weak. He was taken to the hospital and diagnosed with hypoxic failure secondary to acute on chronic diastolic heart failure. Treatment for the events included intravenous (IV) bumetanide. The patient was discharged home with oxygen on an unknown date. Action taken with mRNA-1273 in response to the events was not provided. The outcome for the events, hypoxic failure secondary to acute on chronic diastolic heart failure, shortness of breath, tired, and weak, was unknown.; Reporter's Comments: Based on the diagnosis of hypoxic failure secondary to acute on chronic diastolic heart failure provided by the hospital, the event is assessed as unlikely related to mRNA-1273. Further information has been requested.
RESPIRATORY FAILURE	COVID19 (COVID19 (MODERNA)) (1201)	MODERNA	1042145-1	Patient reported feeling weak, fatigue, fever (102), and loss of appetite. Patient subsequently went to the ER 2/6/2021 and tested positive for COVID-19 on 2/7/21 (collection date). See following discharge summary from ED: 82 y.o. female who initially presented to the ED with complaint of generalized weakness, fatigue, fever, and loss of appetite x at least 4 days since receiving Covid 19 vaccine. Her workup in the emergency room was significant for hypoxia with 02 saturation 88% on 2LPM (home nocturnal 02 requirement) with improvement to mid-90s on 4LPM. Blood sugar was 47, Cr 1.61. CXR showed extensive R lung and moderate left lung opacities. She was started on empiric ceftriaxone and azithromycin and admitted to the hospitalist service for further workup and mgmt. During her stay in the hospital, pt did test positive for Covid 19. She developed rapidly progressive respiratory failure, felt to be secondary to ARDS. There was also question of contributing pulmonary edema, however this was refractory to lasix and thus ARDS was felt to be the most significant factor. She had requested DNR/DNI status, thus as her 02 requirement escalated she was transitioned to 15LPM NRB and then to BiPAP support. Unfortunately, she continued to suffer greatly with the BiPAP in place, and therefore made the decision to transition herself to comfort measures only after visitation from her family. Her other medical issues were supported as appropriate during her stay, with dextrose infusion for hypoglycemia and AKI, also hyponatremia felt to be due to IVVF. Unfortunately, am unable to find any documentation regarding how pt was feeling when she received the vaccine compared to her baseline state of health. thus am unable to say whether the severity of her illness represents vaccinei enhanced disease or the much more common cytokine release syndrome leading to ARDS. Regardless, she developed ARDS as result of her Covid 19 illness. Time of death: 1408 on 2/9/21. Cause of death: ARDS due to Covid 19 pneumonia.
RESPIRATORY FAILURE	COVID19 (COVID19 (MODERNA)) (1201)	MODERNA	1044794-1	acute hypoxic respiratory failure
RESPIRATORY FAILURE	COVID19 (COVID19 (MODERNA)) (1201)	MODERNA	1046301-1	Patient admitted and treated for respiratory insufficiency, CHF, hypotension, AKI, metabolic acidosis, and hyperuricemia
RESPIRATORY FAILURE	COVID19 (COVID19 (MODERNA)) (1201)	MODERNA	1049045-1	I got the vaccine on the 8th and then about at 8 at night on the tenth, and my throat started to close, and I couldn't breathe. I was sent to the hospital where I was intubated. I went into anaphylactic shock and cardiac arrest and then respitory failure.
RESPIRATORY FAILURE	COVID19 (COVID19 (MODERNA)) (1201)	MODERNA	1052724-1	Moderna COVID- 19 Vaccine EUA: one day after vaccination patient reported increasing fatigue after flying on an airplane to a high altitude destination. Two days after vaccination patient fell out of bed overnight and awoke confused with a temperature of 104 degrees Fahrenheit. Patient was transferred to another hospital by ambulance, admitted, received antibiotics, but developed acute hypoxemic respiratory failure. Eight days after vaccination patient transferred to intensive care unit at current hospital with acute respiratory distress syndome and bilateral pulmonary infiltrates requiring intubation and mechanical ventillation three days after arrival. Patient remains in the intensive care unit receiving antimicrobials and steroids.

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RESPIRATORY FAILURE	**COVID19 (COVID19 (MODERNA)) (1201)**	**MODERNA**	1056852-1	Admitted to hospital for acute on chronic respiratory failure following covid vaccination. (patient significantly fatigued, slept most of the day after vaccine, not on BIPAP as needed) HISTORY OF PRESENT ILLNESS: patient is a 78 y.o. female with a history of oxygen-dependent chronic obstructive pulmonary disease, obstructive sleep apnea, and persistent atrial fibrillation who presents today with general malaise. She received her 2nd COVID-19 vaccination yesterday and complained of fatigue, body aches, and general malaise all day. Later in the evening she noticed that her blood oxygen level was low. She denies having any more shortness of breath abnormal. She has had no vomiting, headache, or chest pain. On arrival she was noted to be febrile and required 6 L supplemental oxygen via nasal cannula. She usually uses 2 L nasal cannula at baseline, occasionally increasing it to 3 or 4 with exertion. She also had elevated troponin levels and noted leukocytosis. There was radiographic evidence of congestive heart failure. On exam, she is tired and wants to go to sleep. She is still requiring 4 L of oxygen via nasal cannula. Her daughter is at bedside. Plans are discussed for admission and she is agreeable. ASSESSMENT / PLAN: * Acute on chronic hypoxemic respiratory failure (HCC) Assessment & Plan Admit to medicine- hypoxic requiring 6 L nasal cannula, utilizes 2 L nasal cannula baseline Hypoxia appears to be secondary to robust immune response to COVID-19 vaccination Increased hypoxia, fever, leukocytosis, elevated troponin, radiographic evidence of congestive heart failure Will repeat troponin level in the morning, daily chemistry and blood count, will treat congestive heart failure as below CHF (congestive heart failure) (HCC) Assessment & Plan Transesophageal echocardiogram from October 2020 noted preserved left ejection fraction, and had no evidence for diastolic dysfunction Radiographic evidence of congestive heart failure, normal BNP, elevated troponin with an increase of 18 at the 2 hour mark, will recheck in the morning As this is her 2nd hospitalization since that echo with hypoxia and concern for CHF, will obtain repeat echocardiogram Received 80 mg IV Lasix in the emergency department, will continue 40 mg IV Lasix 2 times a day Daily weights, 2 L fluid restriction Patient was admitted with acute on chronic hypoxic respiratory failure. I think this is due to acute on chronic diastolic congestive heart failure that was brought on after she was sleeping most of the day without her BiPAP. She says she got her COVID-19 booster shot and felt so tired she slept all day. She did not think she needed her BiPAP during the day even if she was sleeping. She has not had a recent sleep study. Patient is diuresing and will likely be able to discharge tomorrow.
RESPIRATORY FAILURE	**COVID19 (COVID19 (MODERNA)) (1201)**	**MODERNA**	1060527-1	loss of consciousness;febrile Narrative: Patient received his 2nd vaccine at 10am 2/17. That evening he felt subjectively febrile and then suffered a ground level fall at 0400 on 2/18. He did not lose consciousness or injure his head. EMS was contacted and assisted him into bed. At 0600, wife noted increased work of breathing, which prompted another EMS call, who found him hypoxic with fever of 106. He was transported to a community hospital, where he was found to have temp 102.9 and blood pressure in 70s-80s systolic. He was transferred to hospital at 1300 on 2/18/21, requiring norepinephrine for pressure support after fluid resuscitation. He c/o stiffness and soreness all over but presenting ROS was otherwise negative. Patient was treated with 4L IV fluids and vancomycin and piperacillin/tazobactam at the outside ER. Here at the hospital he was treated with vancomycin, piperacillin/tazobactam and levofloxacin along with IV fluids and norepinephrine. Despite this he had several fevers with Tmax 103.5F the night of 2/18-2/19 and he required norepinephrine plus vasopressin overnight to maintain blood pressure. Piperacillin/Tazobactam was discontinued in favor of meropenem. His last fever was at 6am on 2/19. ID consult was obtained 2/19/21 and vancomycin and levofloxacin were weaned off. Ultimately his blood pressure improved and he was weaned off of all vasopressors the morning of 2/20. Notably, he never developed severe hypoxemia at rest while in the ICU, but did require BiPAP non-invasive ventilation at night instead of his usual CPAP to keep his oxygen levels > 90% while sleeping and additionally had desaturations into the low 80% range with exertion from which he was slow to recover. His oxygen saturation was >90% on 30-40% FiO2 via aerosol mask overnight and 3L (his current baseline) NC during the day. He was transferred out of the ICU on 2/21 based on hemodynamic improvement, stable oxygenation, and improved mentation and symptoms. Unfortunately, on the morning of 2/22/21, patient had an abrupt change in status and was found to be unresponsive with hypercarbic respiratory failure and hypotension. ABG during this event was 7.16/121/65. BiPAP was initiated as patient's code status was DNR/DNI. CXR with no significant change from 2/18/21. CT of head without contrast was negative for acute processes. Based on lack of rapid improvement, the decision was made by wife to transition to comfort care. Patient died at 1446 on 2/22/21. **Of note: patient was admitted for 1 week for covid 19 pneumonia November 2020. During this hospitalization he was found to have chronic R sided PE, no acute PE.
RESPIRATORY FAILURE	**COVID19 (COVID19 (MODERNA)) (1201)**	**MODERNA**	1064057-1	Fever (max 105F), generalized tonic clonic seizure lasting >60minutes resulting in rhabdomyolysis , leukocytosis (16k) s/p ceftriaxone x 1 with COVID-19, Flu A/B, RSV all PCR negative followed by transfer to hospital (2/25/2021) with ongoing high fever (Tmax 104F), Admission labs found rhabdomyolysis (CK >100,000 on day 2), elevated lactate (4.4), acute liver injury (AST/ALT >5000), elevated Cr (3.8) requiring CVVHD, DIC, shock, and respiratory failure requiring urgent intubation.

Symptoms	Vaccine	Vaccine Manufacturer	VAERS ID	Adverse Event Description
RESPIRATORY FAILURE	COVID19 (COVID19 (MODERNA)) (1201)	MODERNA	1071136-1	sepsis; respiratory failure; Fever; Unresponsive; A spontaneous report was received from Pfizer concerning a 56-year old, female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced respiratory failure, sepsis, fever and sudden death. The patient's medical history was not provided. No relevant concomitant medications were reported. On 04 Jan 2021, the patient received their first of two planned doses of mRNA-1273 (lot/batch: unknown) for prophylaxis of COVID-19 infection. On 11 Jan 2021, the patient began to have a fever. She was sent to the emergency room for evaluation. That evening, she died. No treatment information was provided. Action taken with mRNA-1273 in response to the events was not applicable. The patient died on 11 Jan 2021. The cause of death was reported as respiratory failure and sepsis. Plans for an autopsy were unknown/not provided.; Reporter's Comments: This is a case of 56-year old, female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced sepsis, fever, respiratory failure and sudden death. Very limited information regarding this event has been provided at this time. Further information has been requested.; Reported Cause(s) of Death: Respirtory Failure; Sepsis
RESPIRATORY FAILURE	COVID19 (COVID19 (MODERNA)) (1201)	MODERNA	1080153-1	Pulmonary insufficiency; A spontaneous report received from a Consumer concerning, an unknown age male patient who received a second dose of the Moderna COVID-19 vaccine and experienced pulmonary insufficiency. The patient's medical history was not included. Patient's concomitant was not included. On unknown date, the patient received their Second dose of the two planned doses of mRNA-1273 in unknown arm (Batch #: unknown) intramuscularly for prophylaxis of COVID-19 infection. Reporter stated her daughter's friend apparently developed a severe reaction a day or two after receiving the second dose of the vaccine resulting in pulmonary insufficiency. He had just traveled on vacation. He is now in an ICU at a U. Medical Center and may be moved into a respirator soon because of clinical deterioration. Reporter stated two days of steroids apparently have not helped. Other treatment information was not provided/unknown. Action taken with mRNA-1273 in response to the event was not provided/unknown. The outcome of the event was unknown/ not reported.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. Further information has been requested.
RESPIRATORY FAILURE	COVID19 (COVID19 (MODERNA)) (1201)	MODERNA	1080626-1	Pt with h/o myasthenia gravis presents to ED with 3 week h/o worsening weakness. Unclear exact timing on onset relative to vaccine administration but appears to have been a few days later. During these 3 weeks, patient also diagnosed and treated for a UTI but patient had worsening of weakness leading to falls x2 a few days before presenting to hospital ED. On admission to hospital, pt diagnosed with myasthenic crisis treated initially with non-invasive mechanical ventilation and plasmapheresis. DDx included UTI with encephalopathy and confusion related to it.
RESPIRATORY FAILURE	COVID19 (COVID19 (MODERNA)) (1201)	MODERNA	1080769-1	received vaccine on 1/6; developed shortness of breath/respiratory failure on 1/10. Hospitalized for several weeks with end diagnosis of Multiple Sclerosis (new diagnosis)
RESPIRATORY FAILURE	COVID19 (COVID19 (MODERNA)) (1201)	MODERNA	1081604-1	Possible PEA arrest unclear etiology ~1 hour after receiving first dose COVID-19 moderna vaccine, s/p ROSC in field after 3 minutes CPR, no meds given. Intubated in field, extubated after 2 days.
RESPIRATORY FAILURE	COVID19 (COVID19 (MODERNA)) (1201)	MODERNA	1082280-1	pt states that the next day she had low grade fever, fatigue, nausea and malaise. Pt had incontinence, diarrhea and fever never broke. Pt contacted her PCP and he suggested she may have Covid so she got tested. The results were negative. Pt ended up getting worse so contacted her PCP and she was told to the ER hospital to get labs drawn, test for Covid again which was negative. Fever was 102.3. Chest XRAY showed she Pneumonia. Pt was admitted to hospital where she was given antibiotics and fluids. She went into respiratory failure and her Pneumonia turned into bilateral infection. She was unable eat and diarrhea. After 5th day her fever broke and was released on the 6th day. She was on O2 for two weeks after going home. On 3/8/2021 Pt is better now but still tired.
RESPIRATORY FAILURE	COVID19 (COVID19 (MODERNA)) (1201)	MODERNA	1082345-1	This patient developed a severe pneumonia, clinically diagnosed as COVID-19 pneumonia, with hypercapnic and hypoxemic respiratory failure, and expired. I am not sure if it was related to the vaccine, but the rapid antigen for Sars-CoV2 was positive and the PCR was negative. I am reporting this event because of the lack of clarity on this issue and the positivity of the Sars-CoV2 was beyond the parameters of 14 days in the phase three trials.
RESPIRATORY FAILURE	COVID19 (COVID19 (MODERNA)) (1201)	MODERNA	1092235-1	"2/26/21 History & Physical- History of present illness: ""Pleasant 79 years old female who started to develop recurrent episodes of nausea and vomiting of nonbilious none bloody material 1 week ago then started to have frequent watery bowel movements with the last bowel movement was associated with rectal bleeding, she started to develop generalized weakness and fatigue, she had 3 falls in the last week without hitting her head, she did not have loss of consciousness, over the last 2 days she has been complaining of numbness and tingling to the hands and feet, she was not able to walk due to generalized weakness. She denied fever or chills she had no chest pain or shortness of breath. 2 weeks ago she got her second dose of COVID-19 vaccine. There was no change to her medications according to her, she denies sick contacts."" Intubated and ICU transfer 2/28/21 for ""Possible Guillain-BarrT syndrome and impending respiratory failure"" extubated 3/10/21."

Symptoms	Vaccine	Vaccine Manufacturer	VAERS ID	Adverse Event Description
RESPIRATORY FAILURE	COVID19 (COVID19 (MODERNA)) (1201)	MODERNA	1096602-1	Hospice nurse reported patient started experiencing fatigue, nausea, dizziness, decreased appetite and shortness of breath immediately following vaccination. Hospice medications were ordered and patient began receiving morphine and nebulizer treatments. She then started having dysphasia. She then died on 3/5/21 from presumed respiratory failure.
RESPIRATORY FAILURE	COVID19 (COVID19 (MODERNA)) (1201)	MODERNA	1098611-1	Lethargic, SOB, emesis, Altered mental status, respiratory failure Starting day after 2nd vaccine dose of Thursday afternoon
RESPIRATORY FAILURE	COVID19 (COVID19 (MODERNA)) (1201)	MODERNA	1100650-1	Patient died two days after receiving vaccine. Death certificate said respiratory failure.
RESPIRATORY FAILURE	COVID19 (COVID19 (MODERNA)) (1201)	MODERNA	1105300-1	He went to the hospital for cardiovascular problems and cholecystitis and was under treatment after the first dose. 2/26/2021 at around 11:00 pm she was complaining of high blood pressure, uncontrolled vital signs, uncontrolled sugar, at 6:00 am she has passed away. They certify respiratory failure.
RESPIRATORY FAILURE	COVID19 (COVID19 (MODERNA)) (1201)	MODERNA	1105349-1	Facility transfer resident to ER due to respiratory failure. Symptoms included decrease oxygen stats, difficulty breathing and chest pains. ER transferred to Hospital with diagnosis of myocardial infraction. Admitted to ICU on telemetry. Placed on 50% Bipap for Hypoxia. Placed on IV Amiodarone and Ceftriaxone. Resident was stabilized and discharged back to facility on 2/24/2021.
RESPIRATORY FAILURE	COVID19 (COVID19 (MODERNA)) (1201)	MODERNA	1108941-1	Presents to ED ~9 days after covid vaccine. Next day had fever, cough, muscle aches, diarrhea. Symptoms have persisted. Admitted for respiratory failure and possible pneumonia. D-dimer elevated, covid test negative, CTA chest negative for PE. D/C'd home after 1 week.
RESPIRATORY FAILURE	COVID19 (COVID19 (MODERNA)) (1201)	MODERNA	1116367-1	Respiratory failure; Shortness of breath; A spontaneous report was received from a health care professional (physician) concerning a 64 year old male patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced shortness of breath and respiratory failure. The patient's medical history was not provided. Concomitant medications included amiodarone, apixaban, atorvastatin calcium, vitamin D, dulaglutide, furosemide, hydralazine, insulin, nifedipine and glyceryl trinitrate. On 02-Mar-2021, the patient received his first dose of mRNA-1273 (Lot number: unknown) for prophylaxis of COVID-19 infection. On 09-Mar-2021, the patient started to experience shortness of breath and had respiratory failure. Patient was admitted to the ICU. The patient was treated with antibiotics, IV fluids, paralytics, sedation medications and cardiac medications. Action taken with mRNA-1273 in response to the events was not applicable. The outcome of the events was unknown.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the event (dyspnea), a causal relationship cannot be excluded. Very limited information regarding respiratory failure has been provided at this time.
RESPIRATORY FAILURE	COVID19 (COVID19 (MODERNA)) (1201)	MODERNA	1116652-1	Patient was hospitalized with COVID-19 infection following first vaccination. Patient had a positive COVID test on 3/1 (10 days after 1st COVID vaccination) and presented to ED on 3/2 with fever, chills, weakness, dyspnea. In ED, patient was noted to be afebrile, non-tachycardic, tachypneic, hypoxic at 88% on room air, and hypotensive. Diagnosed with acute hypoxic respiratory failure. Influenza A&B were negative. Patient did receive convalescent plasma on 3/3/21 and 3/8/21. Patient also received 5 days of Remdesivir therapy (started on 3/8/21). Pulmonary embolism was ruled out during hospital stay. Patient was discharged on 3/16/21 to rehab hospital.
RESPIRATORY FAILURE	COVID19 (COVID19 (MODERNA)) (1201)	MODERNA	1123188-1	Prior to the vaccine on 2/13/21, He was a healthy 65 year old active college professor. 32 hours after the vaccination on 2/14/21, He had acute pancreatitis, which led to septic shock and respiratory failure, and he was placed on a ventilator at Hospital. On 2/24/21, he was transferred to Hospital and continued to have additional diagnoses, including polyneuropathy critical illness, acute gangrenous cholecystitis, abdominal pain, anemia, impaired mobility, oropharyngeal dysphagia, pulmonary embolism, and assistance with ADL. On 3/19/21, he was transferred from Hospital to Acute Rehab Unit for acute physical, occupational, and speech therapy. He remains there today. We do not know if this sequence of events is related to the vaccine, but because it occurred one day after the vaccine, we thought it should be reported.
RESPIRATORY FAILURE	COVID19 (COVID19 (MODERNA)) (1201)	MODERNA	1127847-1	Participant felt flushed, feverish, fatigued with general aches and dry cough over the weekend after receiving injection, took acetaminophen and cough syrup on Monday. He became short of breath on 1/20/2021 and was hypoxic on oximeter check, was sent to the ER. He was intubated in ER and went into respiratory failure with sepsis due to COVID19. He was treated with tocilzumab, became paralyzed and DVT in left lower extremity was found. HE required pressors and diuresis, he developed AKI and hyperkalemia. On 2/21 he was in multi-organ failure. His level of cognition decreased until he was no longer responsive and he died on 2/24/2021.

