SAMPLE VAERS RECORDS FROM THE "HEALTHY UNDER 40" CATEGORY

CRITERIA:

1. Less than 40 years of age (but excluding fetuses and babies)
2. Died within 30 days of injection (or not known)
3. Characterized by being in good health (eg. "healthy", "good shape",etc.)
4. Eliminate any record with most any comorbidity (including asthma, ADHD, obesity, but with the exception of very minor things such as allergies)

VAERS DETAIL

VAERS ID: 1820408

Vaccine Type	Vaccine	Manufacturer	Lot	Dose	Route	Site
COVID19	COVID19 (COVID19 (JANSSEN))	JANSSEN	Unknown	UNK		

Event Information			
Patient Age		Sex	M
State/Territory		Date Report Completed	
Date Vaccinated		Date Report Received	10/27/2021
Date of Onset		Date Died	
Days to Onset			
Vaccine Administered By	OTH	Vaccine Purchased By	
Mfr/Imm Project Number			
Recovered	N	Serious	

Event Categories	
Death	Yes
Life Threatening	No
Permanent Disability	No
Congenital Anomaly/Birth Defect	No
Hospitalized	No
Days in Hospital	None
Existing Hospitalization Prolonged	No
Emergency Room/Office Visit	No
Emergency Room	No
Office Visit	No

Symptoms
Death

Adverse Event Description

DIED DAYS AFTER THE SHOT; This spontaneous report received from a consumer via a company representative concerned a 35 year old male with unspecified race and ethnicity. The patient's height, and weight were not reported. The patient's pre-existing medical conditions included: The patient was healthy and an Olympian. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown) dose was not reported,1 total, start therapy date was not reported for prophylactic vaccination. The batch number was not reported. The Company is unable to perform follow-up to request batch/lot numbers. No concomitant medications were reported. On an unspecified date, the patient died days after the shot and the patient died from unknown cause of death. It was unknown if an autopsy was performed. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. This report was serious (Death).; Sender's Comments: V0: 20211048841-Covid-19 vaccine ad26.cov2.s-Died days after the shot. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).; Reported Cause(s) of Death: UNKNOWN CAUSE OF DEATH

Lab Data	Current Illness	Adverse Events After Prior Vaccinations

Medications At Time of Vaccination	History/Allergies
	Comments: The patient was healthy and an Olympian.

VAERS DETAIL

VAERS ID: 1948988

Vaccine Type	Vaccine	Manufacturer	Lot	Dose	Route	Site
COVID19	COVID19 (COVID19 (PFIZER-BIONTECH))	PFIZER\BIONTECH		2		

Event Information			
Patient Age		Sex	M
State/Territory	FR	Date Report Completed	
Date Vaccinated		Date Report Received	12/14/2021
Date of Onset	6/14/2021	Date Died	6/14/2021
Days to Onset			
Vaccine Administered By	OTH	Vaccine Purchased By	
Mfr/Imm Project Number			
Recovered	N	Serious	

Event Categories	
Death	Yes
Life Threatening	No
Permanent Disability	No
Congenital Anomaly/Birth Defect	No
Hospitalized	No
Days in Hospital	None
Existing Hospitalization Prolonged	No
Emergency Room/Office Visit	No
Emergency Room	No
Office Visit	No

Symptoms
Asthenia
Autopsy
Fatigue
Sudden death

Adverse Event Description

Death; reported fatigue and asthenia at all times; reported fatigue and asthenia at all times; This is a spontaneous report received from a contactable reporter(s) (Physician) from the Regulatory number: ES-AEMPS-1055416 (AEMPS). A 27 year-old male patient received bnt162b2 (COMIRNATY), administration date 2021 (Batch/Lot number: unknown) as dose 2, single for covid-19 immunisation. The patient's relevant medical history and concomitant medications were not reported. This is a previously healthy patient with regular medical check-ups as he belonged to the Navy, was a diver and a helicopter pilot. Vaccination history included: Comirnaty (1st dose), for Covid-19 immunisation. The following information was reported: SUDDEN DEATH (death) with onset 14Jun2021, outcome fatal, described as Death; FATIGUE (non-serious), ASTHENIA (non-serious) all with onset 2021, outcome unknown and all described as reported fatigue and asthenia at all times. He completed the complete vaccination schedule and reported fatigue and asthenia at all times. The patient underwent the following laboratory tests and procedures: autopsy: no macroscopic findings were observed, notes: but the histopathological study showed focal lymphocytic myocarditis and lymphoplasmacytic inflammatory foci in the bronchial submucosa, hepatic portal spaces, and gastroesophageal lamina propria. The patient date of death was 14Jun2021. The reported cause of death was sudden death. The autopsy revealed focal lymphocytic myocardites (myocarditis). No follow-up attempts are possible; information about lot/batch number cannot be obtained. No further information is expected.; Reported Cause (s) of Death: sudden death of undetermined cause; Autopsy-determined Cause(s) of Death: focal lymphocytic myocardites