Symptoms	Vaccine	Vaccine Manufacturer	VAERS ID	Adverse Event Description
RESPIRATORY FAILURE	COVID19 (COVID19 (MODERNA)) (1201)	MODERNA	1127860-1	"Not sure if covid vaccine caused this, but this is what happened - Received covid vaccine. two days later had violent shakes in the night. Immediately went to get a covid test out of precaution. Tested negative for covid, but positive for ""flu b"". Went home to treat flu with fluids and rest. Got no better. Went to heart doctor out of precaution, full work up...everything checked out great. Went home, got no better. Went to primary care physician, full work up...found a ""spot"" on left lung. Was given antibiotics and steroids, go home and in a few days will be getting better. 3 days later became incapacitated and had to be rushed to ER. Was admitted into hospital for 6 days to treat ""pneumonia"". Also possible UTI and sepsis. Also while in hospital found out that a mini stroke had happened. Treatment went well, oxygen levels were good. Was released with glowing reports. 24 hours later at home had to be rushed to ER again after becoming incapacitated.. Was admitted again 7 more days. During this time everything took a nose dive in succession. Lungs were failing, multiple unexplained strokes were happening (while on blood thinners, had been on blood thinner 15 years...after first stroke they changed to another blood thinner...only more strokes). After so many strokes and compounding of strokes, his neuro function started failing. He was put on life support. While on life support his organs started failing. He had to be put on comfort mode and was dead within 8 hours. A perfectly healthy 77 year old man who had never been sick a day in his life (literally) got his 2nd covid shot, two days later he fell ill. From that point on his health spiraled out of control until his death on March 19th. Every doctor (pulmonologist, cardiologist, neurologist, and all attending doctors said that it was ""atypical and abnormal"" what was happening. It should not have happened. 180 degrees from normal."
RESPIRATORY FAILURE	COVID19 (COVID19 (MODERNA)) (1201)	MODERNA	1129076-1	Dyspnea, chest pressure, fatigue. Sought care at the hospital/ED -- found to have acute pulmonary emboli (by CT) with hypoxic respiratory failure. Treated with hospitalization, Xarelto, nasal canula oxygen. She improved to be stable on room air with improvement of her symptoms and went home after 3 days.
RESPIRATORY FAILURE	COVID19 (COVID19 (MODERNA)) (1201)	MODERNA	1130306-1	It began on 2/3/2021 to present low saturation, pressures rose and fell (unstable). They gave him therapy, since he could not breathe. On 02/04/2021, POC reports that caregivers took their rounds and he was without vital signs. Doctor certifies that it was due to respiratory failure.
RESPIRATORY FAILURE	COVID19 (COVID19 (MODERNA)) (1201)	MODERNA	1133010-1	shortness of breath; weakness; diffuse chest tightness; confusion; dizziness; cardiac failure; pulmonary failure; A spontaneous report was received from a consumer concerning a 51-year-old, male patient who developed cardiac failure, pulmonary failure/respiratory failure and died. The patient's medical history included hypertension, obesity, bee allergy and bipolar disorder. Concomitant product use was not provided by the reporter. Patient received first dose of vaccine prior to two weeks to his death (died on 09 Mar 2021). A week prior to his vaccination as shortness of breath, weakness, diffuse chest tightness, confusion, and dizziness. These symptoms progressed following his vaccination and he was hospitalzed for two days prior to his death on 09 Mar 2021. Treatment information was not provided. Action taken with mRNA-1273 in response to the events was not applicable. The patient died on 09 Mar 2021 The cause of death was reported as cardio/pulmonary failure with secondary and tertiary causes of hypertension and obesity. Plans for an autopsy were not provided. The outcome of the events, cardiac failure and pulmonary failure were fatal.; Reporter's Comments: This is a case of death in a 51-year-old male subject with a medical history of HTN, obesity, bee allergy and bipolar disorder,who died 7 days after receiving first dose of vaccine. Very limited information has been provided at this time. Further information has been requested.; Reported Cause(s) of Death: cardiac failure; pulmonary failure
RESPIRATORY FAILURE	COVID19 (COVID19 (MODERNA)) (1201)	MODERNA	1139039-1	According to daughter pt was in his usual state of health (pt was critically ill, so daughter provided hx) until he received his 2nd dose of the moderna covid 19 vaccination at 11am on 3/24/2021. He had not had any side effects from the first dose. Around 15 hrs after getting the vaccine he started having fevers, myalgias, fatigue, and sob. He has poor po intake following the vaccine. He arrived to the ER on 3/26 in hypoxic respiratory failure, septic shock, acute renal failure, nstemi, hyperkalemic with severe b/l pneumonia on chest x ray. He expired with in hours of arrival to the ER despite full attempts at resuscitation.
RESPIRATORY FAILURE	COVID19 (COVID19 (MODERNA)) (1201)	MODERNA	1144803-1	Respiratory failure
RESPIRATORY FAILURE	COVID19 (COVID19 (MODERNA)) (1201)	MODERNA	1145531-1	Pt diagnosed with COVID-19 despite 2 COVID vaccines (first given 1/15/2021. Pt developed respiratory symptoms, including dyspnea, which progressed over 3.5 weeks and then systemic symptoms of myalgias, malaise. He was admitted 3/21/2021 and had positive NP swab for SARS-CoV-2 x 2. He required admission to ICU and died of respiratory failure on 3/28/2021.
RESPIRATORY FAILURE	COVID19 (COVID19 (MODERNA)) (1201)	MODERNA	1146320-1	Flu symptoms 14 hours after injection. Respiratory failure within 22 hours after injection leading to dealth

Symptoms	Vaccine	Vaccine Manufacturer	VAERS ID	Adverse Event Description
RESPIRATORY FAILURE	COVID19 (COVID19 (MODERNA)) (1201)	MODERNA	1146789-1	death Narrative: Pt received COVID vaccine dose #1 on 2/27 at facility. Pt admitted to Hospital d/t COPD exacerbation and severe hypoxia. Pt with longstanding hx respiratory complications including air hunger, use of continuous oxygen, panic attacks and pain requiring narcotics (also impacted respiratory drive). Pt evaluated by palliative care/hospice services at Hospital and was deemed appropriate for end-of-life care. Pt unable to discharge home for home hospice services, therefore remained at Hospital where he later passed away. Pt's wife called facility 3/29 to report the death of patient, exact date of death was 3/13. Anticipated cause of death includes respiratory failure d/t severe COPD, hypoxia and narcotic use. Was pt previously covid positive? No Are there any predisposing factors (i.e. PMH, HPI, allergy history etc) for patient experiencing adverse drug event? No Any occurrence of an ADR at time of administration or during time of observation? No Was there and ADR between observation period and date of death? No Was patient hospitalized prior to vaccination? No Was patient hospitalized between vaccination and date of death? Yes - d/t severe hypoxia and COPD exacerbation Was hospitalization attributable to ADE ? No Was patient hospitalized prior to death Yes What are the possible cause of death? severe COPD, hypoxia, reduced respiratory drive d/t narcotic use (chronic pain)
RESPIRATORY FAILURE	COVID19 (COVID19 (MODERNA)) (1201)	MODERNA	1147848-1	Approximately 3-4 days after her first immunization, patient became ill. She contacted our triage line 6 days after immunization with report of chills and weakness. She presented to Medical Center Emergency Room where she was admitted for hypoxia. She was subsequently diagnosed with COVID by PCR. She developed respiratory failure, worsening kidney failure necessitating dialysis, c diff colitis, GI bleed, and acute heart failure. Despite maximal efforts by the ICU/hospitalist team and specialists her conditioned worsened. She was made comfort care and died on 2.26.21
RESPIRATORY FAILURE	COVID19 (COVID19 (MODERNA)) (1201)	MODERNA	1148815-1	Patient was fully vaccinated (dose 1: 1/19 dose 2: 2/16). Patient developed fatigue on 3/1 then tested positive for COVID the following day (3/2). Was self-isolating at home and did not receive any COVID therapies. He reports progressively worsening fatigue, productive cough (white sputum), loss of taste, disorientation, and poor PO intake. Patient arrived to the ED for COVID-19 symptoms (3/13), tested positive and was admitted for severe hypoxic respiratory failure due to COVID-19. Patient with AKI (creatinine =2.48) Patient escalated to HFNC then down to 6L NC to 4L then slowly weaned to RA. Received dexamethasone 6 mg daily x 10 days. Patient was admitted from 3/13 to 3/18 for COVID-19. Creatinine on discharge was 1.29
RESPIRATORY FAILURE	COVID19 (COVID19 (MODERNA)) (1201)	MODERNA	1157587-1	Respiratory failure; Messed up with medication; A spontaneous report was received from a Consumer concerning himself, a 76-year-old, male patient, who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced respiratory failure and messed up with medication/ Medication error. The patient's medical history was not reported. Concomitant medication was not reported. On 24 Feb 2021, the patient received their first of two planned doses of mRNA-1273 mRNA-1273 (Lot number: 001A21A) intramuscularly for prophylaxis of COVID-19 infection. On 24 Feb 2021, after receiving mRNA-1273, the patient experienced respiratory failure and messed up with medication. He was hospitalized in ICU from 27 Feb 2021 till 08 Mar 2021 due to his medication messed up and had a respiratory failure. Action taken with mRNA-1273 in response to the events was not reported. The events respiratory failure and messed up with medication were reported considered resolved on 08 Mar 2021.; Reporter's Comments: There is insufficient details to assess the event of medication error as the specific drug and error was not ddescribed as well as the condition leading to error. In addition, limited information has been provide about the event of respiratory failure but for the fact that it was due to medication error. Hence assessed as unlikely due to mRNA-1273
RESPIRATORY FAILURE	COVID19 (COVID19 (MODERNA)) (1201)	MODERNA	1159214-1	3/11/21: patient presented and was admitted through ED for Shortness of Breath and choking on food. His saturation was as low as 70s and placed on nonrebreather. Patient was brought to ED and eventually required to be intubated because of hypoxic respiratory failure. During hospitalization patient has one episode of seizure. Patient had similar presentation in May 2019 and he had to be intubated for choking fluid. per the EUA, hospitalizations to be reported irrespective of attribution of vaccine.
RESPIRATORY FAILURE	COVID19 (COVID19 (MODERNA)) (1201)	MODERNA	1169835-1	Hypoxic respiratory failure requiring oxygen, Pneumonia, Atypical chest pain with troponin elevation, uncontrolled hypertension.
RESPIRATORY FAILURE	COVID19 (COVID19 (MODERNA)) (1201)	MODERNA	1176374-1	sore arm, lethargy, chronic fatigue, fever, fluid on lungs, lack of oxygen, death Husband received first dose of MODERNA vaccine on 1/30/21. Mild side effects. Received second dose on 2/24/21. For the first week after the second dose, the side effects seemed normal. By the second week he was gasping for air. Rused to ER via ambulance on 3/9/21. High heart rate, poor oxygen. Received numerous blood transfusions over 3-days (typical treatment for his blood disorder), yet body would not retain the transfused products. Died on 3/12/21 at 4:35 am from cardia arrest caused by respiratory failure.
RESPIRATORY FAILURE	COVID19 (COVID19 (MODERNA)) (1201)	MODERNA	1179974-1	pt was diagnosed with covid on 3-29-21 , hospitalized for pneumonia and respiratory failure and expired on 4-6-21 at Hospital

Symptoms	Vaccine	Vaccine Manufacturer	VAERS ID	Adverse Event Description
RESPIRATORY FAILURE	COVID19 (COVID19 (MODERNA)) (1201)	MODERNA	1183418-1	Vaccine breakthrough hospitalization - SOB with O2 sat 50% when EMS arrived. On non-rebreather satting 70%. Chills, fever, cough, and chest pain. BP 152/79, HR 93, RR 20, SpO2 91%. Had been scheduled to receive COVID mAb day of admission, but clinical course worsened. Admitted to Medical ICU for acute respiratory failure with hypoxia and ARDS secondary to COVID-19. Placed on BIPAP and Rx with Remdesivir, dexamethasone, & tociluzumab. Treated for presumed pulmonary embolism with full-dose anticoagulation. Pt expressed wishes to remain DNR/DNI, ultimately she elected to transition to comfort measures only given worsening hypoxia.
RESPIRATORY FAILURE	COVID19 (COVID19 (MODERNA)) (1201)	MODERNA	1199446-1	admitted to the hospital with recurrent hypoxemic and hypercarbic respiratory failure. discharged home. passed away at home after discharge.
RESPIRATORY FAILURE	COVID19 (COVID19 (MODERNA)) (1201)	MODERNA	1205687-1	Undergoing COVID-19 vaccinations and developed acute hypoxemic respiratory failure with bilateral palm infiltrates. Work up inconclusive for infectious etiology. Treated preemptively for pneumonia with antibiotics and glucocorticoids. Remains on oxygen but improving.
RESPIRATORY FAILURE	COVID19 (COVID19 (MODERNA)) (1201)	MODERNA	1209035-1	82YM Admit 3/18/21 to hospital for small bowel obstruction within 1 week of second vaccine dose. PTA bowel obstruction led to a syncopal episode following use of laxative, and several episodes of vomiting in the days prior . Upon admission Patient was receiving conservative therapy for a partial obstruction when he developed increasing shortness of breath. The patient was transferred to the ICU for worsening respiratory status and eventually developed significant hypercapnic and hypoxemic respiratory failure requiring intubation. Neurology was consulted for altered mentation in the setting of respiratory failure. Patient with ascending paralysis. MRI of the head and neck as well as CTA were obtained x2. Patient was ultimately diagnosed with Guillain-Barre, variant and received 5 days of Intravenous Immune Globulin therapy. Patient's small bowel obstruction resolved and ultimately patient required percutaneous tracheostomy tube and gastrostomy tube placement for prolonged respiratory failure and neurologic compromise. The patient had uneventful ventilatory requirements and ultimately was performing intermittent spontaneous breathing trials; however, still had episodes of apnea, but improved. He was tolerating tube feeds at goal with resolution of his small bowel obstruction, which was thought secondary to his Guillain-Barre. The patient did develop abnormal LFTs which were thought secondary to cholecystitis not requiring operative intervention, with improving LFT findings on antibiotics. The patient had a nonobstructive cholecystitis. The patient's mentation was improving to the point where he was able to communicate and open his eyes upon discharge, as well as was working with Physical Therapy for strengthening. He was able to move his upper extremities and followed commands and lower extremities were improving in strength as well. Patient was discharged via private air flight to acute care ICU facility.
RESPIRATORY FAILURE	COVID19 (COVID19 (MODERNA)) (1201)	MODERNA	1209874-1	a few days after receiving 2nd dose of maderna vaccine patient became shor.t of breath. was found to be in acute heart failure, was septic with a lactic acid of 5.6, and sustained a NSTEMI with a troponin of >6.0. stabilized on a bipap for respiratory failure and a nitro gtt for heart profusion. now on impella device r/t severe cardiac decompensation during heart cath procedure
RESPIRATORY FAILURE	COVID19 (COVID19 (MODERNA)) (1201)	MODERNA	1223376-1	"On day of second vaccination, she ""felt like she got hit by truck"" (typical reaction). Over next two days she developed worsening shortness of breath with hypoxia, O2 sats down to 82-84% on room air at home. On presentation to hospital, she is noted to have severe new bilateral diffuse ground glass opacities on CXR, leukocytosis of 15, no fever, no hypotension, negative lactate, negative BNP, no other organ failure. No wheezes or edema on exam, no edema by CXR/CT, no PE by CT. No cough, no phlegm. She continues to have severe hypoxemic respiratory failure, on bipap, not yet intubated. No vaping history, no THC history."
RESPIRATORY FAILURE	COVID19 (COVID19 (MODERNA)) (1201)	MODERNA	1238629-1	Pt was administered second Moderna vaccine at 12:55 pm. Pt stood up from seated position at 1:01 pm and fell to floor, unresponsive to touch, verbal commands, noxious stimuli, and sternal rub. O2 satting at 86%, normal HR, at time of fall. At 1:02 RRT was initiated at Health Center. At 1:03, 911 was called. At 1:07, pt had no pulse or respirations for 30 seconds, during which 20x compressions were administered and AED shock was not advised. ROSC at 1:08, unable to obtain VS. Paramedics responded within 10 minutes and took pt to Emergency Room
RESPIRATORY FAILURE	COVID19 (COVID19 (MODERNA)) (1201)	MODERNA	1241393-1	Death Narrative: The patient did not have any predisposing factors(PMH, allergies, etc.) for experiencing an adverse drug event. Patient transported to ER on 1/14/21 after receiving first COVID-19 vaccine earlier that day. He was reported to have a reaction to the vaccine including diaphoresis, new onset afib, and hypotension(vasovagal reaction). He was discharged the next day with no signs of afib. Patient was later hospitalized around 1/28/21 for COVID pneumonia. He later passed away on 2/5/21 due to hypoxic respiratory failure secondary to COVID-19. Comorbidities include advanced age, obesity, HLD, atherosclerosis, DM2, HTN.
RESPIRATORY FAILURE	COVID19 (COVID19 (MODERNA)) (1201)	MODERNA	1241403-1	Death Narrative: Patient tested positive for COVID-19 on 1/25/21 after receiving her first vaccine on 1/8/21. He was discharged from hospital on 1/26/21 with admitting diagnosis of COVID pneumonia. He did not have any predisposing factors(PMH, allergies, etc.) for experiencing an adverse drug event. The ADR did not occur at the time of administration of the vaccine nor was there an ADR that occurred between the observation period and the date of death. Patient had made it through the COVID infection period but suffered complications including pneumonitis, lung, heart, and kidney failure requiring high flow oxygen. He required readmission to hospital for the complications in 3/2021 but ultimately passed away on 3/24/21 likely due to

Symptoms	Vaccine	Vaccine Manufacturer	VAERS ID	Adverse Event Description
				the multi organ failure complication of COVID
RESPIRATORY FAILURE	COVID19 (COVID19 (MODERNA)) (1201)	MODERNA	1249877-1	Patient received the moderna vaccine (1st dose). Shortly after was hospitalized for a potential MS flare and was treated with pulse dose steroids, discharged home. He then started to feel progressively fatigued and was readmitted to the hospital on 4/19/21 with a diffuse pneumonitis complicated by hypoxemic respiratory failure. He is currently being treated with IV steroids.
RESPIRATORY FAILURE	COVID19 (COVID19 (MODERNA)) (1201)	MODERNA	1252034-1	66-year-old lady with severe COPD on home 2L O2 (initiated 3/21), newly diagnosed SCC of lung (not currently on treatment), HFpEF, schizoaffective disorder, and recent COVID-19 infection (dx 4/6) who presented with shortness of breath on 4/16 in the setting of receiving first dose of Covid vaccine 1 week prior. Found to have sepsis physiology w/ hypoxic respiratory failure from COVID-19 pneumonia. CXR with multifocal pneumonia in the setting of chronic interstitial changes and required up to 6 L nasal cannula. Started on IV remdesivir (x 5 days ending 4/20) and Decadron x6 days, ending 4/21. Clinically improved and weaned to her baseline 2 L O2 and discharged on 4/21 to rehab
RESPIRATORY FAILURE	COVID19 (COVID19 (MODERNA)) (1201)	MODERNA	1258269-1	This pt came in to see me in her normal state of health and then received moderna #1 here on 4/1. Developed SOB 2 hrs after vaccination. Presented to ER on 4/2 with hypoxia (80%) and was + for covid. The ER triage notes states ?C/O SOB, Nausea, vomiting, diarrhea that started yesterday 2 hours after he first COVID Vaccine?. Notes quote her saying ?I got my vaccine yesterday and I started to feel short of breath.? She died from covid respiratory failure on 4/23.
RESPIRATORY FAILURE	COVID19 (COVID19 (MODERNA)) (1201)	MODERNA	1262148-1	"On day 4 following dose 2 of Moderna series, pt developed fever, chills, fatigue, malaise and self-medicated with ibuprofen and acetaminophen. After a ""few"" days of feeling unwell despite treatment, presented to ER and was found to have AKI, hyponatremia, and thrombocytopenia. Over the course of several days rapidly deteriorated and developed MSOF, including liver failure, DIC, respiratory failure requiring intubation, and shock requiring pressors. Workup for VTE, including V/Q scan, LE dopplers, and head CT negative for thrombosis. Ferritin was found to be highly elevated (12,000) suggestive of hemophagocytic lymphohistiocytosis (HLH). Per ER report, marrow positive for hemophagocytosis on smear. At time of report, transferred to Cancer Center for HLH treatment, currently in ICU, intubated, sedated, and on pressors. PF4 antibody pending."
RESPIRATORY FAILURE	COVID19 (COVID19 (MODERNA)) (1201)	MODERNA	1271290-1	After second dose 3/10/21 started having chills, myalgia. On 3/24/21 hospitalized with respiratory failure, kidney failure, heart attack, sepsis and liver malfunction. Had subsequent GI bleed
RESPIRATORY FAILURE	COVID19 (COVID19 (MODERNA)) (1201)	MODERNA	1271737-1	Patient presented to the ED and was subsequently hospitalized with sepsis, respiratory failure and pneumonia on 3/2/2021. Patient presented to the ED and was subsequently hospitalized with pneumonia on 3/22/2021. Patient presented to the ED and was subsequently hospitalized with sepsis on 3/31/2021. He died on 4/4/2021.
RESPIRATORY FAILURE	COVID19 (COVID19 (MODERNA)) (1201)	MODERNA	1271827-1	lungs shut down from 95 to 0 in a blink of an eye
RESPIRATORY FAILURE	COVID19 (COVID19 (MODERNA)) (1201)	MODERNA	1271846-1	Patient presented to ED on 04/25/2021 with complaints of abdominal pain, abdominal distension, and AMS. Patient was admitted to ICU with following diagnoses: 1) Septic Shock, 2) A/C hypoxic/hypercapnic respiratory failure, 3) Acute metabolic encephalopathy, 4) Palliative care patient, 5) AE COPD, 6) ARF w/ATN on CKD3, 7) CAD, 8) Chronic sys/dia CHF, 9) Malnutrition/Failure to thrive. Patient died on 04/26/2021 at 1826. Patient was also previously admitted to hospital on 03/23/2021-03/29/2021 for sepsis.
RESPIRATORY FAILURE	COVID19 (COVID19 (MODERNA)) (1201)	MODERNA	1273804-1	GI Hemorrhage Covid + Respiratory Failure

Symptoms	Vaccine	Vaccine Manufacturer	VAERS ID	Adverse Event Description
				NSTEMI; Septic shock; Hypoxic respiratory; Hyperkalemic; Bilateral pneumonia; Acute renal failure; Shortness of breath; Fever; Myalgia; Fatigue; Poor PO intake following the vaccine; This spontaneous case was reported by a health care professional (subsequently medically confirmed) and describes the occurrence of ACUTE MYOCARDIAL INFARCTION (NSTEMI), SEPTIC SHOCK (Septic shock), RESPIRATORY FAILURE (Hypoxic respiratory), HYPERKALAEMIA (Hyperkalemic), PNEUMONIA (Bilateral pneumonia) and ACUTE KIDNEY INJURY (Acute renal failure) in a 69-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. the concomitant product the patient had taken are Norvasc , vitamin D, Metoprolol , Dexamethasone , Levothyroxine, Lexapro ,Lisinopril. the patient had certain medical history : Renal Cell Carcinoma on Chemotherapy , Hypertension , Hypothyroidism and Type 2 Diabetes Mellitus. Concurrent medical conditions included Renal cell carcinoma (on chemotherapy), Hypertension, Hypothyroidism, Type 2 diabetes mellitus, Critical illness and Penicillin allergy. Concomitant products included AMLODIPINE BESILATE (NORVASC), METOPROLOL, DEXAMETHASONE, LEVOTHYROXINE, ESCITALOPRAM OXALATE (LEXAPRO), LISINOPRIL and VITAMIN D NOS for an unknown indication. On 24-Mar-2021 at 11:00 AM, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 24-Mar-2021, the patient experienced FEEDING DISORDER (Poor PO intake following the vaccine). On 25-Mar-2021 at 11:00 PM, after starting mRNA-1273 (Moderna COVID-19 Vaccine), the patient experienced DYSPNOEA (Shortness of breath), PYREXIA (Fever), MYALGIA (Myalgia) and FATIGUE (Fatigue). On 26-Mar-2021, the patient experienced ACUTE MYOCARDIAL INFARCTION (NSTEMI) (seriousness criteria medically significant and life threatening), SEPTIC SHOCK (Septic shock) (seriousness criteria medically significant and life threatening), RESPIRATORY FAILURE (Hypoxic respiratory) (seriousness criteria medically significant and life threatening), HYPERKALAEMIA (Hyperkalemic) (seriousness criterion medically significant), PNEUMONIA (Bilateral pneumonia) (seriousness criterion medically significant) and ACUTE KIDNEY INJURY (Acute renal failure) (seriousness criterion medically significant). On 26-Mar-2021, ACUTE MYOCARDIAL INFARCTION (NSTEMI), SEPTIC SHOCK (Septic shock), RESPIRATORY FAILURE (Hypoxic respiratory), HYPERKALAEMIA (Hyperkalemic), PNEUMONIA (Bilateral pneumonia) and ACUTE KIDNEY INJURY (Acute renal failure) outcome was unknown. At the time of the report, DYSPNOEA (Shortness of breath), FEEDING DISORDER (Poor PO intake following the vaccine), PYREXIA (Fever), MYALGIA (Myalgia) and FATIGUE (Fatigue) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 26-Mar-2021, Chest X-ray: abnormal (abnormal) Severe bilateral pneumonia. On 26-Mar-2021, Electrocardiogram: abnormal (abnormal) ST depression on V2-V4. On 26-Mar-2021, Troponin: 8.496 (High) High. On 26-Mar-2021, pH body fluid: 7.12 (abnormal) Abnormal. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. The patient expired with in hours of arrival to the ER despite full attempts at resuscitation. Treatment for the events included resuscitation. Based on the current available information and temporal association between the use of the product and the events, a causal relationship cannot be excluded, although it is likely the patient's underlying critical state caused or contributed to the events. The cause of death is not specifically reported and event of death retained separately, although likely caused by MI, septic shock, respiratory failure, or a combination of these events; Sender's Comments: Based on the current available information and temporal association between the use of the product and the events, a causal relationship cannot be excluded, although it is likely the patient's underlying critical state caused or contributed to the events. The cause of death is not specifically reported and event of death retained separately, although likely caused by MI, septic shock, respiratory failure, or a combination of these events
RESPIRATORY FAILURE	**COVID19 (COVID19 (MODERNA)) (1201)**	**MODERNA**	1276708-1	

Symptoms	Vaccine	Vaccine Manufacturer	VAERS ID	Adverse Event Description
RESPIRATORY FAILURE	**COVID19 (COVID19 (MODERNA)) (1201)**	**MODERNA**	1276742-1	Shortness of breath; COVID-19 pneumonia; COVID-19 infection; Hypoxic respiratory failure; sepsis; This spontaneous case was reported by a health care professional (subsequently medically confirmed) and describes the occurrence of RESPIRATORY FAILURE (Hypoxic respiratory failure), SEPSIS (sepsis), COVID-19 PNEUMONIA (COVID-19 pneumonia), COVID-19 (COVID-19 infection) and DYSPNOEA (Shortness of breath) in a 66-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The patient's past medical history included Heart failure with preserved ejection fraction. Concurrent medical conditions included COPD exacerbation (On 2 liters of oxygen at baseline), Squamous cell carcinoma of lung, Schizoaffective disorder and oxygen. On 30-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 06-Apr-2021, the patient experienced COVID-19 PNEUMONIA (COVID-19 pneumonia) (seriousness criteria hospitalization and medically significant) and COVID-19 (COVID-19 infection) (seriousness criterion hospitalization). On 16-Apr-2021, the patient experienced DYSPNOEA (Shortness of breath) (seriousness criterion hospitalization). On an unknown date, the patient experienced RESPIRATORY FAILURE (Hypoxic respiratory failure) (seriousness criteria hospitalization and medically significant) and SEPSIS (sepsis) (seriousness criteria hospitalization and medically significant). The patient was hospitalized until 21-Apr-2021 due to COVID-19, COVID-19 PNEUMONIA, DYSPNOEA, RESPIRATORY FAILURE and SEPSIS. At the time of the report, RESPIRATORY FAILURE (Hypoxic respiratory failure), SEPSIS (sepsis), COVID-19 PNEUMONIA (COVID-19 pneumonia) and COVID-19 (COVID-19 infection) had resolved and DYSPNOEA (Shortness of breath) was resolving. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In April 2021, Chest X-ray: abnormal (abnormal) multifocal pneumonia in the setting of chronic Interstitial changes.. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Treatment information provided included 6L O2 Nasal cannula, Remdesivir for 5 days (stop date : 20 - Apr - 2021) ,Decadron for 6 days (stop date : 21 - Apr - 2021) . The patient was discharged on 21 Apr 2021 to rehabilitation on baseline 2L O2 Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. Reporter did not allow further contact; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.
RESPIRATORY FAILURE	**COVID19 (COVID19 (MODERNA)) (1201)**	**MODERNA**	1285668-1	Covid-19 J96.90 - Respiratory failure (CMS/HCC) N39.0 - Urinary tract infection A41.9 - Sepsis (CMS/HCC) U07.1, J12.82 - Pneumonia due to COVID-19 virus
RESPIRATORY FAILURE	**COVID19 (COVID19 (MODERNA)) (1201)**	**MODERNA**	1286108-1	Hospitalization 4/8/2021-4/16/2021 with discharge home on hospice and death 4/28/2021. Admitting diagnosis: Acute respiratory distress, COPD, acute hypercapnic hypoxic respiratory failure, Hypomagnesemia; HTN; probable UTI with concerns for Severe Sepsis; Altered mental status with concerns for metabolic encephalopathy along with dementia.
RESPIRATORY FAILURE	**COVID19 (COVID19 (MODERNA)) (1201)**	**MODERNA**	1286213-1	Presented to ED on 4/23/21 with weakness, malaise, poor appetite and nausea; elevated temperature, tachycardia, lactic acidosis, chest XRAY patchy infiltrates. COVID test positive. Respiratory failure and COVID19 pneumonia. Patient referred to hospice.
RESPIRATORY FAILURE	**COVID19 (COVID19 (MODERNA)) (1201)**	**MODERNA**	1286842-1	Acute hypoxemic respiratory failure; Hypokalemia; Lactic acidosis; Muscle weakness (generalized); Weakness
RESPIRATORY FAILURE	**COVID19 (COVID19 (MODERNA)) (1201)**	**MODERNA**	1290096-1	4/20/21: patient arrived to ER per EMS status post PEA arrest. Per ER records, patient became unresponsive while sitting in bed witnessed by husband at home. According to husband, they had come home, she sat on the bed and complained she was not feeling good. She then fell back on the bed and began to seize. Subsequently she had intermittent episodes of alertness and was able to speak to the husband followed by unresponsiveness. At time of EMS arrival pt. was unresponsive. EMS noted BS 120s, SBP 50s. En route to hospital, pt. had a CP arrest for which epinephrine was given, CPR initiated with ROSC. Pt. arrived to the ER on a NRB mask attempting to speak. Subsequently, pt. had several CP arrests with asystole, and
RESPIRATORY FAILURE	**COVID19 (COVID19 (MODERNA)) (1201)**	**MODERNA**	1296061-1	Patient presented to the ED and was subsequently hospitalized on 4/6/21 for respiratory failure with hypoxia and hypercapnia. She spent some time in the ICU.
RESPIRATORY FAILURE	**COVID19 (COVID19 (MODERNA)) (1201)**	**MODERNA**	1306873-1	Patient presented to the ED and was subsequently hospitalized within 6 weeks of receiving COVID vaccination. Diagnosis was respiratory failure with hypoxia due to COVID-19 infection.
RESPIRATORY FAILURE	**COVID19 (COVID19 (MODERNA)) (1201)**	**MODERNA**	1307018-1	On 5/8/2021 patient started experiencing dyspnea with it worsening and leading to hospitalization on 5/11/2021 for respiratory failure/COPD exacerbation. Patient is currently inpatient on med surg unit currently on Vapotherm at 40% FiO2.

Symptoms	Vaccine	Vaccine Manufacturer	VAERS ID	Adverse Event Description
RESPIRATORY FAILURE	COVID19 (COVID19 (MODERNA)) (1201)	MODERNA	1307685-1	Patient received first dose of Moderna vaccine after which he immediately experienced weakness, myalgias, fatigue. Progressive weakness in limbs continued and by day 13 following his vaccine patient presented to hospital with difficulty speaking and inability to walk. Admitted to acute care hospital for progressive extremity weakness, bulbar weakness, and respiratory failure. EMG testing demonstrated findings of demyelinating neuropathy. Patient transferred 3/31/21 for intensive inpatient rehabilitation and remains currently hospitalized.
RESPIRATORY FAILURE	COVID19 (COVID19 (MODERNA)) (1201)	MODERNA	1312875-1	Acute hypoxic respiratory failure; adynamic ileus; Pneumonia; Progressive Extremity Weakness; demyelinating neuropathy; Bulbar weakness; Respiratory failure; Weakness; trouble walking; This spontaneous case was reported by a physician assistant (subsequently medically confirmed) and describes the occurrence of RESPIRATORY FAILURE (Respiratory failure), ACUTE RESPIRATORY FAILURE (Acute hypoxic respiratory failure), ILEUS PARALYTIC (adynamic ileus), PNEUMONIA (Pneumonia), DEMYELINATING POLYNEUROPATHY (demyelinating neuropathy), BULBAR PALSY (Bulbar weakness) and MUSCULAR WEAKNESS (Progressive Extremity Weakness) in a 51-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Concurrent medical conditions included Diabetes mellitus, Hypertension, Glaucoma and Hyperlipidemia. On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 06-Mar-2021, the patient experienced RESPIRATORY FAILURE (Respiratory failure) (seriousness criteria hospitalization prolonged and medically significant) and BULBAR PALSY (Bulbar weakness) (seriousness criteria hospitalization prolonged and medically significant). On 15-Mar-2021, the patient experienced DEMYELINATING POLYNEUROPATHY (demyelinating neuropathy) (seriousness criteria hospitalization prolonged and medically significant). On an unknown date, the patient experienced ACUTE RESPIRATORY FAILURE (Acute hypoxic respiratory failure) (seriousness criteria hospitalization prolonged and medically significant), ILEUS PARALYTIC (adynamic ileus) (seriousness criteria hospitalization prolonged and medically significant), PNEUMONIA (Pneumonia) (seriousness criteria hospitalization prolonged and medically significant), MUSCULAR WEAKNESS (Progressive Extremity Weakness) (seriousness criterion hospitalization prolonged), ASTHENIA (Weakness) and GAIT DISTURBANCE (trouble walking). The patient was hospitalized from 06-Mar-2021 to 31-Mar-2021 due to ACUTE RESPIRATORY FAILURE, BULBAR PALSY, DEMYELINATING POLYNEUROPATHY, ILEUS PARALYTIC, MUSCULAR WEAKNESS, PNEUMONIA and RESPIRATORY FAILURE. At the time of the report, RESPIRATORY FAILURE (Respiratory failure), ACUTE RESPIRATORY FAILURE (Acute hypoxic respiratory failure), PNEUMONIA (Pneumonia), DEMYELINATING POLYNEUROPATHY (demyelinating neuropathy), BULBAR PALSY (Bulbar weakness), MUSCULAR WEAKNESS (Progressive Extremity Weakness), ASTHENIA (Weakness) and GAIT DISTURBANCE (trouble walking) outcome was unknown and ILEUS PARALYTIC (a dynamic ileus) was resolving. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 15-Mar-2021, Electromyogram: abnormal (abnormal) consistent with demyelinating neuropathy.. On 30-Mar-2021, SARS-CoV-2 test: negative (Negative) Negative. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medications reported by investigator. Patient was presented to hospital on 3/6/21 with progressive extremity weakness, bulbar weakness, and respiratory failure attributed to AIDP s/p 5days IVIG. He had received his first Moderna COVID vaccination approximately two weeks prior to this and immediately following administration began experiencing weakness and trouble walking. EMG 3/15/21 consistent with demyelinating neuropathy. Hospitalization was complicated by the development of adynamic ileus which is improving and acute hypoxic respiratory failure (previously requiring O2 support). Patient was also treated for pneumonia with a 5 day course of azithromycin. Once medically stable he was deemed appropriate for inpatient rehabilitation and was transferred from Hospital to rehab on 3/31/21 under care. The patient tested negative COVID-19 on 3/30, and repeat testing since also has been negative. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.
RESPIRATORY FAILURE	COVID19 (COVID19 (MODERNA)) (1201)	MODERNA	1314199-1	Shortly after 1st dose pt developed SOB and cough, was treated for pneumonia w/ marginal improvement. After 2nd dose, symptoms worsened and on March 26, pt was hospitalized w/ hypoxic respiratory failure 2/2 organizing pneumonia. Is now improving with high dose steroids. Pt had no prior respiratory problems. May have had COVID in March 2020.
RESPIRATORY FAILURE	COVID19 (COVID19 (MODERNA)) (1201)	MODERNA	1317701-1	Hospitalization kidney failure heart failure respiratory failure had to be ventilated. Six days in Medical Center and 10 days in Medical Center
RESPIRATORY FAILURE	COVID19 (COVID19 (MODERNA)) (1201)	MODERNA	1320905-1	Pt w/hx of COVID positive (5/3) in the setting of an exposure and onset of symptoms including arthralgias, body aches, non-productive cough, loss of taste/smell sensations, shortness of breath upon exertion despite receiving Moderna vaccines (2/12 & 3/12/21). Pt presented to ED w/worsening SOB upon rest and was admitted for management of acute hypoxemic respiratory failure due to COVID-19. Was treated w/dexamethasone, remdesivir. She was ultimately discharged on 5/12 after significant improvement with follow-up.

Symptoms	Vaccine	Vaccine Manufacturer	VAERS ID	Adverse Event Description
RESPIRATORY FAILURE	COVID19 (COVID19 (MODERNA)) (1201)	MODERNA	1320958-1	Pt p/w a 5 day hx of diarrhea, nausea chills, dry consistent cough w/some intermittent cramping of bilat lower abdomen. COVID test positive (4/28) despite receiving Moderna vaccines (2/4 & 3/3/21). Given drops in her O2 saturation, admitted for medical management of acute hypoxic respiratory failure secondary to COVID-19. Received dexamethasone, tocilizumab during admission and ceftriaxone for catheter-related UTI. Pt recovered and ultimately was discharged on 5/11 with followup.
RESPIRATORY FAILURE	COVID19 (COVID19 (MODERNA)) (1201)	MODERNA	1330857-1	5/12 Admitted to medical center with new dysphagia and slurred speech. 5/17 Acute Hypercarbic respiratory failure; Neuromuscular dysfunction - 5/19 -CONCERN FOR GBS. Patient on BiPAP (no history of pulmonary disease)
RESPIRATORY FAILURE	COVID19 (COVID19 (MODERNA)) (1201)	MODERNA	1332652-1	Patient reported fatigue and progressive weakness since given vaccination. Now admitted to ICU in hypercarbic and hypoxemic respiratory failure on invasive vent support.
RESPIRATORY FAILURE	COVID19 (COVID19 (MODERNA)) (1201)	MODERNA	1339087-1	onset of respiratory failure on 05/14/2021 to be eventually diagnosed with pulmonary embolism. hospitalized at facility .
RESPIRATORY FAILURE	COVID19 (COVID19 (MODERNA)) (1201)	MODERNA	1350405-1	Patient manifested with flu-like symptoms (myalgias, fatigue, cough, abdominal discomfort, shortness of breath) with high-grade fevers (TMax 103F) approximately 4-6 hours following administration of 2nd Moderna vaccine on 5/4/2021 per patient's wife. The symptoms progressively worsened to the point that he presented to an outside hospital on 5/12/2021 at which time he was found to be tachycardic and febrile (T 103.1F). Labs at that time were notable for significant thrombocytopenia, elevated creatinine, elevated lactate, elevated procalcitonin. Chest imaging showed bilateral airspace disease. CT of the abdomen noted hepatosplenomegaly with no evidence of lymphadenopathy. Echocardiogram showed normal cardiac function. He was empirically started on broad-spectrum antibiotics. Labs on 5/13/2021 were notable for a markedly elevated ferritin level, fasting hypertriglyceridemia, elevated CRP, elevated transaminase levels, hyperbilirubinemia, markedly elevated CXCL-9 level, markedly elevated IL-18 level, normal natural killer cell function. Of note, while his blood and urine cultures were negative, he was found to have elevated EBV viral load on peripheral blood draw. He had a bone marrow biopsy which reportedly showed rare evidence of cells with what appeared to be erythrocytes within their cytoplasm, concerning for HLH. Given strong clinical and serological suspicion for HLH, he was transferred to our hospital for a higher level of care. Upon transfer to our facility on 5/18/2021, his inflammatory markers were persistently elevated. He unfortunately developed worsened renal and respiratory failure, and required both hemodialysis and intubation respectively. He was continued on empiric broad-spectrum antibiotics, however we additionally initiated high-dose steroids as well as anakinra for treatment of HLH. Given EBV viremia, we also began rituximab therapy. He was successfully extubated, however as of 5/26/2021 remains dialysis-dependent with continued improvement in urinary output. His post-intubation course has been complicated by encephalopathy of unknown etiology. We have consulted infectious disease to proceed with a diagnostic lumbar puncture to ascertain potential CNS pathogens explaining the cause of his altered mental status. MRI of the brain showed no evidence of pathology. CNS involvement by HLH remains on our differential.
RESPIRATORY FAILURE	COVID19 (COVID19 (MODERNA)) (1201)	MODERNA	1354875-1	Acute limb ischemia- with left internal iliac, common femoral, popliteal artery occlusive thrombosis- underwent emergent Fem-Fem bypass with fasciotomy. Patient subsequently developed respiratory failure with shock and encephalopathy- remains undertreatment.
RESPIRATORY FAILURE	COVID19 (COVID19 (MODERNA)) (1201)	MODERNA	1364956-1	Patient admitted to referring hospital on 5/18/2021 for fatigue and SOB, found to have pulmonary embolism (CT with central pulmonary emboli with right heart strain), alteplase was given at referring hospital and was admitted to ICU for continued monitoring. Venous duplex done also revealed bilateral DVTs. Patient was doing well after fibrinolytic with heparin anticoagulation, but had sudden decompensation on 5/21 (hypotension and respiratory failure requiring intubation). Transferred to current institution for ECMO evaluation due to severe cardiopulmonary compromise. Patient deemed not ECMO candidate based on co-morbid conditions based on CT findings. He underwent mechanical thrombectomy with improvement. He was continued on heparin infusion, then had sudden decrease in platelet on 5/25 with worsening cardiopulmonary status. HITT was suspected and heparin was transitioned to argatroban. Results of heparin induced platelet antibodies (PF4 ELISA assay) and Serotonin Release assay was negative. Repeat imaging revealed increase clot burden and therefore patient underwent catheter directed thrombolysis followed by aspiration suction thrombectomy. Due to high clinical suspicion of HITT, repeat heparin induced platelet and SRA sent and pending at the time of report. Of note, patient still in hospital at the time of this report

Symptoms	Vaccine	Vaccine Manufacturer	VAERS ID	Adverse Event Description
RESPIRATORY FAILURE	COVID19 (COVID19 (MODERNA)) (1201)	MODERNA	1368501-1	Pfizer Vaccine Dose 1 2/5/2021 (lot not listed in system) Pfizer Vaccine Dose 2 3/6/2021 (lot not listed in system) COVID Positive 3/27/2021 Hospitalized 3/27-4/2/21 for COVID 5/19/21: Presented to ED. This is a 77-year-old male with history of hypertension, hyperlipidemia, dementia, paroxysmal atrial fibrillation, COVID-19 infection, chronic obstructive pulmonary disease and recent Pseudomonas pneumonia who presented to the emergency department with complaint of worsening shortness of breath. Patient reports that his symptoms started few days ago. He has been having cough and shortness of breath. Patient uses 2 L of oxygen at home. Patient reports that he was fully vaccinated for COVID-19 but then had COVID-19 infection after that. He has no chest pain, abdominal pain, nausea, vomiting or dizziness currently. In the emergency department, patient was found to be hypoxic. Patient was started on BiPAP with FiO2 of 45%. Labs showed potassium level of 5.4, negative troponin level and a normal WBC count. Chest x-ray showed patchy bilateral infiltrates along with marked background emphysema. He received nebulizer treatments and a dose of IV Solu-Medrol, azithromycin and Rocephin. 5/24/21: 77-year-old male with COPD on 2 L home oxygen, atrial fibrillation anticoagulated on Eliquis presented with worsening shortness of breath and increased oxygen requirement. Patient was admitted for acute on chronic hypoxic respiratory failure secondary to COPD exacerbation and pneumonia. Patient was treated with steroids, initially with ceftriaxone/azithromycin and later switched to levofloxacin based on sputum culture growing Pseudomonas aeruginosa. Subsequently his oxygen requirement and dyspnea improved, patient was cleared for discharge by Pulmonary team with a total 10 day course of levofloxacin and he was also given a script for steroid taper. Patient was having intermittent confusion and agitation during hospitalization, started on low-dose Seroquel 25 mg p.o. b.i.d. with good effect and discharged on same dose. Patient was discharged home with VNA and also have 24 hour care at home.
RESPIRATORY FAILURE	COVID19 (COVID19 (MODERNA)) (1201)	MODERNA	1371859-1	"COVID -19 Vaccine, Primary care MD. Wife, 5/23/2021 patient admitted through ED for chief complaint of 5 days shortness of air, tested positive for COVID-19; patient vaccinated 3/30/2021 at 'local church'. 5/24/2021 admitted to ICU - Attending, 5/26/2021 rapid response due to vitals, 5/27/2021 patient intubated due to respiratory failure/distress/hypoxia; identified in septic shock. 5/31/2021 went to surgery for left forearm and hand compartment syndrome. 6/3/2021 Code blue called, 6/3/2021 date of death. Allergies: Losartan (other) and Verapamil (intolerance) Date of Vaccination: 3/30/2021, Dose: 2, Vaccine Manufacturer: Moderna Lot #: Clinic Administering Vaccine: ""local church"" - no specific name was provided, Injection site: Description of event/reaction: Patient does not have vaccination card and reports not knowing date of first vaccine or exact clinic location. Date of Hospitalization: 5/24/2021 Reason for clinic visit or hospitalization: Shortness of air COVID-19 positive test result: Yes or No; if Yes, date 05/23/2021"
RESPIRATORY FAILURE	COVID19 (COVID19 (MODERNA)) (1201)	MODERNA	1374548-1	86-year-old woman with a history of COPD who presented with complaints of shortness of breath. She was admitted with an impression of acute on chronic hypoxic respiratory failure secondary to COVID-19 pneumonia. She was initially started on antibiotics which were stopped due to low procalcitonin level and no evidence of bacterial pneumonia. She qualified for remdesivir and finished it. She was also getting Decadron with vitamin C and zinc and bronchodilator. Patient continued to do well and has tolerated Remdesivir well and has finished it. She is back to her baseline oxygen requirements.
RESPIRATORY FAILURE	COVID19 (COVID19 (MODERNA)) (1201)	MODERNA	1388182-1	Two weeks after receiving the final injection, my father was admitted to the hospital with pneumonia. He had poor oxygen saturation which prompted a visit to the ER. Upon x-ray he was found to have a large pneumonia in his left lung. After 10 days at the local hospital, and being placed on a ventilator, he became septic and was air lifted to one of our area's larger hospitals. There, he was diagnosed with necrotizing pneumonia caused by pseudomonas aeruginosa. He also had heart rate accelerations that would climb into the 150s and they could never figure out why. He was treated aggressively with antibiotics and was successfully weaned off the vent. However, his body was unable to fight off the infection and he ended up passing away from necrotizing pneumonia that caused his respiratory system to fail. My father had underlying COPD that was well-managed at home and he did not require oxygen. I was questioned several times as to whether he'd gotten into or been around anyone or anything different from his usual, but he had not. The only thing out of the ordinary he had was the Moderna injections.
RESPIRATORY FAILURE	COVID19 (COVID19 (MODERNA)) (1201)	MODERNA	1392027-1	5/15 sustained syncope, fall hypoxic respiratory failure COPD pneumonia vomiting/diarrhea admitted to the hospital acute kidney injury 5/15--ED--cervical fracture, acute MI, elevated troponin multiple cardiology appointments, follow up appointments since then another emergency room visit on 6/10/21.