Lab Data	Current Illness	Adverse Events After Prior Vaccinations
Test Name: autopsy; Result Unstructured Data: Test Result:no macroscopic findings were observed; Comments: but the histopathological study showed focal lymphocytic myocarditis and lymphoplasmacytic inflammatory foci in the bronchial submucosa, hepatic portal spaces, and gastroesophageal lamina propria		

Medications At Time of Vaccination	History/Allergies

VAERS DETAIL

VAERS ID: 1991633

Vaccine Type	Vaccine	Manufacturer	Lot	Dose	Route	Site
COVID19	COVID19 (COVID19 (JANSSEN))	JANSSEN		2	OT	

Event Information			
Patient Age		Sex	F
State/Territory		Date Report Completed	
Date Vaccinated		Date Report Received	12/30/2021
Date of Onset		Date Died	
Days to Onset			
Vaccine Administered By	UNK	Vaccine Purchased By	
Mfr/Imm Project Number			
Recovered	N	Serious	

Event Categories	
Death	Yes
Life Threatening	No
Permanent Disability	No
Congenital Anomaly/Birth Defect	No
Hospitalized	No
Days in Hospital	None
Existing Hospitalization Prolonged	No
Emergency Room/Office Visit	No
Emergency Room	No
Office Visit	No

Symptoms
Myocardial infarction

Adverse Event Description

MASSIVE HEART ATTACK; This spontaneous report received from a consumer via a company representative via social media concerned a 35 year old female of unspecified race and ethic origin. The patient's height, and weight were not reported. The patient was 100% healthy and never had any problems of any kind at the time of vaccination. On an unspecified date, the patient previously received covid-19 vaccine ad26.cov2.s (dose number in series: 1) (suspension for injection, route of admin, and batch number were not reported), 1 in total, dose was not reported, for prophylactic vaccination. It was unknown whether patient had any adverse event following vaccination with covid-19 vaccine ad26.cov2.s. (dose number in series: 1). The patient received covid-19 vaccine ad26.cov2.s (dose number in series: 2) (suspension for injection, route of admin, and batch number were not reported) dose, 1 in total, start therapy date were not reported, for prophylactic vaccination. The batch number was not reported. The Company is unable to perform follow-up to request batch/lot numbers. No concomitant medications were reported. As per the report, the reporter stated that Hmmm my 35 year old cousin she was 100% healthy never had any problems of any kind single mother of a 15year old daughter 1 week after her second J&J shot dropped dead of a massive heart attack autopsy confirmed it was a direct result of the vaccine (dose number in series: 2). On an unspecified date, the patient died from massive heart attack (dose number in series 2). An autopsy was performed on an unspecified date. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. This report was serious (Death).; Sender's Comments: V0-20211255629-covid-19 vaccine ad26.cov2.s-Massive heart attack. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).; Reported Cause(s) of Death: MASSIVE HEART ATTACK

Lab Data	Current Illness	Adverse Events After Prior Vaccinations

Medications At Time of Vaccination	History/Allergies
	Comments: The patient was 100% healthy and never had any problems of any kind at the time of vaccination.

VAERS DETAIL

VAERS ID: 1845028

Vaccine Type	Vaccine	Manufacturer	Lot	Dose	Route	Site
COVID19	COVID19 (COVID19 (PFIZER-BIONTECH))	PFIZER\BIONTECH		1		

Event Information			
Patient Age		Sex	M
State/Territory	FR	Date Report Completed	
Date Vaccinated	6/8/2021	Date Report Received	11/5/2021
Date of Onset	6/13/2021	Date Died	6/13/2021
Days to Onset	5		
Vaccine Administered By	OTH	Vaccine Purchased By	
Mfr/Imm Project Number			
Recovered	N	Serious	