Symptoms	Vaccine	Vaccine Manufacturer	VAERS ID	Adverse Event Description
				Can't even walk; Couldn't catch his breath; fatigue; Acute hypoxy respiratory failure; Pleuritic chest pain; Red ithcy eyes; HS pneumonitis; Decreased level of conciousness; ILD; non necrotizing granuloma; Flushing; Pulse ox reading in the 70's; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of RESPIRATORY FAILURE (Acute hypoxy respiratory failure), CHEST PAIN (Pleuritic chest pain), OCULAR HYPERAEMIA (Red ithcy eyes), HYPERSENSITIVITY PNEUMONITIS (HS pneumonitis), DEPRESSED LEVEL OF CONSCIOUSNESS (Decreased level of conciousness), INTERSTITIAL LUNG DISEASE (ILD), PULMONARY GRANULOMA (non necrotizing granuloma), FLUSHING (Flushing), OXYGEN SATURATION DECREASED (Pulse ox reading in the 70's), GAIT INABILITY (Can't even walk), DYSPNOEA (Couldn't catch his breath) and FATIGUE (fatigue) in a 56-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 017B21A) for COVID-19 vaccination. No adverse event reported. The patient's past medical history included Type 2 diabetes mellitus. Previously administered products included for an unreported indication: Accupril in 1996 and Accupril. Past adverse reactions to the above products included Ankle swelling with Accupril; and Knee swelling with Accupril. Concomitant products included HYDROCHLOROTHIAZIDE, LOSARTAN POTASSIUM (HYZAAR) for Blood pressure, METFORMIN, SERTRALINE, CYCLOBENZAPRINE HYDROCHLORIDE (FLEXERIL [CYCLOBENZAPRINE HYDROCHLORIDE]), IBUPROFEN, TADALAFIL (CIALIS), INSULIN LISPRO, CALCIUM, COLECALCIFEROL (CALCIUM VITAMIN D) and INSULIN GLARGINE (BASAGLAR KWIKPEN) for an unknown indication. On 25-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 25-Mar-2021, the patient experienced OXYGEN SATURATION DECREASED (Pulse ox reading in the 70's) (seriousness criterion medically significant), GAIT INABILITY (Can't even walk) (seriousness criterion hospitalization), DYSPNOEA (Couldn't catch his breath) (seriousness criterion hospitalization) and FATIGUE (fatigue) (seriousness criterion hospitalization). On an unknown date, the patient experienced RESPIRATORY FAILURE (Acute hypoxy respiratory failure) (seriousness criteria hospitalization and medically significant), CHEST PAIN (Pleuritic chest pain) (seriousness criterion hospitalization), OCULAR HYPERAEMIA (Red ithcy eyes) (seriousness criterion hospitalization), HYPERSENSITIVITY PNEUMONITIS (HS pneumonitis) (seriousness criteria hospitalization and medically significant), DEPRESSED LEVEL OF CONSCIOUSNESS (Decreased level of conciousness) (seriousness criteria hospitalization and medically significant), INTERSTITIAL LUNG DISEASE (ILD) (seriousness criteria hospitalization and medically significant), PULMONARY GRANULOMA (non necrotizing granuloma) (seriousness criterion hospitalization) and FLUSHING (Flushing) (seriousness criterion hospitalization). The patient was hospitalized from 27-Mar-2021 to 02-Apr-2021 due to CHEST PAIN, DEPRESSED LEVEL OF CONSCIOUSNESS, FLUSHING, HYPERSENSITIVITY PNEUMONITIS, INTERSTITIAL LUNG DISEASE, OCULAR HYPERAEMIA, PULMONARY GRANULOMA and RESPIRATORY FAILURE. At the time of the report, RESPIRATORY FAILURE (Acute hypoxy respiratory failure), CHEST PAIN (Pleuritic chest pain), OCULAR HYPERAEMIA (Red ithcy eyes), HYPERSENSITIVITY PNEUMONITIS (HS pneumonitis), DEPRESSED LEVEL OF CONSCIOUSNESS (Decreased level of conciousness), INTERSTITIAL LUNG DISEASE (ILD), PULMONARY GRANULOMA (non necrotizing granuloma), FLUSHING (Flushing), OXYGEN SATURATION DECREASED (Pulse ox reading in the 70's), GAIT INABILITY (Can't even walk), DYSPNOEA (Couldn't catch his breath) and FATIGUE (fatigue) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Glycosylated haemoglobin: 7.6. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Treatment While hospitalized, the consumer was started on 100mg Prednisone, now at 60mg of Prednisone, calcium, vitamin D, insulin lispro, protonix, bactrim, and is currently on oxygen. Concomitant medications Glucometer, Insullin pen and Lansets. Company Comment: Although a temporal association exists, provided information is not adequate to assess the causal association between the event and mRNA-1273. The detailed medical history and diagnostic report has not been provided. Causality is also confounded by the patient's comorbidities. Most recent FOLLOW-UP information incorporated above includes: On 09-Jun-2021: Follow-up received on 09/6/21: New event added: Acute hypoxy respiratory failure, Pleuritic chest pain, Red ithcy eyes, HS pneumonitis, Decreased level of consciousness, ILD, non necrotizing granuloma and Flushing.; Sender's Comments: Although a temporal association exists, provided information is not adequate to assess the causal association between the event and mRNA-1273. The detailed medical history and diagnostic report has not been provided. Causality is also confounded by the patient's comorbidities.
RESPIRATORY FAILURE	**COVID19 (COVID19 (MODERNA)) (1201)**	**MODERNA**	[1409891-1]	
RESPIRATORY FAILURE	**COVID19 (COVID19 (MODERNA)) (1201)**	**MODERNA**	[1410369-1]	Patient received 2nd dose of the COVID-19 vaccine on 2/10/21 and was considered fully vaccinated two weeks later on 2/24/21. On 6/10/21 patient was hospitalized with a possible upper GI bleed. Overnight the patient began to have increased oxygen needs and crackles on auscultation. She was transferred to the ICU, had an abnormal chest x-ray, and tested PCR positive for COVID-19. The patient had acute kidney failure and respiratory failure with a DNR and DNI. She expired on 6/11/21.

Symptoms	Vaccine	Vaccine Manufacturer	VAERS ID	Adverse Event Description
RESPIRATORY FAILURE	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)	PFIZER\BIONTECH	0923935-1	I got my shot on the 19th and that evening it was like a light switch and I was so tired I went to sleep at 730pm I had severe chills and fever and had to go to bed. The next day I still wasn't feeling well and I was called in to get covid tested and I went to the ER on the 21st and took a rapid covid test that was positive. I was stable and had good oxygenation and was discharged. I have fever nausea vomiting I also had problems with O2 stat i was in the 80s and realized I was having respiratory failure so I was admitted on the 27th and I've been here ever since. I had kinetic storm and infusions my O2 stats were bad and I was sent to the covid unit and put on high flow oxygen and negative for a PE, I'm still on the covid unit but I feel much better today
RESPIRATORY FAILURE	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)	PFIZER\BIONTECH	0934966-1	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
RESPIRATORY FAILURE	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)	PFIZER\BIONTECH	0944169-1	altered mental status, hypoxic, fever 39.3, agitated
RESPIRATORY FAILURE	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)	PFIZER\BIONTECH	0955467-1	Patient had received second Pfizer vaccination after no reported issues with the first dose. Patient was observed post vaccination without incident and released. Patient developed wheezing and attempted to treat with her albuterol inhaler but did not improve. patient presented to the ED approximately 2 hours after vaccination and was admitted for respiratory failure and placed on BiPAP for a brief period of time. patient has known history of Asthma Exacerbation requiring hospitalization and intubations. D/C diagnosis Asthma Exacerbation
RESPIRATORY FAILURE	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)	PFIZER\BIONTECH	0962390-1	Admitted to hospital after vaccination with Acute hypoxemic respiratory failure, Septic shock; Aneurysm of arteriovenous dialysis fistula; expired 1/16/2021
RESPIRATORY FAILURE	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)	PFIZER\BIONTECH	0962851-1	presented to the ED 1/5/21 with syncope 1 hour after receiving COVID vaccine found to have acute hypoxic resp failure at rest. Per family patient's pulse ox low with exertion at baseline for the past couple of months, but she always recovers to above 90%. She was discharged home with home health with oxygen 1/19/21
RESPIRATORY FAILURE	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)	PFIZER\BIONTECH	0967830-1	Patient was was brought to the ED from facility which he received the vaccine via ambulance with BiPAP, hypoxia, and one dose of Epi of 0.3 mg. He then required intubation, and had struggled with hypoxia, even on increasing PEEP. CODE BLUE called in the ED for PEA. He was medicated for such (please see the code run sheet for details), and he came in and out of the code 5 times. After 95 minutes, with the wife at the bedside, and family conference by phone, the code was called, and he was pronounced at 18:20. He received in total 8 me of Epi, 3 shots of Atropine, 3 amps bicarb. He got lasix 40 mg, lovenox 60 mg subcutaneous once. He had a CVC into the right internal jugular, and levophed was started, then Epinephrine drip was started. Prior to the code he got steroids (solumedrol 125 mg, then later decadron 6 mg iv), benadryl iv, antibiotics (ceftraixone / zithromax), and lasix 40 mg. All this time while in the ED, the Rt was at the bedside, and lots of secretions from the lungs were aspirated, bloody color. á Code was the result of PEA secondary to hypoxia (

Symptoms	Vaccine	Vaccine Manufacturer	VAERS ID	Adverse Event Description
RESPIRATORY FAILURE	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)	PFIZER\BIONTECH	0973808-1	"shortness of breath, chest xray with pulmonary edema, periorbital edema Narrative: 73 yo M w/ PMH HTN, HLD, EVAR (2013) for AAA c/b persistent type II endoleak s/p multilple repairs (2015 & 2017) c/b glue embolization down into the R CIA secured with additional stent placement with the R iliac limb, s/p b/l Iliac artery aneurysm stent 08/31/20, and PTSD. Former smoker, quit 12+ yrs ago. 11/1/20-11/6/20: Hospitalized for acute on chronic back pain, found to multiple hypermetabolic lesions in the axial skeleton. Diagnosed with epithelioid angiosarcoma. Patient discharged to facility. 12/17/20: Patient received his 1st COVID-19 vaccine w/o complications at facility. 12/21/20: Underwent cyberknife treatment. 12/31/20: Transferred from facility to ER for new O2 requirement, SOB, cough, chest X ray / pulm edema, tachycardic and new periorbital edema. 12/31/20: Admitted to ICU before transfer to acute care. 1/1/21: Pulmonary consult, ""Labs are notable for progressive left shift with bandemia, markedly elevated inflammatory markers (D-dimer, ESR, CRP, ferritin, LDH), mild elevation in procalcitonin, mild elevation in lactate that has improved, and negative viral panel including COVID-19 x2. CT chest is notable for b/l GGOs along with some interstitial infiltrates with an upper and particularly mid zone and perihilar predominance, septal thickening and crazy paving, and numerous cystic lesions or pneumatoceles. There is a lack of lobar consolidation and pulmonary nodules. Of note, PET/CT about 2 months ago only demonstrated some mild to moderate emphysema mostly in the upper lobes. Therefore, there has been a relatively dramatic change in a few months, suggesting a more subacute process, rather than an acute infectious process such as a viral pneumonia, including COVID-19 infection, in which the GGOs tend to be subpleural and peripheral. Overall, our suspicion for COVID-19 is relatively low, with negative testing x2 yesterday, negative testing a few weeks ago, and lack of sick contacts, but it is possible. Therefore, higher on the differential is a more subacute infection or chemotherapy-induced pneumonitis. Risk factors include malignancy, chemotherapy, and use of steroids (equivalence of about 27 mg of Prednisone in the form of Dexamethasone since 11/6/20 without PJP prophylaxis). These risk factors, along with consistent imaging and elevated LDH, make PJP quite likely. Fungal infection is less likely based on imaging. Chemotherapy-induced pneumonitis is a possibility, especially given the more subacute picture based on imaging. Both Gemcitabine and Docetaxel can cause pneumonitis. However, the patient has been on steroids, which is used to treat drug-induced pneumonitis, although this does not exclude it completely."" 1/2/21: Transferred to ICU for worsening hypoxemia as patient reached 40L/100% FIO2 and remained on COVID isolation/COVID patient under investigation per ID recommendation. 1/4/21: Isolation precautions discontinued due to lower suspicion for active COVID infection to explain current presentation 1/6/21: Went into atrial fibrillation w/o RVR overnight 1/6. Tolerating, with MAPs in low 60s and HR in high 90s/low 100s. Suspect due to being-1L yesterday from diuresis, lasix stopped. S/p amiodarone bolus + drip, albumin 5% bolus 1/5/21: Macrocytic anemia NOS w/ slowly worsening H/H s/p PRBC x 1 unit 1/7/21: Per ICU Life-sustaining treatment note, ""Following discussion w/ patient that his lung dx has been refractory to txt and hasn't improved despite maximal therapy, patient agreed to transition to hospice after he settles affairs. "" 1/7/21 Infectious Disease note: ""This is an immunocompromised host due to cancer on active chemotherapy (albeit ANC>4000 on admission) and notably had been on daily PO dexamethasone 1 mg TID (total daily dose 3 mg, equivalent to 20 mg PO prednisone) since 11/6/20 without any PJP ppx. There was elevated c/f COVID-19 infection in setting of patient's presenting symptoms, especially in conjunction with b/l GGOs on imaging. Has undergone multiple COVID test that have all resulted negative. Discussed radiographic findings with radiology colleagues, and overall, it is difficult to definitively narrow the differential with imaging alone, but overall density of GGOs seem to appear less likely PJP and more in line with chemical pneumonitis vs COVID, although less typical for viral pneumonia as well. Given false-negative COVID tests are not unheard of, especially in the immunocompromised population, patient was kept on isolation precautions as a PUI for abundance of caution. He is now off precautions. In setting of patient having been on prednisone for some time without PJP ppx, he was also started on treatment dose TMP/SMX. Beta-d-glucan has returned positive, and although not the ideal test for PJP, this can certainly support a potential dx of PJP. Unfortunately, DFA from sputum was not performed due to insufficient sample and currently the patient is unable to produce an additional sample for testing. He is tolerating the high-dose TMP/SMX; we adjusted the dose to three SS tablets TID based on his somewhat declining UOP. Other fungal etiologies are pending work-up as well. Lastly, patient's chemotherapy is known to cause pneumonitis, but per pulmonology team, he receives prophylactic dexamethasone with his chemo cycles that should help to prevent drug-induced pneumonitis. Remains on the differential for now and this should also be concurrently treated with the steroids he is receiving."" 1/10/21: Comfort care initiated. All non-comfort measures were discontinued. Time of death: Jan 10,2021@14:56; immediate cause of death per death note is ""hypoxic respiratory failure"""

Symptoms	Vaccine	Vaccine Manufacturer	VAERS ID	Adverse Event Description
RESPIRATORY FAILURE	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)	PFIZER\BIONTECH	0975434-1	"vomiting x3 1/8/21 1/9/21 00:34 - called to resident room by CNAs, staff stated resident was ""different"". Vitals taken and 02 sat was low, O2 in room and applied via NC @3L, O2 sat returned to 98 and all other vitals WNL including BS. Resident asked how he felt, stated he felt ""okay"". Resident exhibiting some shakey movements and clearing throat, states he does not have any phlegm or drainage or trouble swallowing. MD called and updated on situation, voicemail left. 1/9/21 11am- resident has been making a ""growling"" noise this shift. resident also has tremors. resident alert and answers questions appropriately. when asked if resident wants to go to hospital, resident firmly states ""no"". vitals wnl. no emesis noted. will continue to monitor resident. 1/9/21 12p- resident not answering questions appropriately. resident only answering yes or no. resident cannot tell me name, or the year, resident cannot state where he is currently or birthdate."
RESPIRATORY FAILURE	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)	PFIZER\BIONTECH	1002808-1	According to medical report, Pt presented to the ED on 1/14/21 w/ cc of SOB for 1 day. She received her COVID-19 vaccine on 1/9/21. Pt stated that she developed a dry hacking cough 2 days prior to the vaccine on 1/7/21. Over the last few days prior to admission, she developed generalized weakness, SOB, loss of sense of taste and smell w/ associated decreased appetite and nausea ultimately SOB in the24 hours prior to admission. Final Diagnosis- acute hypoxic respiratory failure secondary to COVID-19 pneumonia. Pt died on 2/3/21. See Medical report for more information.
RESPIRATORY FAILURE	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)	PFIZER\BIONTECH	1006220-1	Pt from home via EMS. Pt reports increased weakness since getting the covid vaccine on the 24th. Pt is normally ambulatory at baseline, but has not been able to get around his house. Pt was found to be 83% on RA and was audibly wheezing per EMS. No history of respiratory issues. Denies fever, but has had a productive cough. A&O x4. Pt received Duoneb treatment in route. Acute respiratory failure with hypoxia , Pneumonia due to COVID-19 virus , Elevated LFTs. Patient admitted to hospital on 2/3 and is still inpatient
RESPIRATORY FAILURE	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)	PFIZER\BIONTECH	1011983-1	"Narrative: See ""Other Relevant History"" in Section 6 above Other Relevant Hx: 76yo man with a history of for C5 tetraplegia 2/2 cervical stenosis leading to neurogenic bowel/bladder (chronic suprapubic catheter) and chronic respiratory failure with tracheostomy, severe dysphagia s/p G tube placement and multiple aspiration pneumonias, COPD GOLD III, hx MRSA bacteremia (7/2018) and E coli bacteremia (12/2019). Patient transferred from Spinal Cord Injury until to ICU on 1/11/2021 due to worsneing dyspnea, hypoxia (80s) and tachycardia and was found to have acute hypoxic respiratory failure likely 2/2 multifocal pneumonia. CXR findings of ""There is interval increase in patchy airspace infiltrates and consolidation in bilateral lungs concerning for pneumonia"" Patient was started on vancomycin and pip/tazo on 1/11 and tracheal aspirate cultures were obtained for VAP diagnosis which ultimately grew Serratia liquifaciens and Proteus mirabilis. Infectious Diseases was consulted who recommended a switch to ertapenem therapy for a total 10 day course for VAP. UCx/BCx remained negative. On 1/20, a therapeutic bronchoscopy was completed with cultures growing Stenotrophomonas maltophilia and pan-S Klebsiella pneumoniae. The following day a chest tube was inserted and the course of ertapenem completed but vancomycin was continued. By 1/22, patient developed shock liver with ALT/AST 2135/1579 from normal range the day prior and SCr increased to 1.3 from baseline 0.7/cystatin C of 2.46 up from 1.15. Levofloxacin was added for Stenotrophomonas coverage. By 1/25, patient's clinical status continued to decline and Cardiology was consulted for new onset Afib with RVR. Discussion was documented with patient's family who requested DNR. Patient passed away in the early AM on 1/26. Demise does not appear to be related to COVID-19 vaccination but occurred in recent timeframe. Symptoms: ElevatedLiverEnzymes & death, pneumonia, afib"
RESPIRATORY FAILURE	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)	PFIZER\BIONTECH	1012986-1	Hospitalized for community-acquired pneumonia and sepsis 6 days following administration of COVID-19 vaccine, complicated by acute hypoxemic respiratory failure and acute kidney injury requiring. Admitted to ICU, treated with intravenous antibiotics and initial pressor support. Intubated on hospital day #3, extubated on hospital day #8. Remains in ICU at time of this report.
RESPIRATORY FAILURE	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)	PFIZER\BIONTECH	1017167-1	Respiratory distress sent to the ER and admitted on 2/3 with respiratory failure
RESPIRATORY FAILURE	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)	PFIZER\BIONTECH	1020010-1	Pt c/o coughing and SOB pt states he received 1st dose of covid vaccine on the 01/22/21 presented to the ED with fever, chills and shortness of breath. He tested positive for covid. In the ED he was hypoxic to 87% on RA. # Hypoxic respiratory failure: 2/2 covid pna. Room air sats 87%, up to 92% on 4L # COVID pneumonia: no suspicion for bacterial etiology. REMDESIVIR administration started on 1/25/21. Transferred to Hospital, (2/3/21) for higher level of care Intubated COVID 19.

Symptoms	Vaccine	Vaccine Manufacturer	VAERS ID	Adverse Event Description
RESPIRATORY FAILURE	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)	PFIZER\BIONTECH	1020135-1	"death Narrative: 92 yo male seen in clinic on 12/30/2020 for transfusion, hbg 6.9. PMH includes HLD, CKD, myelodysplastic syndrome, DM, prostate cancer, HTN. Pt also received COVID19 Pfizer vaccine the same day. The patient denied any prior severereaction to this vaccine or its components. Post-transfusion, patient had a mechanical fall (per patient he was seated and used the cane to help him stand. However the cane slipped on the floor causing the patient to fall, patient hit his head and injured his right hip, no loss of consciousness at the time). Rapid response team was called and patient was admitted to the ED. Pt was found to have subcapital right femoral neck fracture, scalp contusion, and TBI (per ED provider's note). Ortho evaluated and said patient wasn't a surgical candidate. During his hospitalization, patient tested positive for COVID19 on 1/12/2021, pt was asymptomatic at the time. On 1/13/2021, pt exhibited mild URI symptoms, no respiratory distress. He was started on cetirizine, Montelukast, albuterol, and inhaled steroids to manage his symptoms. Dexamethasone was started on 1/14/2021. Chest Xray was ordered on 1/17/2021, pt's respiratory was slowly getting worse, resting O2 sats were in the high 80s and low 90s with IS. On 1/18/2021, CXR shows patchy bilateral airspace opacities suspious for pneumonia of bacterial or viral etiology. Pt was started on remdesivir 01/18/2021 (5 doses, from 1/18-1/22/2021). Pt required 5-6 LPM of oxygen at rest. Pt was then transferred to the ICU. His oxygen demand continued to increase and his condition worsened. On 2/14/2021, pt started to desat into the 70s on max high flow. Patient/family agree to comfort care. Medical cause of death was listed as ""acute hypoxic respiratory failure due to COVID19."" Patient expired 1/24/2021."
RESPIRATORY FAILURE	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)	PFIZER\BIONTECH	1024451-1	CHF, Resp failure, intubated, on Levophed, suspected septic and cardiogenic shock.
RESPIRATORY FAILURE	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)	PFIZER\BIONTECH	1026094-1	Patient tested positive for COVID-19 on 2/4/21, she had symptoms of cough and sore throat on 2/2/21. She was admitted to hospital on 2/12/21 COVID-19 pneumonia and hypoxic respiratory failure.
RESPIRATORY FAILURE	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)	PFIZER\BIONTECH	1027076-1	"Resident observed shirtless sitting in wheelchair with 02 @ 2L/M via NC in progress, using substernal accessory muscles, flared nostrils, pursed lip breathing. Alert verbally responsive, unable to speak more than 2-3 words at a time. Reports "" I cant breathe"". R 30 P 100 02 Sat 89%. Rebreather mask administered, and EMS initiated and transferred patient to emergency room, where he was admitted for respiratory failure."
RESPIRATORY FAILURE	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)	PFIZER\BIONTECH	1032880-1	Received Pfizer 1/22/2021. RNA+ 2/4/2021. S/S SOB, cough, confusion. COVID assoc. resp. failure, stage 4 lung cancer, COPD, HTN, former smoker. patient in hospice and died 2/10/2021.
RESPIRATORY FAILURE	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)	PFIZER\BIONTECH	1036675-1	61 yo F with history of bilateral lung transplant 6/23/17 presented to ED on 2/4/21 with chief complaint of worsening shortness of breath, nausea and diarrhea for past week since receiving since receiving COVID-19 vaccine (Pfizer) on 1/28/21. Upon arrival to triage she was obviously dyspneic with significantly low oxygen saturations. O2 sats on arrival were 65%, improved to mid 90's with O2 6 liters per NC. Admitting diagnosis: hypoxic respiratory failure post COVID vaccine. Lab work shows an elevation of the BUN and creatinine at 31 and 1.71 which is slightly higher than her usual baseline levels. BNP is elevated at 2 448 with a mildly elevated troponin. Procalcitonin is also elevated. Patient's white blood cell count is 11.07. Full viral panel including COVID-19 is not detected. All blood cultures and respiratory cultures were negative. Patient chest x-ray shows numerous bilateral patchy opacities which is significantly different from her previous chest x-ray here. Empiric rejection treatment initiated including high dose methylprednisolone, plasmapheresis, IVIG, Thymoglobulin. She continued to decline and ultimately required intubation, proning and paralyzing on 2/8/2021 and then VV ECMO cannulation on 2/13/2021. EGD done 2/14/2021 as unable to pass the TEE probe during cannulation prior day (unable to complete due to abnormal anatomy). Acute pupil exam change in the early am hours of 2/15/2021 prompted urgent head CT which revealed catastrophic brain bleed. Brainstem reflexes were lost soon after. Despite placing an EVD emergently at bedside, brain stem reflexes were not recovered. GOL engaged and patient not an organ donation candidate. Therefore discussion with sister at bedside resulted in decision for cessation of life support. Patient expired shortly after support withdrawn and pronounced dead on 2/15/2021 at 11:11 AM.

Symptoms	Vaccine	Vaccine Manufacturer	VAERS ID	Adverse Event Description
RESPIRATORY FAILURE	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)	PFIZER\BIONTECH	1037865-1	respiratory failure from COVID19; presented to the ER with COVID symptoms and was diagnosed/died on 09Feb2021 from respiratory failure from COVID19; presented to the ER with COVID symptoms and was diagnosed/died on 09Feb2021 from respiratory failure from COVID19; This is a spontaneous report from a contactable physician. An 89-year-old male patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration in 10Jan2021 at 12:00 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient had no COVID prior to vaccination. The patient received one dose of Pfizer vaccine on 10Jan2021. The patient was presented to the ER with COVID symptoms and was diagnosed on 27Jan2021. Patient subsequently died on 09Feb2021 from respiratory failure from COVID19. It was unknown if autopsy was done. The patient was tested for COVID post vaccination via nasal swab: covid-19 virus test positive on 27Jan2021. The events resulted in emergency room/department or urgent care, hospitalization, and patient died. No follow-up attempts are possible, information about batch number cannot be obtained. No further information is expected.; Sender's Comments: The Company cannot completely exclude the possible causality between the reported COVID post vaccination and respiratory failure with fatal outcome, and the administration of COVID 19 vaccine, BNT162B2, based on the reasonable temporal association. More information on the underlying medical condition in this 89-year-old male patient is required 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: presented to the ER with COVID symptoms and was diagnosed on 27Jan. Patient subsequently died on 09Feb from respiratory failure from COVID19; presented to the ER with COVID symptoms and was diagnosed on 27Jan. Patient subsequently died on 09Feb from
RESPIRATORY FAILURE	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)	PFIZER\BIONTECH	1041983-1	Admitted with covid pneumonia, Acute hypoxic respiratory failure, currently in ICU ventilator dependent respiratory failure. Patient tested 1/26 with 1/29 positive results. never symptomatic. presented to receive covid vaccine and received it on 2/1, (reportedly discussed with a physician to make sure getting vaccine was ok) Then hospitalized 2/11 with urosepsis and discharged 2/14. 2/15 presented to oncology office with o2 sats 78% on RA. transported to Hospital.
RESPIRATORY FAILURE	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)	PFIZER\BIONTECH	1044185-1	She received 2nd COVID vaccine on 1/7//21. On 1/13/21, she developed sore throat, earache, dizziness, dyspnea, diarrhea, vomiting and fever. She required hospitalization on 1/18/21 for Acute hypoxic respiratory failure secondary to bilateral Pneumonia with left pleural effusion. Sepsis secondary to Gram-Positive bacteremia (strep pneumococcus). UTI. Acute Kidney Injury
RESPIRATORY FAILURE	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)	PFIZER\BIONTECH	1046447-1	2/12/2021 Vaccine 2/13/2021 Weakness, oral ulcers 2/17/2021 Brought to ER for loss of consciousness, altered mental status, rectal bleeding; work up showed sepsis, UTI, anemia, pneumonia, pleural effusion, pancytopenia, hypotension; persistent hypotension and respiratory failure 2/18/2021 Passed away at 5:54AM
RESPIRATORY FAILURE	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)	PFIZER\BIONTECH	1052711-1	The patient has developed an acute deep venous thrombosis in the right popliteal and trifurcation vessels of the calf. She has an elevated d-dimer of 14,738 and acute hypoxic respiratory failure due to pulmonary embolism.
RESPIRATORY FAILURE	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)	PFIZER\BIONTECH	1055417-1	Emergency room HPI Patient is a 91 y.o. male who presents from nursing home with positive coronavirus a and flu A positive tests. Test was done yesterday. Patient sent to ER because of low oxygen saturation. Patient unable to answer or respond to questions. No fever or chills, no cough or shortness of breath and no complaint of pain when patient was moved around. Oxygen saturation on presentation was 89% on room air and went up to 93% on 4 L of oxygen admission: HPI: Patient is a 91 y.o. male with a history of severe dementia and severe COPD. He currently resides at Rehab. He had a routine coronavirus (COVID-19) test yesterday that was positive. Then, today he started having increasing oxygen requirement. He was not responding to his typical breathing treatments or oxygen and so they sent him in. In the ER he was found to be in some respiratory distress and did require increased oxygen concentration. Once they got him calm down, his oxygen saturation state over 90% with 4 L. His ABG did show an oxygen Saturation of 86% on 4 L. The patient reportedly had coronavirus (COVID-19) several months ago, but then did test positive for both coronavirus (COVID-19) and influenza on rapid testing at the nursing home yesterday. The patient is being admitted due to his increasing oxygen requirement and respiratory distress

Symptoms	Vaccine	Vaccine Manufacturer	VAERS ID	Adverse Event Description
RESPIRATORY FAILURE	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)	PFIZER\BIONTECH	1058239-1	Received COVID vaccine 1 on 1/13 and COVID vaccine #2 2/1. 49 y/o previously healthy female who had a COVID 19 exposure ~ 1/3. The person she was exposed to tested positive 1/6 (daughter had a fever and cough). On 1/11 the patient received the 1st dose of the Pfizer vaccine. 12-24 hours after the Pfizer vaccine she developed fevers, malaise, myalgias that lasted 2-3 days (Called off work). She then returned to a normal state of health. On 2/1 she received the second dose of the vaccine. On 2/6 she developed right pleuritic chest pain so went to an urgent care. COVID 19 PCR was positive and CXR unremarkable. She was told to take naproxen and her pleuritic chest pain slowly improved. On 2/8 she started to have general malaise followed by nausea. On 2/11 she developed increased nausea and vomiting followed by diarrhea-eventually that day she had a near syncopal episode prompting her presentation to the hospital. Seen at an outside hospital between 2/11-2/12. CT abd/pelvis showed patchy ground glass opacities at the base of the lungs and she was noted to have diffuse mural thickening. There was concern for possible cholecystitis so a perc cholecystostomy tube was placed. Ultimately she developed significant hypoxic respiratory failure and had to be intubated.She was transferred to another hospital on 2/12. Initially she was started on treatment with dexamethasone but continued to clinically get worse. Also on empiric antibiotics.
RESPIRATORY FAILURE	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)	PFIZER\BIONTECH	1062962-1	[COVID-19 mRNA vaccine (Pfizer-BioNtech] treatment under Emergency Use Authorization (EUA)
RESPIRATORY FAILURE	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)	PFIZER\BIONTECH	1063283-1	Admitted to hospital on 2/28/21 for covid pneumonia and acute hypoxic respiratory failure, covid test positive. receiving dexamethasone 6 mg BID and received 1 dose of actemra. concern for bacterial infection.
RESPIRATORY FAILURE	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)	PFIZER\BIONTECH	1073816-1	RESPIRATORY FAILURE Narrative: PT PASSED AWAY WHILE IN THE HOSPITAL
RESPIRATORY FAILURE	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)	PFIZER\BIONTECH	1076188-1	Out of hospital cardiac arrest and refractory shock, acute kidney injury, shock liver, respiratory failure leading to death
RESPIRATORY FAILURE	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)	PFIZER\BIONTECH	1079864-1	9 days after receiving vaccine, pt developed rapid onset of ascending paralysis. No use of legs, minimal use of right arm. Limited use of left arm. Repiratory difficulty/failure.
RESPIRATORY FAILURE	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)	PFIZER\BIONTECH	1081416-1	Pt. presented to ED via EMS for emergent coma. EMS intubated patient in field due to respiratory failure. Pt. was severely hypertensive with nearly total loss of brainstem reflexes. Patient had known L MCA cerebral aneurysm with appointment to undergo intervention to address in the near future. NCCT reported massive multifocal brain hemorrhage, SAH, SDH, and parenchymal hemmorhage with midline shift and subfalcine herniation. Due to dismal/poor prognosis, family requested withdrawal of support approximately 4 hours after presentation and patient expired shortly thereafter.
RESPIRATORY FAILURE	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)	PFIZER\BIONTECH	1085452-1	SOB a few days after vaccination; one week later, new onset of acute exacerbation of HFrEF with subsequent respiratory failure and hospitalization
RESPIRATORY FAILURE	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)	PFIZER\BIONTECH	1089615-1	The patient had possible syncopal episode and an increased white blood count with lactic acidosis on admission. He is currently still in hospital and had delirium and acute hypercapnic respiratory failure requiring BiPAP ventilatory support.
RESPIRATORY FAILURE	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)	PFIZER\BIONTECH	1090240-1	Cardiac arrest; Pulmonary embolus; Renal failure; Fever; Dehydration; Not eating or drinking; COVID-19 confirmed by positive COVID-19 test / COVID pneumonia; blood clot; blood pressure was low; Respiratory arrest; Respiratory failure; Hypoxemia; ventricular tachycardia; This is a spontaneous report from a contactable nurse reporting on behalf of the husband. A 71-year-old male patient received the first single dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot EL9264) on 10Feb2021 at about 19:00 (at the age of 71 years), in left deltoid, for COVID-19 immunisation. No other vaccines were given on the same day or within 4 weeks. The patient declined flu vaccine and pneumococcal vaccine (PNEUMOVAX), he had never had another vaccine except maybe his childhood vaccines. Medical history included rotator cuff surgery and cataract removed in 2020. The patient exercised regularly, he was healthy, he walked for miles and didn't eat any non-sense, he did not eat out, he did not smoke. The patient's mother was 100 years old and fully competent. The patient had two sisters older than him, the oldest one had hypertension the second sister did not have anything that they were aware of. The patient's father lived until he was 98 years old. The patient concomitant medications were none. The patient was told to take vitamin D 50,000 units but didn't even take them (he still had 9 of them in the bottle and they gave him 13). The patient experienced fever on 11Feb2021, renal failure on 14Feb2021, pulmonary embolus on 28Feb2021, cardiac arrest on 04Mar2021, dehydration and not eating or drinking on an unspecified date in Feb2021. These events required ER visit and were reported as serious as involved hospitalization from

Symptoms	Vaccine	Vaccine Manufacturer	VAERS ID	Adverse Event Description
				ER visit and were reported as serious as involved hospitalization from 14Feb2021 to 04Mar2021 and as fatal events. The patient died on 04Mar2021. Clinical course of the events included the following information. The patient received the first vaccine on 10Feb2021, the next day he developed a fever. The reporter spoke with the patient's doctor who told to give the patient paracetamol (TYLENOL) thinking the fever was from the vaccine. On 12Feb2021 and 13Feb2021, the patient's temperature was 102. Then the doctor advised to take the patient to the hospital. The patient's temperature was still 102, he was in renal failure, and they had to dialyze him. The patient was otherwise healthy, the patient's last physical was in Dec2020 and the only thing it showed was that his A1C was 5.7. The patient had no cholesterol or hypertension. The doctor advised the patient to decrease sugar and carbs because the holidays were coming up. The patient's follow up was scheduled on Mar2021. The reporter felt that the vaccine has something to do with the patient renal failure. The reporter spoke with the doctors at the hospital who didn't want to commit to anything. The reporter believed this was an adverse event. The caller mentioned that she had her vaccine before and she was fine. The patient was admitted on 14Feb2021 and by Wednesday he was not eating or drinking, he was dehydrated. The patient's admitting diagnoses was elevated temperature and ruling out COVID. The patient tested positive for Covid on 14Feb2021 (COVID-19 PCR test). The patient's temperature was 99.8 and then kept creeping up, on Saturday it was 102. The caller gave the patient Tylenol cold and flu (lot T0CL001021, expiry date Oct2021) took the edge off but in three hours the temperature was back up again. The patient never complained of pain and didn't want to take Tylenol. On 15Feb2021 the patient's numbers were getting better after the fluid challenge and then his numbers kept creeping up after that. The patient had the fever a week until they had it under control. The fever went away, it was gone for like 5 days, then it spiked again. The patient was started on piperacillin/tazobactam (ZOSYN) for like 3 or 5 days and the fever went away but then it kept getting worse. On 28Feb2021, the medical personnel thought the patient had a pulmonary emboli but because of the renal failure, they couldn't do a computerized tomography on the patient. The doctors mentioned that the patient was in renal failure and they thought they heparinized the patient and he had a blood clot who led to pulmonary embolus, cardiac arrest, and death. The patient was diagnosed with a pulmonary emboli on 28Feb2021. The patient started de-saturating and the doctors intubated and sedated him that whole time until this. Dialysis was started on 01Mar2021 and the patient received it every day except 04Mar2021. The patient's blood pressure was normal, it hardly ever went above 120. The patient was on the medical floor from 22Feb2021 to 04Mar2021. When the patient was on the medical surgical floor, he was on high flow 5 liters. After the patient started desaturating, he went to the intensive care unit and was put on a non-rebreather on 45%. The patient's highest heart rate was after intubation was 135, but the patient's blood pressure was low so they started him on some vasopressors. They did the fluid challenge on the patient and his labs were a little better than the labs kept creeping up until the doctor inserted a shiley catheter for dialysis. Respiratory: Respiratory arrest and then cardiac arrest. Respiratory failure, they intubated the patient. The reporter assumed dyspnea because the patient was intubated. Tachypnea was when the patient was in the intensive care unit already intubated. Hypoxemia, they intubated the patient so the caller guessed it was for the oxygen saturation drop. Covid pneumonia: yes. Chest x-ray showed mild pneumonia. The caller requested a follow up x-ray and the doctors said they were going to do another one but the caller is unsure if they did or when. The patient received additional therapies for COVID-19: remdesivir. Other radiological investigations: unable because of the patient's kidney function. They were looking at the D dimer and BMP to come up with the embolus since the patient couldn't have the scan. ARDS: no. Cardiovascular: The patient had a heart attack on 04Mar2021. The reporter thought it was from the pulmonary embolus which led to cardiac arrest. Arrhythmia: the caller guessed so, the patient was being worked on for 10 minutes before the caller got there. The caller saw a rhythm strip which showed a flat line and then she noticed ventricular tachycardia, then a flat line. The patient did not have SARS-CoV2 antibodies at diagnosis. Gastrointestinal/Hepatic, neurological, hematological, dermatological: none. Vascular: pulmonary embolus: yes, deep vein thrombosis, limb ischemia, vasculitis: no. Renal: renal failure: yes, acute kidney injury: no. The patient was scheduled for his second vaccine dose on 03Mar2021 at 04:15 but did not receive it. Time of death was 4:15 in the afternoon on 04Mar2021. The reporter considered renal failure, fever, dehydration, not eating or drinking, cardiac arrest and pulmonary embolus as fatal and related to the suspect vaccine. The outcome of the other events was unknown. Cause of death was unknown. No autopsy was performed.; Sender's Comments: Based on current information available, the company considered there is a possibility that all reported events are consequence of COVID-19 pneumonia on the basis of advanced age. The positive COVID-19 test occurred 4 days after the first injection of suspect vaccine BNT162B2. No complete effect can be achieved for short time interval. The COVID-19 is more likely pre-existing colonization or intercurrent condition, unrelated to suspect vaccine 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 RAs, Ethics Committees, and Investigators, as appropriate.; Reported Cause(s) of Death: Renal failure; Fever; Dehydration; Not eating or drinking; Cardiac arrest; Pulmonary embolus

Symptoms	Vaccine	Vaccine Manufacturer	VAERS ID	Adverse Event Description
RESPIRATORY FAILURE	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)	PFIZER\BIONTECH	1096600-1	Per the patient's spouse and Hospital: The patient received a rapid COVID test at clinic prior to vaccination, which read negative. The patient received vaccination on 2/23/21 and the following day (2/24/21) began to experience breathing difficulties. The patient was admitted to the emergency room at Hospital on 2/26/21 and diagnosed with hypoxic respiratory failure d/t COVID-19 (oxygen saturation < 50%). Patient was intubated on 3/2/21. Per Hospital pharmacist, patient expired on 3/12/21 at 6:40pm.
RESPIRATORY FAILURE	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)	PFIZER\BIONTECH	1108279-1	deceased Narrative: Patient was a 68M with advanced ALS, long-term need for mechanical ventilation, total care, TF, who developed worsening respiratory failure increasing difficulty with mech ventilation, unresponsive to COPD exacerbation treatment, in the setting of persistently abnormal CXR findings concerning for malignancy or other processes. After discussion with family, they did not want to patient to suffer any more and asked for mechanical ventilation be stopped after adequate comfort medications were administered. Patient was allowed to pass away naturally from his underlying advanced ALS.
RESPIRATORY FAILURE	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)	PFIZER\BIONTECH	1109552-1	Family call Clinical Lead to car for elderly woman in backseat of car who had become unresponsive. Patient lying on side. Wearing portable NC o2. Unresponsive to verbal/sternal rub. No pulse, No resps. Called AMR to car side who called 911. Transferred patient to a gurney and began CPR as we transferred to AMR rig. EKG - showed PEA - CPR continued - patient intubated by AMR - epi is given. Pt transported by AMR/Fire to hospital. Pt was a full code on Hospice - she passed away 3/11/21 with the following cause of death: 1.Acute-on-chronic hypoxemic/hypercarbic respiratory failure, multifactorial in origin. 2. Possible aspiration pneumonia, present on admission. 3. Bronchiectasis, chronic, secondary to asbestosis. 4. Acute combined metabolic and toxic encephalopathy, present on admission. 5. Out of hospital pulseless electrical activity arrest. 6. Hyperkalemia. 7. Cardiogenic shock. 8. Acute kidney injury. 9. Lactic acidosis. 10. Acute diastolic congestive heart failure. 11. Severe protein-calorie malnutrition.
RESPIRATORY FAILURE	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)	PFIZER\BIONTECH	1116557-1	Patient experienced respiratory failure and cardiac arrest on day of vaccination. Received CPR, targeted temperature management
RESPIRATORY FAILURE	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)	PFIZER\BIONTECH	1119983-1	admitted to inpatient medicine floor on 02Mar2021 for COVID-19 pneumonia; increasing O2 (oxygen) requirements; This is a spontaneous report from a contactable pharmacist reporting for a patient. A 70-years-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Lot Number: EN6200), intramuscular, administered in Arm Left on 24Feb2021 as SINGLE DOSE for covid-19 immunisation at 70 years old on a hospital. Medical history included colitis ulcerative, rosacea, systemic lupus erythematosus from an unknown date. It was unknown if other vaccines were given in four weeks. No COVID prior vaccination. Concomitant medications included hydroxychloroquine taken for systemic lupus erythematosus; sulfasalazine taken for an unspecified indication; mercaptopurine taken for colitis ulcerative; and doxycycline (DOXYCYCLINE) taken for rosacea; all start and stop dates were not reported (other medications in two weeks). The patient was admitted to inpatient medicine floor on 02Mar2021 for COVID-19 Pneumonia (onset date 02Mar2021). The patient was transferred to ICU on 04Mar2021 given increasing O2 (oxygen) requirements (onset date 04Mar2021). Treatment included dexamethasone and tocilizumab. The patient underwent lab tests and procedures which included Nasal Swab (PCR) (Sars-Cov-2 Test): positive on 02Mar2021. Outcome of the events was unknown.; Sender's Comments: The event COVID-19 pneumonia is likely an intercurrent condition and unrelated to suspect drug BNT162B2. Full immunity is expected 7 days after the second dose. 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.