Event Categories	
Death	Yes
Life Threatening	No
Permanent Disability	No
Congenital Anomaly/Birth Defect	No
Hospitalized	No
Days in Hospital	None
Existing Hospitalization Prolonged	No
Emergency Room/Office Visit	No
Emergency Room	No
Office Visit	No

Symptoms
Blood pressure measurement
Histology
Immunohistochemistry
Myocarditis

Adverse Event Description

myocarditis; This is a literature report. A 22-year-old male patient received BNT162B2 (COMIRNATY) via an unspecified route of administration on 08Jun2021 (Batch/Lot number was not reported) as dose 1, single for covid-19 immunisation. Medical history included blood pressure increased. The patient's concomitant medications were not reported. The patient experienced myocarditis on 13Jun2021 01:00. Therapeutic measures were taken as a result of myocarditis. The outcome of events was fatal. The patient died on 13Jun2021. An autopsy was performed and results were not provided. Abstract We present autopsy findings of a 22-year-old man who developed chest pain 5 days after the first dose of the BNT162b2 mRNA vaccine and died 7 hours later. Histological examination of the heart revealed isolated atrial myocarditis, with neutrophil and histiocyte predominance. Immunohistochemical C4d staining revealed scattered single-cell necrosis of myocytes which was not accompanied by inflammatory infiltrates. Extensive contraction band necrosis was observed in the atria and ventricles. There was no evidence of microthrombosis or infection in the heart and other organs. The primary cause of death was determined to be myocarditis, causally-associated with the BNT162b2 vaccine. We recently observed a case of sudden cardiac death in a young male six days after receiving the first dose of the BNT162b2 mRNA vaccine and report the distinctive clinical and pathological findings of this case. CASE DESCRIPTION The deceased was 22-year-old male military recruit. His blood pressure was elevated on physical examination 17 and 7 months before his death (156/94 mmHg and 128/74 mmHg, respectively), but he was otherwise healthy. On June 13, 2021, 5 days after the first dose of BNT162b2 mRNA vaccination, he complained to a colleague of chest pain at 1:00 AM, during a smoke break, and went to bed. At 8:00 AM, he was found unconscious hunched beside the bed. He was taken to an emergency department and was found to have ventricular fibrillation on electrocardiography. Cardiopulmonary resuscitation was performed for two hours, but he could not be resuscitated. An autopsy was performed 24 hours after his death. The deceased was well-nourished with no visible injuries on external examination. The heart weighed 470 g and had multiple petechiae on its surface. The pericardium was smooth with no fibrin deposition or exudate. The coronary arteries were patent, and the heart valves were unremarkable. The myocardium was of normal thickness and there was no dilation of the atria or ventricles. The myocardium was homogeneously brown with no obvious necrosis or fibrosis. On microscopic examination, diffuse inflammatory infiltration, with neutrophil and histiocyte predominance, was observed within the myocardium. Notably, the inflammatory infiltrates were dominant in the atria, and around the sinoatrial (SA) and atrioventricular (AV) nodes, whereas ventricular area displayed minimal or no inflammatory cells. Occasional myocyte necrosis or degeneration was found adjacent to the inflammatory infiltrates, without abscess formation or bacterial colonization. There was also scattered single-cell necrosis of myocytes without accompanying inflammation. Multiple scattered foci of contraction band necrosis (CBN) was identified throughout the myocardium, predominantly in the left ventricle. No other specific pathological changes were found in the lung, liver, kidney, spleen, pancreas, or brain on macroscopic or microscopic examination. Masson's trichrome staining highlighted dense eosinophilic intracellular strips of myocytes, consistent with CBN. CD68 and CD3 immunostaining showed a moderate number of histiocytes and sparse lymphocytes in the inflammatory infiltrates. Degenerated or ischemic myocytes exhibited positive C4d immunoreactivity. The cause of death was determined to be myocarditis. Given that the myocarditis showed a temporal relationship to vaccine administration and there was no other explanation for the sudden cardiac death, on July 26, 2021, Centers for Disease Control and Prevention acknowledged that myocarditis and vaccination were possibly related in this case. Histopathology of the heart. (A) Hematoxylin and eosin stains of atrial septum shows massive inflammatory infiltration with neutrophil predominance. (B) The myocytes often show contraction band necrosis (yellow arrows), which were highlighted by Masson's trichrome staining. (C) The atrioventricular node area shows extension of atrial myocarditis to the superficial layer of the node. (D) The ventricular myocardium is free of inflammatory infiltrates, but there are multiple large foci of contraction band necrosis (yellow arrows) particularly in the left ventricular wall and the ventricular septum. Bars represent 100 um. The blue arrows in insets show where the section was taken from the low magnification views. Hematoxylin and eosin stain was used for the specimen shown in (A) and Masson's trichrome stain was used for the specimen shown in (B-D). RA = right atrium, LA = left atrium, RV = right ventricle, LV = left ventricle. Fig. 2. Immunohistochemistry of the heart. (A) Immunohistochemical staining for CD68 shows that most of the inflammatory cells are histiocytes. (B) Most of the inflammatory cells are negative for CD3 staining, indicating a paucity of lymphocytes. (C) Positive staining for C4d shows scattered single-cell necrosis of atrial myocytes. Bars represent 100 um Ethics statement Informed consent for publication of clinical data was obtained from the deceased's family. DISCUSSION There were three main histological findings in the heart: 1) myocarditis predominantly involving the atrial wall, with neutrophil and histiocyte predominance; 2) non-inflammatory single-cell necrosis; and 3) diffuse CBN throughout the myocardium, predominantly in the left ventricle. These pathological findings were not evident on macroscopic examination. The only abnormal gross finding was cardiac enlargement, which may have been secondary to hypertension. In this case, the myocarditis was histologically different from viral or immune-mediated myocarditis in that the inflammatory infiltrates were predominantly neutrophils and histiocytes, rather than lymphocytes. Multinucleated giant