Symptoms	Vaccine	Vaccine Manufacturer	VAERS ID	Adverse Event Description
RESPIRATORY FAILURE	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)	PFIZER\BIONTECH	1122743-1	severe thrombocytopenia; Bleeding at Impella insertion site; peripheral swelling in hands/feet; cardiogenic shock; myocarditis; hypoxic respiratory failure; mural thrombus; hypotensive despite pressors; fever; cough; myalgias; This is a spontaneous report from a contactable physician. A 46-year-old non-pregnant female patient received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Formulation: Solution for injection, Lot number and Expiration date was not provided), intramuscularly on 05Feb2021 as a single dose for COVID-19 immunisation. The patient's medical history included hyperlipidemia and COVID-19 pneumonia from an unspecified date in Jan2021 to an unspecified date in Jan2021 (the patient was diagnosed with COVID-19 pneumonia prior to the vaccination. Recovered. Returned to work on 25Jan2021). Concomitant medications included atorvastatin orally at 10 mg, once a day, acetylsalicylic acid (ASPIRIN) orally at 81 mg, once a day, colecalciferol (VITAMIN D); all the drugs were received within two weeks. The patient previously took clindamycin and experienced known allergies: Clindamycin. The patient did not receive other vaccine in four weeks. The patient developed fever, cough, myalgias on 19Feb2021 at 12:00 AM. She developed peripheral swelling in hands/feet on 24Feb2021, she was evaluated in the ER; admitted to (hospital name withheld) on 24Feb2021 with cardiogenic shock, myocarditis, hypoxic respiratory failure. The patient was started on IV vancomycin and Unasyn. TTE (transthoracic echocardiogram) demonstrated LVEF (left ventricular ejection fraction) 35%; reduced biventricular function; mural thrombus on 24Feb2021. Remained hypotensive despite pressors on 24Feb2021. Patient had elevated PCW with preserved cardiac index. Patient underwent VA ECMO (veno-arterial extracorporeal membrane oxygenation) and Impella placement on 25Feb2021. COVID-19 PCR was negative. Blood cultures were no growth. She developed severe thrombocytopenia and developed bleeding at Impella insertion site on 25Feb2021; required multiple, PRBC transfusions. Evaluated for HLH; Soluble IL2 receptor on 26Feb2021 elevated at 7232 pg/mL; ferritin 3054; CRP > 300. ECMO stopped 03Mar2021. The patient was treated with IV antibiotics, mechanical ventilation, pressor support, underwent VA ECMO and Impella placement. The patient was hospitalized from 24Feb2021 to 16Mar2021. Number of days of hospitalization was 20 days. The patient tested COVID post vaccination. The patient underwent lab tests and procedures which included blood pressure: hypotensive despite pressors, LVEF: 35 %, nasal swab: Negative on 24Feb2021, blood cultures: No growth, nasal swab: Negative on 25Feb2021, ferritin: 3054, HLH: Evaluated, Soluble IL2 receptor: 7232 pg/mL (elevated at 7232 pg/mL), CRP: > 300 on 26Feb2021, nasal swab: Negative on 11Mar2021, nasal swab: Negative on 14Mar2021. The events were considered as serious (hospitalization and life threatening) by the physician. The outcome of the events was recovering. Information about lot/batch number has been requested.; Sender's Comments: the events being serious, life threatening and hospitalisation ,medical intervention required are assessed as possibly related to the suspect drug __BNT162B2____ based on strong temporal association, but consider also possible contributory effects from patient's medical history and/or concomitant medications.
RESPIRATORY FAILURE	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)	PFIZER\BIONTECH	1123165-1	generalized weakness respiratory failure
RESPIRATORY FAILURE	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)	PFIZER\BIONTECH	1125861-1	shortness of breath chest pain respiratory failure with hypoxia multifocal pnuemonia
RESPIRATORY FAILURE	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)	PFIZER\BIONTECH	1144302-1	"Patient is a 72 yr/o male with PMH significant for COPD, OSA (non-compliant with CPAP), DM2, HTN, HLD, CAD s/p CABG, AFIb (on Xarelto), and chronic diastolic CHF who presented to the ED by EMS due to respiratory failure. Per family- pt had been feeling unwell overnight and the checked on him several times and noted some ""gurgling"" respirations. EMS was called this morning as patient was found unresponsive. Upon EMS arrival they noted he was completely unresponsive with apneic respirations. He did have a palpable pulse. He was hypoxic to the 50s and cyanotic. He was nasally intubated without complication. During transport his mental status did improve. Patient unable to provide additional history at this time. On arrival to the ED, pt was placed on CPAP however TVs noted in the 200s and tachypneic therefore he was placed back on VC mode. Pt will be admitted to the ICU for further management"
RESPIRATORY FAILURE	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)	PFIZER\BIONTECH	1147032-1	Pt reports generalized body aches, fatigue, fever 3/26, one day after receiving vaccine. Evaluated at ED 3/28, received Ketorolac and was discharged. While in parking lot, patient experienced blurring of vision, lightheadedness, nausea, SOB, and left-sided chest pain with return for re-evaluation. Pt treated for possible allergic reaction and concurrent EKG and blood work showed elevated troponin and transient ST elevation. Cardiology consulted and evaluated patient to have severe acute onset systolic heart failure, cardiogenic shock with pulmonary edema, Idiopathic fulminant myocarditis with myonecrosis, and hypoxic respiratory failure. Placed on furosemide, supplemental oxygen, and pending MRI.

Symptoms	Vaccine	Vaccine Manufacturer	VAERS ID	Adverse Event Description
RESPIRATORY FAILURE	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)	PFIZER\BIONTECH	1154151-1	FALLS, CHEST PAIN, HEMORRAHAGIC CONTUSION, COVID, PNEUMONIA, HYPOXIC RESPIRATORY FAILURE Narrative: 2/22/2021 Patient presented to hospital with multiple complaints. He was reporting falls, chest pain, his wife was diagnosed with Covid. While he was there, he was found to have hemorrhagic contusion in the right frontoparietal region with minimal surrounding edema, Covid, pneumonia, elevated troponin. He was accepted in transfer by trauma surgeon Dr. and arrives with no complaints. 2/26/2021 Patient died after code blue was called Death Diagnosis: s/p fall with head trauma Focal area right intracranial hemorrhage per initial CT - serial CT head showing stability Acute hypoxic respiratory failure secondary to COVID-19 viral illness COVID-19 viral illness Acute chest pain, improved Elevated troponin, suspected type 2 NSTEMI Elevated D-dimer - V/Q scan with intermittent probability PE Acute kidney injury on CKD, improving unlikely that vaccine contributed to patient's death.
RESPIRATORY FAILURE	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)	PFIZER\BIONTECH	1155785-1	NA Advanced age PVD, Heart failure ,respiratory failure
RESPIRATORY FAILURE	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)	PFIZER\BIONTECH	1159744-1	patient presented to ED 2/6/2021 with CC of SOB. Patient reported that she started having a cough and runny nose 14 days prior to presentation. Patient was admitted due to further evaluation of respiratory failure. Patient was started on IV decadron due to symptomatology and worsening hypoxia. Infectious disease was consulted for this patient and recommended supportive care and dexamethasone. Patient hospitalized for 10 days due to shortness of breath and oxygen requirements.
RESPIRATORY FAILURE	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)	PFIZER\BIONTECH	1160210-1	Patient was a 79 yo F who presented to hospital on 1/29/2021. On admission patient was severely hypoxic with symptoms of SOB, cough, and severe dyspnea . The patient was COVID-19 positive on admission with symptoms starting 4 days prior to admission. Patient's labs on admission showed elevated ferritin, CRP, and d-dimer. Patient was diagnosed with COVID-19 infection with sepsis and respiratory failure with hypoxia. On arrival to hospital patient's O2 sats were in 60's and improved to upper 80s after nebulizer treatment. Patient was started on azithromycin 500mg once daily for 3 days, ceftriaxone 2g once daily for 2 days, dexamethasone 6mg once daily for 3 days, zinc 220 mg once daily for one dose, and duo-neb 3ml q4h for 3 days. Patient's respiratory status declined and was placed on BiPAP and comfort measures. The patient continued to decline until her passing on 2/3/2021.
RESPIRATORY FAILURE	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)	PFIZER\BIONTECH	1175454-1	Died on 2/12/2021; diagnosed as a COVID-19 related death; 1st vaccine dose on 12/22/2020, 2nd vaccine dose on 1/14/2021. Hospitalized for acute respiratory failure with hypoxia and pneumonia due to COVID-19 infection.
RESPIRATORY FAILURE	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)	PFIZER\BIONTECH	1203542-1	Unknown if pt had s/s at time of vaccination on 1/29/2021 and 2/19/2021. From 3/1/2021-3/6/2021, pt hospitalized w/ covid, resp insufficiency, acute on chronic diastolic HF, dyspnea, ele. D-dimer, acute pulm edema and acute on chronic renal insufficiency. Dcd to home. Six hrs later, readmitted w/ worsening multifocal airspace opacities, enlarged cardiac silhouette, sob, cough. No PE on CXR. Recd O2, cefepime, remdesivir, vanco, Lasix, heparin, rivaroxaban, dexamethasone, tocilizumab. On 3/8/2021, pt had onset R weakness, CT w/ distal R MZ occlusion, Intubated for decline. Not TPA candidate. Per neuro, CVA r/t either a fib hx or hypercoagulability r/t covid. Pt died.
RESPIRATORY FAILURE	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)	PFIZER\BIONTECH	1203575-1	Patient contracted COVID-19 after receiving 2 COVID-19 vaccine doses (Pfizer) and was admitted to the hospital for treatment and is still an inpatient currently. Patient admitted with hypoxic respiratory failure on 3/25/2021 for severe COVID-19. Patient is s/p convalescent plasma on 3/26, and s/p remdesivir 3/26-3/30. Received tocilizumab x 1 dose prior to intubation. Patient with persistent respiratory failure/ARDS requiring intubation. Course further complicated by CMV viremia as well as shock with rising procalcitonin concerning for superimposed bacteria pneumonia as respiratory culture is growing Enterobacter. Goals of care conversations occurring with ICU team and family.
RESPIRATORY FAILURE	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)	PFIZER\BIONTECH	1204616-1	Two days after receiving vaccine patient and family reports patient developed nausea and headache. symptoms seemed to worsen over time and not improve. was evaluated on 3/3/2021 where patient reported weakness, body aches, slight ear discomfort, slight headache. Seen again on 3/8/2021 by other provider reports symptoms of fatigue, dizziness, weakness, diarrhea, nausea. Admitted on 3/11/2021 for COPD exacerbation, treated and sputum cultures grew pseudomonas readmitted on 3/18/2021 due to recurrence of symptoms, diagnosed with Covid pneumonia, increasing oxygen requirements. complication of subcutaneous emphysema with small bilateral pneumothorax from continuous noninvasive ventilation and eventually with worsening hypoxia on 100% FiO2 was intubated and chest tube placed. 4/4/2021 removal of invasive care, comfort care. patient passed away inpatient Prior to covid vaccine patient did have several co morbidities and then subsequently covid that resulted in her death, family is adamant that her decline in health started after her covid vaccine and requested adverse reaction report.
RESPIRATORY FAILURE	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)	PFIZER\BIONTECH	1207083-1	Pt received her 2nd covid 19 vaccine on 4/7/2021 and was admitted severe sob, respiratory failure and hypoxia on 4/10/2021/ she remains hospitalized as of 4/14/2021. she is being treated with oxygen, antibiotics, steroids and nebulizers.

Symptoms	Vaccine	Vaccine Manufacturer	VAERS ID	Adverse Event Description
RESPIRATORY FAILURE	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)	PFIZER\BIONTECH	1211826-1	Patient received 2nd Pfizer dose at 10:00 am. She left the facility after 15 minute wait time. Within the next 5 - 10 minutes she became SOB with respirations 40 per minute. She was taken to Medical Center and seen by 10:45 - 11:00 am. She was treated for anaphylaxis and was worked up for any other underlying problems. She had to be put on the vent due to acute respiratory failure. She was negative for COVID, pulmonary emboli and pneumonia. As her status declined, ED felt she needed higher acuity care. She was over the weight limit to be airlifted so she was transported by critical care ambulance to hospital where she is in ICU and on ventilator.
RESPIRATORY FAILURE	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)	PFIZER\BIONTECH	1212474-1	Death R05 - Cough J96.90 - Respiratory failure R55 - Syncope R41.82 - Altered mental status I95.9 - Hypotension M25.551 - Right hip pain Z79.01 - On apixaban therapy
RESPIRATORY FAILURE	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)	PFIZER\BIONTECH	1220590-1	- In the early morning of 4/14/21 Pt called Kaiser help line complaining of cold hands/ feet, restlessness, pallor, R arm pain. - Telephone visit 4/14/21 complained of chills, nausea, vomiting, abdominal cramping, diarrhea. Fluids and rest recommended. - 4/15/21 presented to Kaiser with chest pain, shortness of breath, abdominal pain. Diagnosed with late presentation of acute coronary syndrome / anterior ST elevation MI. Echo with low EF < 25%, LV apical thrombus - 4/16/21 heart catheterization showed 100% occlusion of LAD treated with PCI / DES x 2, IABP. Endotracheal intubation for respiratory failure.
RESPIRATORY FAILURE	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)	PFIZER\BIONTECH	1230082-1	Reporting Per EUA Covid 19 positive, admitted to hospital, transferred to higher level of care after 3 days for respiratory failure
RESPIRATORY FAILURE	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)	PFIZER\BIONTECH	1246256-1	Hospice Care Sepsis associated hypotension Discharge Diagnoses: acute on chronic hypoxic/hypercapnic resp failure requiring intubation, acute on chronic CHF, severe COPD with likely exacerbation, possible CAP, likely medical non compliance
RESPIRATORY FAILURE	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)	PFIZER\BIONTECH	1262151-1	After 1st dose of Pfizer: Nausea, and trouble breathing (Oxygen went up and down from 90 to 95) - Took to Dr and advise to watch oxygen levels After 2nd dose of Pfizer: Nausea, Dry heaves, Stomach Pain, Head Aches, Back Pain, Loosing Control of Bladder (Kidney Failure), Trouble Breathing (Oxygen went under 90) - Took to her Dr and she said to take her to the Emergency Room due to her Oxygen going below 90. I took her to Hospital.
RESPIRATORY FAILURE	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)	PFIZER\BIONTECH	1262668-1	Patient found unresponsive and transported to ED. Currently hospitalized and admitted with following issues: Present on Admission: ? Intraventricular hemorrhage (HCC) ? Bilateral thalamic hemorrhage ? Acute encephalopathy ? Abnormal eye movements ? Respiratory failure requiring intubation (HCC) ? Mucoid impaction of bronchi
RESPIRATORY FAILURE	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)	PFIZER\BIONTECH	1264347-1	4 days after vaccination, patient presented with dyspnea and chest pain, was found to have bilateral pulmonary emboli. Was admitted the following day after re-presenting with worsening symptoms and hypoxemic respiratory failure. He was hospitalized one day and then discharged.
RESPIRATORY FAILURE	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)	PFIZER\BIONTECH	1267218-1	Patient presented to the ED and was subsequently hospitalized within 6 weeks of receiving COVID vaccination. Date of service was 4/2/21 and patient is still currently hospitalized. Diagnosis is acute hypoxemic respiratory failure due to COVID 19.
RESPIRATORY FAILURE	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)	PFIZER\BIONTECH	1267468-1	patient received her covid vaccine per her record: 1/3 and 1/24/21. Patient presented to Facility 4/20/21 diagnosed with COVID, patient died 4/23/21 due to hypoxic respiratory failure/ bilateral pneumonia due to covid.
RESPIRATORY FAILURE	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)	PFIZER\BIONTECH	1270874-1	Patient experienced progressive facial palsy and ophthalmoplegia, respiratory failure requiring intubation. possible diagnosis of Guillain-Barre syndrome, likely Miller-Fisher +/- Bickerstaff variant. Still in hospital

Symptoms	Vaccine	Vaccine Manufacturer	VAERS ID	Adverse Event Description
RESPIRATORY FAILURE	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)	PFIZER\BIONTECH	1272164-1	"46 year old male with history of depression, polio, HTN/HLD, chronic lung disease 2/2 remote PNA, and cirrhosis suspected 2/2 schistosomiasis, who presents with 1wk of dyspnea, w/ waxing waning subjective fevers. Per ED Note: Endorses chronic fatigue until 4/16 when he received first dose of Covid vaccine (Pfizer). Since then, pt reports persistent dyspnea, worsening fatigue. Reports 2 days of left-sided chest pain w/ periumbilical abd pain and enlarging abdomen. Pt believes these are 2/2 covid vaccination. Chest pain is described as constant generalized discomfort under left breast that worsens with pressure. Also worse with deep inspiration. No radiation or migration since onset. Pt describes abdominal pain as periumbilical tightness, ""pain"". Describes subjective, unmeasured fevers that ""come and go"" over last week. When asked to repeat the story of what happened on arrival to the unit, wife speaks for the patient since he is slightly dyspnic. States this morning, went to small clinic, husband had a headache and slight fever. Clinic said to come in to the big hospital. Fever and pain in legs and head, started a few days after he got the covid vaccine. The fever came and went. Didn't measure the fever. Also has some problems with Abdominal pain - doesn't know how to describe it. Feels like stomach ache. Stomach pain is getting better. Has since gone away since arriving to the hospital. He denies any cough, denies chills, denies nausea or vomiting. States he took some medications at home for constipation because he felt like he couldn't go. From the conversation it appears he does not take lactulose for HE, more for constipation. ED workup included an Xray, CT C/A/P with multifocal lung lesions suspicious for multifocal pneumonia. Lactate of 16. Na of 124. Noted to be anemic and thrombocytopenic. UA cloudy, pyuric, w/protien >100. Chest and abdominal pain resolved by the time pt was examined on the floor. Still tachypnic and tachycardic. Stated most bothersome was feeling anxious. Has anxiety at a baseline. Not complaining of any pain at the moment. Cannot describe chest pain in more detail, put his hand over the right side of his chest and presses on it but does not say if it hurt more when he would press on it, does not say it was reproducible. Not painful when he touches or presses on it now. Per chart, patient recently re-established care after long-time from follow up during pandemic. At visits last month c/o gingival bleeding, fatiguem & found to have Hgb drop from 13 in 2018-> 9.7 on 3/2/21. Referred for EGD but cancelled due to anxiety. I am the Infectious Diseases attending asked to see him for septic shock. He developed septic shock and respiratory failure requiring mechanical ventilation and 3 vasopressors. He has evidence of DAH, DIC, acute renal failure, progressive liver failure and he has Klebsiella pneumoniae bacteremia."
RESPIRATORY FAILURE	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)	PFIZER\BIONTECH	1274702-1	presented to the ER with complaints of abdominal pain. Found to have a ruptured appendix with intra-abdominal abscess, UTI, acute hypoxic respiratory failure related to bilateral aspiration pneumonia, and sepsis. Principal Problem: Perforated appendix POA: Unknown Active Problems: Sepsis (CMS/HCC) (HCC) POA: Yes
RESPIRATORY FAILURE	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)	PFIZER\BIONTECH	1290132-1	"4/10/21-Patient presented to an outlying hospital ED w/acute N/V/D and abdominal pain. She was found to have pancreatitis and was found to be SARS-CoV-2 with screening for admission. She had a history of symptomatic COVID with a positive NP swab 1/2/21. Because the patient had no respiratory symptoms she was considered ""asymptomatic."" She rapidly progressed to having severe necrotizing pancreatitis. She was transferred to tertiary care center where she remains hospitalized. Her hospitalization has been complicated by acute hypoxic and hypercapnic respiratory failure requiring intubation x 24 hours. She had mental status changes and an MRI revealed posterior reversible encephalopathy syndrome, acute kidney injury, splenic vein thrombosis -parital occlusion."
RESPIRATORY FAILURE	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)	PFIZER\BIONTECH	1292715-1	Client has a history of former tobacco abuse, CAD, DVT on apixaban, PAD s/p stenting, COPD, end-stage interstitial lung disease, chronic hypoxic respiratory failure (4L), sepsis complicated by aorto-embolic lower extremity thrombosis ultimately requiring L BKA, aorto-embolic RUE embolism treated with thrombectomy, RLE stent thrombosis while on anticoagul ation, GERD, steroid-induced diabetes, C difficile colitis, stress-induced cardiomyopathy. Client presented to the Emergency Room with shortness of breath, fever, and respiratory failure in the setting of COVID-19 and severe underlying pulmonary illness. Admitted with: Severe COVID-19 bronchopneumonitis
RESPIRATORY FAILURE	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)	PFIZER\BIONTECH	1302209-1	death from covid 3 months after completing series
RESPIRATORY FAILURE	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)	PFIZER\BIONTECH	1306598-1	Pt came to ER with nausea, vomiting, difficulty breathing. Pt was coughing up blood O2 sat 90 room air initially then down to low 80's. Put on high flow 10 L nasal cannula. Diagnosis hypoxia, dyspnea at rest, pericarditis, elevated troponin 35. Transferred to second hospital. Update from them : likely myopericarditis with cardiogenic shock, respiratory failure, diffuse ST elevation on EKG, on Inotropes
RESPIRATORY FAILURE	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)	PFIZER\BIONTECH	1307456-1	history of hypertension, mild cognitive impairment. Prior COVID pneumonia treated as an outpatient November 2020. Completed dose 2 of Pfizer vaccine 4/11 with progressive fatigue low-grade fevers and white count of 14 CRP elevated at 4 (see this would equate to a CRP of 40 with most other lab references) on 04/27. He was admitted and treated for community-acquired pneumonia with ceftriaxone and azithromycin. He was discharged 04/30 and then presented again 5/5 with progressive right greater than left consolidative ground-glass opacities and hypoxemic respiratory failure requiring up to FiO2 80% of high-flow nasal cannula. Infectious workup has been negative. He has been too unstable to bronch. COVID-19 testing has been negative. He was started on high-dose steroids 5/8 with stability and

Symptoms	Vaccine	Vaccine Manufacturer	VAERS ID	Adverse Event Description
RESPIRATORY FAILURE	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)	PFIZER\BIONTECH	1310517-1	Pneumonia due to COVID-19 virus Chronic respiratory failure with hypoxia (CMS/HCC) Shortness of breath remdesivir
RESPIRATORY FAILURE	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)	PFIZER\BIONTECH	1311276-1	Pneumonia due to COVID-19 virus ED to Hosp-Admission Discharged 4/14/2021 - 4/22/2021 (8 days) Last attending ? Treatment team Maxillary fracture Principal problem Final Summary for Deceased Patient Admission Date: 4/14/2021 Discharge Date: 4/22/2021 Final Diagnosis Principal Problem: Maxillary fracture (CMS/HCC) Active Problems: Pneumonia due to COVID-19 virus Demand ischemia (CMS/HCC) Dyslipidemia Essential hypertension Acute kidney injury (CMS/HCC) Glomerulonephritis, IgA Lactic acidosis Septic shock (CMS/HCC) Cytomegalovirus (CMV) viremia (CMS/HCC) Acute respiratory failure with hypoxia (CMS/HCC) Left femoral vein DVT (CMS/HCC) Malnutrition (CMS/HCC) Hypothermia DETAILS OF HOSPITAL STAY Presenting Problem/History of Present Illness/Reason for Admission Hypoxia [R09.02] Acute respiratory failure with hypoxia (CMS/HCC) [J96.01] Fall, initial encounter [W19.XXXA] COVID-19 [U07.1] COVID-19 virus infection [U07.1] Hospital Course Patient is a 72-year-old female with past medical history of hypertension, hyperlipidemia, recent hospitalization due to CMV viremia and an AKI and myelosuppression. Who presented to the emergency room after a fall in her house on 4/14. She had significant face pain and was hypoxic with an O2 saturation of 68% on room air on presentation. She was then found to be Covid positive. Initially admitted to the medical floor however required increasing amounts of oxygen and was ultimately transferred to the ICU on 4/16. She was maintained on nonrebreather oxygen until the evening of 4/21 when she was intubated and increasing vasopressor requirements. Given her worsening condition, her husband elected to palliatively extubate and pursue comfort care. Time of death was 10:02 AM on 4/22/2021. Disposition of the body: morgue
RESPIRATORY FAILURE	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)	PFIZER\BIONTECH	1317283-1	"""Pfizer-BioNTech COVID-19 Vaccine EUA"" - patient admitted with Covid-19 after 2 doses of vaccine (2/18/21 and 3/11/21) 81F history of diabetes mellitus, HTN admitted to hospital 4/6/21 with septic shock, hypothermia, COVID+ pneumonia, pseudomonas bacteremia and AVN blockade. Patient had been having worsening lethargy, dry cough (only associated with eating), and right axilla pain for 1-2 days. Found to be hypoxic with nadir O2 saturation 87% on 4/6/2021 (day of admission). COVID-19 positive test on 4/6/2021. No sick contact reported."
RESPIRATORY FAILURE	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)	PFIZER\BIONTECH	1317615-1	16-year-old medically complex female, JIA, bronchiectasis and chronic nighttime oxygen requirement who presented to the hospital on 5/6 with fever, increased stool output, and perianal skin breakdown. Her course was complicated by respiratory failure (requiring ICU admission for CPAP), pancytopenia, diarrhea with buttock skin breakdown requiring rectal tube for wound and stool management, and extensive workup which was unrevealing for an infectious cause. She clinically improved with respect to pancytopenia with discontinuation of felbamate, and completed a treatment course with Zosyn for suspected buttock SSTI.
RESPIRATORY FAILURE	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)	PFIZER\BIONTECH	1323749-1	5/2/21 Pt was hospitalized for 2 days for COVID is a 89 y.o. male patient of , MD with history of steroid and oxygen dependent COPD with chronic hypoxic respiratory failure on 6 L, coronary artery disease, gout, hypertension, hyperlipidemia, BPH, and recent exacerbation of his COPD who presents with fevers, body aches, generalized weakness for 5 days found to have COVID-19 infection Acute on chronic hypoxic respiratory failure Due to COVID-19 infection. On home requirement of 6L NC. Expect he may have a milder course given vaccinated status (though not fully vaccinated until 5/7/21). Update 05/4/2021 Patient stated that he feels that he is back to his baseline Currently on 6 L nasal cannula oxygen His sats was~98 %t rest, with no evidence of respiratory distress Covid-19 Virus Infection Date of onset of symptoms: 4/28/21, Symptoms present on admission: fevers, myalgias, dyspnea, weakness Date of covid positive test: 5/2/21 Vaccination status: vaccinated on 4/1 and 4/23/21 but had exposure on 4/22/21 Imaging: CXR with low lung volumes with bronchovascular crowing and strandy bibasilar pneumonia with small pleural effusions Oxygen requirements on admission: 6L Current oxygen requirements: 6L Medical therapy: Received x3 doses of remdesivir while in the hospital, will complete total 10 days of dexamethasone treatment Consultants following: pulmonary Anticipated special isolation end date: 5/8/21 Generalized weakness Due to above issues -PT/OT consults COPD with chronic hypoxic respiratory failure GOLD grade 3, group D, follows with Dr. as an outpatient and recently completed a course of prednisone taper and augmentin on 5/1/21.Chronically declines PFTs in the past. He is on chronic prednisone at 5mg daily and uses 4-6L NC continuously at home. Pneumovax 2010, prevnar 2015. -Continue home spiriva, symbicort, singulair, and albuterol MDI 4x daily -ST consulted, recommended chopped/NDD 3, thin liquids -Discharge home to complete total 10 days of dexamethasone -Can restart his home prednisone afterwards

Symptoms	Vaccine	Vaccine Manufacturer	VAERS ID	Adverse Event Description
RESPIRATORY FAILURE	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)	PFIZER\BIONTECH	1324453-1	pt received pfizer #2 on 2/20. on ~3/7 family noticed that he was waking up at night more than his usual. They noticed that the patient was more lethargic and was starting to have visual hallucinations. Reportedly, the patient never endorsed any fevers or chills, neither did he complain of headaches. He also reported that the patient had been having a nonproductive cough since 3/3, constipation around this time. he was admitted 3/10 with altered mental status, respiratory failure s/p intubation. difficult LP, no cell count, had elevated protein. hospital course complicated by delirium, gout flare. he was empirically treated with broad spectrum abx bacterial and viral meningitis, completed 5/6, without significant improvement in mental status. repeat LP concerning for possible autoimmune encephalitis, started on steroids.
RESPIRATORY FAILURE	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)	PFIZER\BIONTECH	1324469-1	Pt received vaccination on 05/13. The following day developed fever. On 05/15 she developed sore throat and vomiting. Her sore throat progressed where she could not speak or talk. She was seen in the ER and in respiratory failure. She was intubated and developed septic shock. Labs notable for WBC 0.1, platelets 32. INR elevated at 2.2. She had renal failure and shock liver and evidence of DIC. Blood cultures grew gram negative rods. She eventually died from septic shock.
RESPIRATORY FAILURE	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)	PFIZER\BIONTECH	1324803-1	Patient received first COVID19 Pfizer vaccine on 4/18. At that time, had about 3 days of cough and chest tightness. Subsequently began having neck pain on 5/8 and received second Pfizer vaccine on 5/9. Then began having fevers (Tmax 103F), cough. Admitted to Hospital on 5/15 with respiratory failure and shock. Unclear etiology of pneumonia vs multisystem inflammatory syndrome in children (MIS-C). Did not initially respond to antibiotics so treatment for MIS-C was initiated. Now slowly improving but still hospitalized.
RESPIRATORY FAILURE	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)	PFIZER\BIONTECH	1330699-1	Vaccinated for COVID-19 with Pfizer on 3/11/2021 and 4/16/2021, tested positive for Covid-19 by PCR on 5/12/2021. Entered emergency department with complaints of knee pain on 5/14/2021 (knee aspiration done 5/12/2021). Also noted to have Covid-19 pneumonia and hypoxemic respiratory failure and was admitted to hospital.
RESPIRATORY FAILURE	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)	PFIZER\BIONTECH	1333885-1	ED to Hosp-Admission Discharged 5/4/2021 - 5/10/2021 (6 days) Treatment team COVID-19 Principal problem Hospital Course HPI: Please see H&P for details Hospital Course: 76-year-old gentleman was admitted to hospital because of COVID-19 pneumonia and respiratory failure with hypoxemia secondary to it. He was placed on oxygen which was titrated. He was started on remdesivir and finished the course. Initially his condition got worsened and ID was consulted and he was given Tocilizumab. He also was started on dexamethasone from day 1. His condition has improved significantly. He is requiring 2 L of nasal cannula. At this point he is going to finish his course of dexamethasone as outpatient and he will be discharged home with oxygen. He was also educated about proning and he is very good at this. He also had remote patient monitoring arranged. He is going to follow-up with his PCP. Admission Diagnosis Medical Problems Hospital Problems POA * (Principal) COVID-19 Yes Depressive disorder Yes Type 2 diabetes mellitus (CMS/HCC) Yes Chronic lymphoid leukemia in remission (CMS/HCC) Yes Pneumonia Unknown Acute respiratory failure with hypoxia (CMS/HCC) Yes
RESPIRATORY FAILURE	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)	PFIZER\BIONTECH	1336930-1	Patient presented to the ED on 4/22/21 and was subsequently hospitalized within 6 weeks of receiving COVID vaccination. Diagnoses were: Severe sepsis (HCC) due to pneumonia causing acute on chronic hypoxic respiratory failure and hypotension that resolved with fluids. He also presented to the ED on 5/13/21 and was subsequently hospitalized for sepsis secondary to UTI.
RESPIRATORY FAILURE	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)	PFIZER\BIONTECH	1341523-1	Post vaccine #2 on 5/18 he developed hives, shortness of breath and reportedly did not feel with fatigue. Symptoms worsened and he was admitted to ICU on May 21st via the ED for multiorgan failure including respiratory failure with R pneumonia, Shock, Renal failure, Disseminated intravascular coagulation, shock liver failure requiring invasive vent support and treatment for septic shock including vasopressor support and antibiotic therapy. He was started on CRRT on the 22nd. His INR continues to rise and Hb dropping consistent with worsening DIC. Blood cultures are positive for MRSA. He will likely die from progressive septic shock and MSOF.
RESPIRATORY FAILURE	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)	PFIZER\BIONTECH	1343269-1	She got her vaccine in the left arm, and felt fine. She went shopping in the store and noticed that she was short winded when she was leaving, but felt that it was possibly asthma and left. She had a temperature between 102 and 103 for a couple of days and having fever and chills as well. She continued with the shortness windedness, and had company and on 5/9/21 they left and she started having severe pain, felt like it was either on the right side kidney or the lung, and was spasming horribly and knocking her down with the pain. She went to the ER and they did a CAT Scan thinking it was kidney stones, but told her that she had three blood clots in her lungs, lower base right and lower base left and mid right and part of her lung has apparently died due to this. They put her on blood thinners, Xarelto. She was admitted on 5/10 early morning and released on 5/12/21. The doctor in the hospital said that it did not make sense that she had blood clots in her lungs, but nothing in her legs. She told her that she was short winded, and he told her to report her reaction. Since being home she has been coughing a lot due to possibly the blood clots. She was told that she will be on the Xarelto for a very long time. She was also informed that she had lymph node enlargement as well.

Symptoms	Vaccine	Vaccine Manufacturer	VAERS ID	Adverse Event Description
RESPIRATORY FAILURE	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)	PFIZER\BIONTECH	1347439-1	3/9 MHN, admitted day after covid vaccine with weakness/SOB. Patient with history of small cell lung cancer metastatic on chemotherapy, COPD, diabetes, Sjogren's who presents with shortness of breath, confusion, and generalized fatigue as well as fall 1 week ago found to have recurrent pleural effusion, T7 fracture, new metastases, UTI. Shortness of breath: Suspicion is that this is related to malignancy plus effusion. Shortness of breath markedly improved after removal of Transudative fluid, 470cc obtained on thora 3/10 with cytology negative. Encephalopathy: Daughter notes that she has been more confused. The patient is off on her timeline of details. CT shows no evidence of brain metastases nor does recent MRI. Chronic hypoxemic respiratory failure: Patient is on 3 L of oxygen at baseline and she is currently at baseline. Generalized weakness: Her neuro exam is nonfocal aside from her confusion of timeline. CT and MRI have been unremarkable. I discussed her T7 fracture with spine surgery who recommends CT of entire spine which showed additional metastases. Patient has no pain and has declined the need for brace. Metastatic small cell lung cancer: Patient admits that she does not like to talk much about the big picture however her daughter at bedside did speak with me outside the room and understands that she may have a poor prognosis. UTI: With increased frequency/urgency/incontinence. There is trace leuk esterase on UA. She has been on ceftriaxone but urine culture showing 80,000 colonies of Enterococcus. Changed to vancomycin. I discussed with the microbiology lab who stated that sensitivities would not be available until 3/13. Discharged with sensitivities pending initially with plan for amoxicillin but given interaction with methotrexate change to Macrobid. Normocytic anemia: Likely related to malignancy and chemotherapy. No blood loss has been noted. She received 1 unit RBCs prior to discharge.
RESPIRATORY FAILURE	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)	PFIZER\BIONTECH	1350978-1	78y.o. male with a past medical history of COPD, DM II, and HTN who presented to the hospital's emergency department from an extended care facility. Patient was recently hospitalized and treated with IV antibiotics for HCAP. Patient tested positive for COVID on 3/24/2021. EKG was negative for ischemic signs but patient had an elevated troponin. CXR showed right pleural effusion. Patient was admitted with COVID-19 pneumonia and severe respiratory failure. Patient's oxygenation continued to deteriorate despite Remdesivir, decadron and lovenox. Patient went into respiratory failure and expired from progressive respiratory failure.
RESPIRATORY FAILURE	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)	PFIZER\BIONTECH	1355806-1	My father received his vaccines through the hospital, on 1/23/21 and 2/13/21. The week of April 17, 2021, he started with diarrhea and cough. He spoke with his PCP and was told to quarantine and report any worsening symptoms. Wednesday or Thursday he began with vomiting and unable to hold down any fluids. His cough was nonproductive. On Saturday 4/17/21 he reported to Hospital ER with SOB, cough, vomiting & diarrhea. He was diagnosed with COVID PNA. He passed away 5/7/21 of COVID PNA, respiratory failure. He tested positive the week of 5/7/21 again of COVID 19. I feel this needs to be reported as he had both PFIZER vaccines in January & February and still ended up intubated and deceased from COVID 19.
RESPIRATORY FAILURE	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)	PFIZER\BIONTECH	1361131-1	s/p 2 doses of Covid-19 vaccine. Pt presented for weakness, SOB, fatigue progressive over the past month prior to admission. Found to be pancytopenic with bone marrow biopsy consistent with MDS. He was started on chemo but stay was complicated by neutropenic fevers, epistaxis, retinal hemorrhage, AKI, fluid overload, hypoxic respiratory failure, atrial fibrillation with RVR, and shock. He ultimately had a heart attack while admitted and was transitioned to comfort care after medical interventions could not stabilize hemodynamics.
RESPIRATORY FAILURE	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)	PFIZER\BIONTECH	1361447-1	Patient developed cough about one month after the second dose of his vaccine. He does not have history of underlying lung disease. His CT scan showed diffuse ground glass appearance. Developed progressive and rapid respiratory failure. He was admitted to hospital on 5/13 and expired 5/30.
RESPIRATORY FAILURE	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)	PFIZER\BIONTECH	1367547-1	death D69.6 - Thrombocytopenia, unspecified Respiratory failure Intercranial mass
RESPIRATORY FAILURE	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)	PFIZER\BIONTECH	1368313-1	COVID-19 - patient admitted for 5 days of shortness of breath. Tested COVID+ upon admission, Received vaccine in March. Patient admitted 5/25, still inpatient but improving. Allergies (drug/food and reaction):NKDA Date of Vaccination:02/03/2021 and 02/25/2021 Dose: 1 and 2 Vaccine Manufacturer: Pfizer Lot #: 1st dose 2/3 Lot # EL9269 2nd dose 2/25 Lot # EN6203 Clinic Administering Vaccine: Healthcare Injection site: L deltoid Description of event/reaction: Pt was hospitalized for COVID-19 after receiving vaccination Date of Clinic Visit or Hospitalization: 5/24/2021 Reason for clinic visit or hospitalization: hypoxia COVID-19 positive test result: Yes ; if Yes, date 5/22/2021 Plans to monitor (include medications if prescribed):Treatment with dexamethasone, remdesivir, tocilizumab

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RESPIRATORY FAILURE	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)	PFIZER\BIONTECH	1381212-1	Hypoxic respiratory failure; pneumonia; Stomach cramps; Could not breathe well; She had back problems; COVID-19; COVID-19; This is a spontaneous report from a contactable consumer (patient's husband). A 65-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 2 via an unspecified route of administration, administered in Arm Left on 07Mar2021 (Lot Number: EN6206) at the age of 65 years, as single dose for covid-19 immunisation. Medical history included back disorder from an unknown date and unknown if ongoing. The patient's concomitant medications were not reported. Previously the patient received the first dose of bnt162b2 on 14Feb2021 at the age of 65 years, lot number: ENG201, injection in arm, possibly in left arm: patient had no problems with the first shot. The patient experienced covid-19 (death, medically significant) on 07Mar2021, hypoxic respiratory failure (death, hospitalization) on 08Mar2021, pneumonia (death, hospitalization) on 08Mar2021, stomach cramps (non-serious) on an unspecified date with outcome of unknown, could not breathe well (non-serious) on an unspecified date with outcome of unknown, she had back problems (non-serious) on an unspecified date with outcome of unknown. Patient went to Emergency Room (ER) 8 hours later administration of the second dose and on 08Mar2021 was admitted to hospital. Patient was in hospital from 08Mar2021 till she died. Patient was positive for covid 19 on unknown date. She was diagnosed with covid when she went to ER. Patient was on a ventilator. The patient underwent lab tests and procedures which included endoscopy: gerd or abdomen problem on unspecified date, COVID test: positive on unknown date. Therapeutic measures were taken as a result of hypoxic respiratory failure and pneumonia (on ventilator). The patient died on 16Apr2021. An autopsy was not performed. It was stated that cause of death on death certificate listed as Covid 19, pneumonia, hypoxic respiratory failure. Follow attempts are needed. Further information is expected; Reported Cause(s) of Death: COVID-19; Drug ineffective; pneumonia; Respiratory failure
RESPIRATORY FAILURE	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)	PFIZER\BIONTECH	1381906-1	Vaccine recieved 5/11/21 5/19/21 Presented to ED with respiratory failure. Noted bilateral ground glass opacity, respiratory failure 5/25/21 Intubated for respiratory failure with ARDS 5/30/21 Deceased
RESPIRATORY FAILURE	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)	PFIZER\BIONTECH	1385879-1	Myasthenia gravis exacerbation causing respiratory failure and intubation. Today is day 12 of symptoms. She also has profound weakness from her myasthenia gravis. Treated with intubation, high dose steroids, and increased pyridostigmine.
RESPIRATORY FAILURE	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)	PFIZER\BIONTECH	1386076-1	6/8/21 -Presented with respiratory failure requiring intubation about 12 hours after 2nd dose of COVID-19 vaccine. Desaturated to the low 80's despite oxygen. Febrile to 38.8 after admission and had several breakthru seizures requiring loading doses of Keppra. 5/17/21-Had event of tachycardia into the 140s, and slight fever of 100.6, and 8 minute seizure after 1st dose.
RESPIRATORY FAILURE	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)	PFIZER\BIONTECH	1391226-1	My brother started with some swelling in the legs/feet, followed by chest pains that led him into a heart attack, followed by cardiac arrest. He was shocked back to life where he lay in a coma. His kidneys stopped functioning followed by his lungs and liver?he was kept alive on life support and dialysis, he died after having 4 more heart attacks back to back on June 4, 2021.
RESPIRATORY FAILURE	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)	PFIZER\BIONTECH	1395974-1	Stage IV COPD with chronic hypercarbic and hypoxic respiratory failure. He is quite physically declining at this time. He is constantly anxious from breathlessness. Since the pulmonary prognosis is much worse, I will recommend palliative care consult to explore his options. COPD cachexia. Very poor prognostic sign. Increased chest pain, dizziness, no COPD exacerbation since October 2020. Now hospice patient. Oxygen dependence Right upper lobe lung mass consistent with malignancy Respiratory failure: hypoxic and hypercapnia Pulmonary cachexia Chronic anxiety
RESPIRATORY FAILURE	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)	PFIZER\BIONTECH	1402395-1	"2 days after vaccine developed diarrhea & body aches, then loss of smell and appetite. ED visit 4/8/2021, lymphopenia noted, COVID PCR positive. Returned to ED 4/11/2021 with SOB, oximetry low 70s, cyanotic, respiratory distress, elevated D dimer, CXR: COVID pneumonitis. ""Deteriorated quickly despite maximal medical management"" per Discharge Summary. Died 4/24/2021 from hypoxic respiratory failure and multiorgan failure, shock. Had also developed heparin induced thrombocytopenia during treatment for DVT Right lower and upper extremities."
RESPIRATORY FAILURE	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)	PFIZER\BIONTECH	1407084-1	"Component Results: Component Your Value Standard Range Flag; Troponin T, 2 hr., 5th gen 1923 ng/L<=10 ng/L<=10 ng/L H; Consider acute myocardial injury 2H Delta 862 ng/L ng/Lng/L;2H Delta Interp Changing Evaluate for acute myocardial injury; Troponin T, 6 hr., 5th gen; 2104 ng/L; <=10 ng/L<=10 ng/L H; Consider acute myocardial injury; 6H Delta SEE COMMENT ng/L ng/Lng/L; Test cancelled. Specimen not received within delta timeframe.; 6H Delta Interp SEE COMMENT; Test cancelled. Specimen not received within delta timeframe. General Information-Ordered by, M.D., Ph.D._____ Your Admission - 03/30/21Printer friendly page--New window will open-Admission Summary-Notes-Clinical Notes H&P by M.D., Ph.D. at 3/30/2021 3:55 AM-Status: Signed-CARD 3 Admission Note-SUBJECTIVE- CHIEF COMPLAINT= Chest pain. HISTORY OF PRESENT ILLNESS Patient is a 56 y.o. female who presented to the Emergency Department due to chest pain. She has experienced this pain each evening for the past 3 evenings, and states that it starts in her right arm then migrates through her shoulder and across to her chest. The pain can last for anywhere from 5 minutes to 4 hours. This has come on at rest, but in the setting increased personal life stressors as well as uncontrolled hypertension. She states that she is normally on hydrochlorothiazide for hypertension, but ran out of this medication about a

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				week ago. When she checked her blood pressure at home it was in the 230s/120s, therefore she presented to the emergency department locally. Her medical comorbidities are notable for poorly controlled hypertension, mixed hyperlipidemia that is untreated, current tobacco use (1-2 packs per day for 40 years), and medically complicated obesity. In the emergency department she was found to have mild polycythemia with hemoglobin of 15.2 and leukocytosis of 13.7. INR, D-dimer, and BMP were normal. High sensitivity troponin T was found to be 770 ng/L. ECG showed normal sinus rhythm with T-wave inversion in aVL that was not present on 08/25/2004. Chest x-ray was largely unremarkable. Her chest pain resolved, but given the elevated troponin ECG changes she was treated for NSTEMI with heparin infusion, and loaded with aspirin and clopidogrel and directly admitted to the Hospital Cardiology service. Upon arrival she remained free of chest pain but continued to have significant hypertension. I have reviewed and updated the following: Past Medical History, Family History, Social History, and Allergies. Current Outpatient Medications on File Prior to Encounter: hydrochlorothiazide (HYDRODIURIL) 25 mg tablet, Take 1 tablet (25 mg total) by mouth daily., Past Week at Unknown time; Lorazepam (ATIVAN) 0.5 mg tablet, Take 0.5 mg by mouth daily as needed for anxiety., More than a month at Unknown time. REVIEW OF SYSTEMS Pertinent items are noted in HPI; all other review of systems was negative. OBJECTIVE VITAL SIGNS Temperature: [36.8 ¦C-36.9 ¦C] 36.9 ¦C; Heart Rate: [83-117] 83; Resp Rate: [20-26] 22; Blood Pressure: (164-195)/(81-129) 164/106; SpO2:[92 %-97 %] 95 %;Weight: [104 kg-106 kg] 104 kg; Pulse Rate: [90-109] 94. PHYSICAL EXAM General: Alert, oriented, no acute distress; HEENT: Mucous membranes moist, JVP difficult to assess due to body habitus; CV: Regular rate and rhythm without murmur; Lungs: Clear to auscultation bilaterally; Abdomen: Obese, soft, nontender, nondistended, normoactive bowel sounds; Extremities: No peripheral edema appreciated; Neuro: No focal deficits appreciated. DIAGNOSTICS I have reviewed labs and imaging from the past 24 hours. ASSESSMENT / PLAN Patient is a 56 y.o. female who was directly admitted to the Cardiology Service from Emergency Department due to NSTEMI and poorly controlled hypertension. She also has untreated mixed hyperlipidemia and is a current smoker. We will continue to trend troponins and treat NSTEMI was heparin infusion, aspirin, and clopidogrel. I will start a statin and initiate low-dose lisinopril and carvedilol for blood pressure control with plans to up titrate as tolerated. I will update a lipid panel in checked for diabetes. I will obtain a TTE in the morning and keep her NPO for probable coronary angiogram pending negative COVID swab. #1 Non-ST Elevation Myocardial Infarction; #2 Poorly controlled systemic hypertension; #3 Mixed hyperlipidemia, previously untreated; #4 Medically complicated obesity (BMI 38-trend troponin- loaded with aspirin and clopidogrel- Aspirin 81 mg daily- clopidogrel 75 mg daily- moderate intensity heparin infusion- rosuvastatin 20 mg daily- lisinopril 2.5 mg daily, up titrate as tolerated- carvedilol 6.25 mg twice daily, up titrate as tolerated- holding home hydrochlorothiazide in lieu of lisinopril and carvedilol- lipid panel - hemoglobin A1c- TTE- NPO for probable angiogram (not-ordered)- cardiac rehab consult ordered;#5 Abuse Tobacco Smoking- nicotine patch- nicotine inhaler as needed- nicotine cessation consult; #6 Anxiety She is prescribed lorazepam 0.5 mg which she takes when she has a panic attack which only occurs a couple times per year. For now we will just monitor. Diet: NPO; Tubes/lines: PIV; VTE prophylaxis: heparin infusion; Code status: Full Code; Disposition: anticipate discharge to home when clinically stable. Counseling was provided face-to-face at bedside regarding the plan of care as stated above. I personally spent over half of a total 70 minutes in counseling and coordination of care as documented above. M.B.B.S. at 3/30/2021 10:58 AM Status: Signed. SUBJECTIVE HISTORY OF PRESENT ILLNESS Patient is a very pleasant 56-year-old female who is owner of multiple nursing facilities who presented with chest pain and hypertensive emergency. She ran out of her hydrochlorothiazide last week, was fairly busy managing all her nursing homes with COVID pandemic and vaccination program. She was having intermittent chest pain, chest pressure radiating to the right arm. In this setting she checked her blood pressure, and it was noted to be 240 systolic over 140 diastolic. In this setting was sent to the ER and subsequently sent here. Initial troponin was 770. Subsequently, it went up to 1923. Delta was 862. ECG showed sinus rhythm with clear ST depression in the inferolateral leads. Patient currently is chest pain-free. She was initiated on carvedilol and restarted her home hydrochlorothiazide. Blood pressure is better. She had a good night's sleep. OBJECTIVE PHYSICAL EXAMINATION; Vital Signs: Noted.; General: Alert and oriented x3. Cardiac: S1, S2 normal.; Lungs: Clear.; Abdomen: Soft.; Extremities: No edema of feet.; Vessels: Peripheral pulses well-felt.; DIAGNOSTICS Creatinine is 0.7. Bicarb is 30. ASSESSMENT / PLAN Patient, is a 56-year-old female with obesity, hypertension, smoking, presented with hypertensive emergency. Blood pressure is better controlled now. She did have clear ST-T changes with troponin elevation, and we will treat it as NSTEMI at this point. Certainly, this can be demand ischemia in setting of hypertensive emergency, but she has multiple risk factors which would warrant coronary artery disease evaluation. We will plan for an angiogram today. We will get an echo today. Post that, we will reassess and see how things go. It appears that this was in setting of medication noncompliance. However, if this happens again, we may also look for other secondary causes of hypertension, especially with the fact that her bicarbonate was 30. All her questions were answered. DIAGNOSES: #1 Hypertensive emergency; #2 NSTEMI; #3 Obesity. M.B.B.S. DD: 03/30/2021 08:54:32 CT; DT: 03/30/2021 09:13:15 CT; Job ID: 914158020/mjb. Sedation Note by HCP at 3/30/2021 10:22 AM Status: Signed. INTERVAL HISTORY AND PHYSICAL PRE-PROCEDURE UPDATE H&P reviewed. The patient was examined and there are no significant changes to the H&P. PRE-SEDATION ASSESSMENT Consent Consents Obtained: written. The benefits, risks and alternatives to the procedure and the potential need for sedation or anesthesia as well as the names, roles, and responsibilities of healthcare team members

Symptoms	Vaccine	Vaccine Manufacturer	VAERS ID	Adverse Event Description
				performing significant interventional tasks were discussed with the patient and/or decision maker: yes. Indications / Reason for Visit. Procedure / Reason for Visit: coronary angiogram with possible intervention. Presedation Assessment. The following portions of the patient's history were reviewed and updated as appropriate: allergies, current medications, family history, medical history, social history and problem list: Yes. Review of Symptoms pertinent ROS negative. Physical Exam Mallampati: II - soft palate, uvula, fauces visible. Assessment Plan ASA Physical Status: class 3 - patient with severe systemic disease Sedation Plan: moderate sedation. Patient seen, evaluated, and approved for sedation: yes. Cardiology Fellow 11053 Discharge Instr - Referrals / Follow-Ups by HCP at 3/30/2021 11:18 AM Status: Written Take a copy of this after visit summary to your appointment(s).---------- Monday, April 5th, 2021:-- 12:30 p.m. -- Hospital follow-up with Dr. primary care provider, at Medical Center---------- ---------- You may have outpatient appointments at Clinic that changed during your hospitalization. Refer to your Clinic Patient Visit Guide (PVG) for the most current schedule of appointments and detailed instructions of tests/procedures. Call, if you did not receive an PVG or need to CANCEL any Clinic appointment(s). H&P by HCP at 3/30/2021 12:33 PM; Status: Signed; CARDIOLOGY 3 H&P HISTORY OF PRESENT ILLNESS; Patient is a 56 yo F with history of hypertension, dyslipidemia, smoking history, and obesity who presents with chest pain, found to have NSTEMI. She owns and runs 4 assisted living facilities. In the past three days, she has had chest pain at rest following dinner, while sitting in the living room. It has lasted from minutes to hours and was relieved on its own. Yesterday she was prompted by her husband to present for medical attention. She has smoked 1-2 packs daily for the past 40 years. She is on hydrochlorothiazide 25mg daily for her blood pressure. Blood pressure was 171/129 here in the ED. Troponins rose from 770 to 1061 to 1923. Current Medications: [MAR Hold] acetaminophen tablet 1,000 mg (TYLENOL), Q6H PRN; acetaminophen tablet 1,000 mg (TYLENOL), TID PRN; [START ON 3/31/2021] aspirin chewable tablet 81 mg, Daily; [MAR Hold] aspirin DR tablet 81 mg, Daily; atropine injection 0.5 mg, Q5 Min PRN; bisacodyl suppository 10 mg (DULCOLAX), Daily PRN; [MAR Hold] calcium carbonate chewable tablet 400 mg of calcium (TUMS), Q2H PRN; carvedilol tablet 25 mg (COREG), BID with meals; [MAR Hold] Clopidogrel tablet 75 mg (PLAVIX), Daily; [START ON 3/31/2021] Clopidogrel tablet 75 mg (PLAVIX), Daily; docusate sodium capsule 100 mg (COLACE), BID PRN; fentanyl injection 25 mcg (SUBLIMAZE), Q2 Min PRN; fentanyl injection 25 mcg (SUBLIMAZE), Once PRN; flumazenil injection 0.2 mg (ROMAZICON), Once PRN; heparin (porcine) 1,000 unit/mL injection 3,200 Units, PRN **OR** heparin (porcine) 1,000 unit/mL injection 6,400 Units, PRN; heparin (porcine) 100 Units/mL in NaCl 0.45% 250 mL infusion, Continuous; [MAR Hold] lisinopril tablet 2.5 mg (PRINIVIL,ZESTRIL), Daily; Lorazepam injection 1 mg (ATIVAN), Once PRN; midazolam (PF) injection 0.25 mg (VERSED), Q2 Min PRN; midazolam (PF) injection 0.5 mg (VERSED), Once PRN; midazolam (PF) injection 0.5 mg (VERSED), Q2 Min PRN; midazolam (PF) injection 1 mg (VERSED), Q2 Min PRN; NaCl 0.9 % bolus 250 mL, Once; NaCl 0.9% infusion, Once PRN; naloxone injection 0.2 mg (NARCAN), Once PRN; naloxone injection 0.2 mg (NARCAN), PRN; MAR Hold] nicotine 10 mg inhaler 1 puff (NICOTROL), PRN [MAR Hold] nicotine 21 mg/24 hr. 1 patch (NICODERM CQ), Daily; ondansetron (PF) injection 4 mg (ZOFRAN), Once PRN;[MAR Hold] polyethylene glycol powder packet 1 packet (MIRALAX), Daily PRN; promethazine injection 6.25 mg (PHENERGAN), Q6H PRN; [MAR Hold] rosuvastatin tablet 20 mg (CRESTOR), Daily at bedtime; sodium chloride 0.9 % injection 10 mL, PRN; sodium chloride 0.9 % injection 3 mL, PRN; sodium chloride 0.9 % injection 3 mL, Q12H SCH. OBJECTIVE BP 143/83 | Pulse 71 | Temp 36.6 ¦C (Oral) | Resp 21 | Ht 165.1 cm | Wt 104 kg | SpO2 94% | BMI 38.19 kg/m¦. Intake/Output Summary (Last 24 hours) at 3/30/2021 1212. Last data filed at 3/30/2021 1130. Gross per 24 hour Intake 323.71 ml; Output 700 ml; Net-376.29 ml; GEN: Pleasant, no distress CV: Regular, no extra heart sounds, JVP is flat; PULM: Clear bilaterally; EXTR: No edema, strong R radial pulse ; ;EKG: NSR, nonspecific changes. ASSESSMENT / PLAN NSTEMI, s/p PCI to circumflex 3/30/21; Hypertension, uncontrolled; Nicotine dependence; Dyslipidemia; Obesity. She has an NSTEMI with significant elevation in her troponin. We will proceed with coronary angiography for this and anticipate PCI. We will intensify her antihypertensive regimen. Nicotine cessation is critical and we will consult our cessation specialists. We will refer her to cardiac rehab. DAPT for 1 year. Plan:1. Coronary angiography with intervention today; 2. High intensity statin, uptitrate carvedilol, keep lisinopril 2.5mg, restart hctz later this evening.; 3. Nicotine cessation referral. Cardiac rehab referral; 4. F/u TTE. Addendum: Angiography demonstrated her culprit lesion to be in the circumflex for which she received a 2.5 x 16 mm synergy stent. Mild disease elsewhere. She will require DAPT for one year. The patient was seen and discussed with the attending consultant, Dr. and PA. M.D. Cardiology fellow 3/30/2021 Consults by HCP at 3/30/2021 1:51 PM Status: Signed Consult Orders 1. Cardiac Rehabilitation consult (hospital) [2222776702510] ordered by M.D. at 03/30/21 1136; 2. Cardiac Rehabilitation consult (hospital) [2222776391034] ordered by M.D., Ph.D. at 03/30/21 0343 Cardiac Rehabilitation Referral. Reason for Visit: Cardiac Health Clinic consultation for referral to cardiac rehabilitation. Liaison met with the patient/family to discuss cardiac rehabilitation referral. Patient/family was provided with progressive verbal and printed home-going exercise guidelines. Patient/family understands and agrees with the exercise guidelines.1. Participation in a Phase II cardiac rehabilitation program is recommended. Patient was informed about what cardiac rehabilitation has to offer and why it is beneficial. The plan of care for the rehabilitation program consists of risk factor modification, monitored and supervised exercise and assistance in the recovery process with ongoing education and support

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				assistance in the recovery process with ongoing education and support. Patient is interested in attending a cardiac rehabilitation program.; 2. Eligibility: MI and PCI; 3. Exceptions/exclusions: None;.4. Referral: Patient agreed with referral to a cardiac rehabilitation program. Please see discharge order and/or letter for program details. Clinic Health System Phone:; 5. Appropriate referral information will be sent to the receiving cardiac rehabilitation program as applicable. Patient provided verbal authorization to send relevant materials to the cardiac rehab program. Recommend that the patient check with insurance company to verify coverage of the cost of cardiac rehabilitation program visits. Discharge Summary by PA at 3/31/2021 10:20 AMStatus: Addendium CARDIOLOGY HOSPITAL DISCHARGE SUMMARY DATE OF ADMISSION: 3/30/2021 DATE OF DISCHARGE: 3/31/2021 Discharge Provider: M.B.B.S. Discharge Provider Team: RST CARD 3 PRINCIPAL DIAGNOSIS Non-ST Elevation Myocardial Infarction. DISMISSAL DIAGNOSES #1 Non-ST Elevation Myocardial Infarction; #2 Poorly controlled systemic hypertension; #3 Mixed hyperlipidemia, previously untreated;#4 Medically complicated obesity (BMI 38); #5 Abuse Tobacco Smoking, Nicotine Dependence; #6 Anxiety. RECOMMENDATIONS FOR FOLLOW-UP APPOINTMENTS CBC and Basic metabolic panel; Cardiovascular risk factor modification; Cardiac rehabilitation participation (set up); Nicotine cessation; Blood pressure monitoring and management; Plavix for one year, aspirin lifelong; Assess right radial access site. *Statin Therapy Initiated: *A fasting lipid profile showed: Total Cholesterol 173 mg/dL, Triglycerides 218 mg/dL, HDL 39 mg/dL, LDL 90 mg/dL. *Baseline LDL is [ ] mg/dl. Please titrate to meet goal lipid levels.*Please recheck lipids and ALT/AST in 6 to 8 weeks.*Goal of statin therapy is a LDL less than 70 mg/dl or a 50% reduction in LDL. FOLLOW-UP APPOINTMENTS For appointment details refer to your Patient Appointment Guide. HOSPITAL COURSE Admission Weight: 104 kg; Dismissal Weight: 103 kg; BMI: Body mass index is 37.82 kg/m¦.Patient is a 56 y.o. female who presented to the Emergency Department due to chest pain. She has experienced this pain each evening for the past 3 evenings, and states that it starts in her right arm then migrates through her shoulder and across to her chest. The pain can last for anywhere from 5 minutes to 4 hours. This has come on at rest, but in the setting increased personal life stressors as well as uncontrolled hypertension. She states that she is normally on hydrochlorothiazide for hypertension, but ran out of this medication about a week ago. When she checked her blood pressure at home it was in the 230s/120s, therefore she presented to the emergency department locally. Her medical comorbidities are notable for poorly controlled hypertension, mixed hyperlipidemia that is untreated, current tobacco use (1-2 packs per day for 40 years), and medically complicated obesity(BMI 38.19 kg/m2). Intravenous heparin was initiated for the heparin nomogram. She was Plavix loaded and received aspirin. Carvedilol, lisinopril and Rosuvastatin were initiated. She proceeded to coronary angiogram with drug-eluting stent to the left distal circumflex artery. Transthoracic echocardiogram demonstrated ejection fraction 63%. Nicotine dependence was consulted and provided cessation information and prescriptions for nicotine replacement therapy. TEST RESULTS PENDING AT DISCHARGE :Pending Labs; None; DISCHARGE DISPOSITION: Home or Self Care [1]; CONDITION ON DISCHARGE: Stable. DIET AT DISCHARGE: Cardiac diet consisting of low sodium (1500 mg to 2000 mg per day), low cholesterol, low fat. No alcohol, (or discuss with physician).PRIMARY PROVIDER Patient Care Team:D.O. as External Primary Care Physician (Family Medicine) Primary Care Providers: Pcp (General); No address on file Primary Care Provider Phone Number: None Primary Care Provider Fax Number: None MARGIN CODE Operative Note Report Case/Log ID: 1507626443 Case Time: 10:44 AM Procedure Information CORONARY ANGIOGRAPHY Laterality N/A; Left Heart Catheterization Laterality N/A; Percutaneous Coronary Angioplasty Laterality N/A; Stent Placement Laterality N/A. Surgeons Surgeon Role M.D. Primary M.D. First Assistant, M.D. First Assistant, Diagnosis. Pre-op diagnosis: Non-ST Elevation Myocardial Infarction , Morbid Obesity Body Mass Index >= 35 with Comorbid Condition. Post-op diagnosis: Non-ST Elevation Myocardial Infarction , Morbid Obesity Body Mass Index >= 35 with Comorbid Condition. Anesthesia Type Moderate sedation (rn). Surgeon Documentation. No notes of this type exist for this encounter. Specimens None. Implants Implant Name LRB; Site No. Used; Manufacturer Mfr No.; Serial No.; Status; Type STNT SYNERGY XD DE 2.50X16 - LOG1507626443 N/A; Coronary Scientific H7493941816250 Implanted Cardiac Stent; Drains None Estimated Blood Loss None. Worsening shortness of breath COVID-19 positive on 06/06, Sxs started on 06/01 HPI: This is a 61 year old female who presents with complain of worsening Shortness of breath, COVID-19 positive PMHx Kidney transplant for glomerulonephritis, 1998, 2nd transplant in 2009 on Cellcept and prednisone and recurrent UTIs since then and since then when she gets UTI, she starts Cipro or Keflex HOCM myectomy 2009. Just saw yesterday. Denied CP/ SOB/ orthopnea/ cough/ leg swelling/ syncope/ PND. stated "" no gradients across LVOT. At acceptable risk for planned procedure. Afib in 2009, Legally blind, Gout, Hand amputation 2017 at work , Hip replacement Ventriculostomy - cyst removed 1999] Pt completed COVID vaccination series (Pfizer 2/25/21, 3/18/21) but has been on immunosuppression 2/2 renal tx. Her symptoms have been persistent since 6/1. She states that she has been having fever morning and evening, cough, fatigue. She states that over the past 1-2 days prior to presentation to the ED she has had hypoxia to 85-89% on home pulse ox and intermittent episodes of fever, pt reports worse dyspnea w/ ambulation. Pt called her nephrologist on 06/01 and recommended course of Amoxicillin w/out improved, given worsening and not improving sxs her nephrollogist recommended to presented to the ED, On arrival to the ED she was initially tachypnic with ambulation to the bed, but has since improved. On initial exam she is not in any acute respiratory distress. CXR showed finding of viral PNA. Creatinine 1.17 baseline < 1.0 Sodium 126 This is a 61 year old

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RESPIRATORY FAILURE	**COVID19 (COVID19 (UNKNOWN)) (1202)**	**UNKNOWN MANUFACTURER**	**1123504-1**	Pt received vaccine and two days later displayed reduced appetite, shortness of breath, chills, and cough productive of grayish thick sputum. Pt presented to hospital 5 days later (7 days after vaccination) with these symptoms, deemed to be in acute on chronic hypoxic/hypercarbic respiratory failure.

Note: Submitting a report to VAERS does not mean that healthcare personnel or the vaccine caused or contributed to the adverse event (possible side effect).

Notes:

Caveats: 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.

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. As part of CDC and FDA's multi-system approach to post-licensure vaccine safety monitoring, VAERS is designed to rapidly detect unusual or unexpected patterns of adverse events, also known as "safety signals." If a safety signal is found in VAERS, further studies can be done in safety systems such as the CDC's Vaccine Safety Datalink (VSD) or the Clinical Immunization Safety Assessment (CISA) project. These systems do not have the same limitations as VAERS, and can better assess health risks and possible connections between adverse events and a vaccine.

Key considerations and limitations of VAERS data:

- Vaccine providers are encouraged to report any clinically significant health problem following vaccination to VAERS, whether or not they believe the vaccine was the cause.
- Reports may include incomplete, inaccurate, coincidental and unverified information.
- The number of reports alone cannot be interpreted or used to reach conclusions about the existence, severity, frequency, or rates of problems associated with vaccines.
- VAERS data are limited to vaccine adverse event reports received between 1990 and the most recent date for which data are available.
- VAERS data do not represent all known safety information for a vaccine and should be interpreted in the context of other scientific information.

Some items may have more than 1 occurrence in any single event report, such as Symptoms, Vaccine Products, Manufacturers, and Event Categories. If data are grouped by any of these items, then the number in the Events Reported column may exceed the total number of unique events. If percentages are shown, then the associated percentage of total unique event reports will exceed 100% in such cases. For example, the number of Symptoms mentioned is likely to exceed the number of events reported, because many reports include more than 1 Symptom. When more then 1 Symptom occurs in a single report, then the percentage of Symptoms to unique events is more than 100%. More information. (/wonder/help/vaers.html#Suppress)

Data contains VAERS reports processed as of 06/18/2021. The VAERS data in WONDER are updated weekly, yet the VAERS system receives continuous updates including revisions and new reports for preceding time periods. Duplicate event reports and/or reports determined to be false are removed from VAERS. More information. (/wonder/help/vaers.html#Reporting)

For more information on how many persons have been vaccinated in the US for COVID19 to date, see https://covid.cdc.gov/covid-data-tracker/#vaccinations/ (https://covid.cdc.gov/covid-data-tracker/#vaccinations/)

Help: See The Vaccine Adverse Event Reporting System (VAERS) Documentation (/wonder/help/vaers.html) for more information.

Query Date: Jun 27, 2021 5:10:35 PM

Suggested Citation:

United States Department of Health and Human Services (DHHS), Public Health Service (PHS), Centers for Disease Control (CDC) / Food and Drug Administration (FDA), Vaccine Adverse Event Reporting System (VAERS) 1990 - 06/18/2021, CDC WONDER On-line Database. Accessed at http://wonder.cdc.gov/vaers.html on Jun 27, 2021 5:10:35 PM

Query Criteria:

State / Territory:	The United States/Territories/Unknown
Symptoms:	RESPIRATORY FAILURE; RESPIRATORY PARALYSIS
Vaccine Products:	COVID19 VACCINE (COVID19)
VAERS ID:	All
Group By:	Symptoms; Vaccine; Vaccine Manufacturer; VAERS ID
Show Totals:	False
Show Zero Values:	Disabled