cells were not observed. The area of myocarditis was confined to the atrial wall, but the ventricles were free of cellular infiltration. Inflammatory cells were also present in the SA and AV nodes. Myocyte necrosis or degeneration was observed adjacent to the inflammatory infiltrates. Neutrophil infiltration of the myocardium is an uncommon histological type of myocarditis, and is generally observed in immunocompromised patients with bacterial infection.14 The deceased was previously healthy and there were no signs of infective myocarditis. Dissemination of infective endocarditis and pneumonia were also excluded. The underlying mechanism of myocardial injury in this case is unclear, but it may have involved cytokine-mediated or histiocyte-linked immunologic injury to the myocardium. Isolated atrial myocarditis is very rare and thus is an unfamiliar disease entity to pathologists. To our knowledge, only two case reports of sudden cardiac death caused by isolated atrial myocarditis have been published previously. Previous reports noted that atrial myocarditis may be overlooked on postmortem examination because sampling of atrium is not routinely performed. In the present case, extensive myocardial sampling enabled accurate diagnosis. A total of 35 sections were examined (25 sections of ventricular and atrial myocardium and 10 sections of the conduction system) and 9 sections had evidence of myocarditis. Myocarditis is usually not apparent on gross examination. Even if the heart is grossly unremarkable, pathologists should examine a sufficient number (more than or equal to 10) of atrial and ventricular sections in order not to overlook or misdiagnose the cause of death, especially if the deceased had myocarditis symptoms and a recent mRNA vaccination history. Notably, single-cell necrosis (or single-cell ischemia) of myocytes without inflammation was observed in multiple sites throughout the atria. Several autopsy studies of the cardiovascular pathological findings of individuals who died of COVID-19 have also found single-cell necrosis, and this might be a distinctive pathological characteristic of COVID-19. Thus, myocardial injury due to COVID-19 vaccination may histologically present not only as myocarditis, but also as scattered single-cell necrosis, similar to myocardial lesions of COVID-19. Another major histological finding was abundant CBN throughout the myocardium, especially in the left ventricle. CBN is usually observed after irreversible myocyte injury and is associated with ischemic heart disease or a catecholamine excess state. The CBN in this case was extensive throughout the ventricular myocardium and we are cautious about drawing a conclusion about the causality. The association between the CBN and COVID-19 vaccination is unclear. The CBN may have occurred as a result of ventricular fibrillation or catecholamine administration during resuscitation. There was no evidence of coronary atherosclerosis or microthrombosis, which could explain the presence of CBN. We were able to find only one previously published case report of a death due to myocarditis after COVID-19 vaccination with a comprehensive clinicopathological analysis. Reported the case of a 42-year-old man, who presented with chest pain and dyspnea 2 weeks after the second dose of mRNA-1273 vaccination, and died 3 days after symptom onset. On microscopic examination, myocyte damage with a mixed inflammatory infiltrate of macrophages, lymphocytes, and eosinophils was observed in the myocardium of both ventricles, whereas the atria showed no evidence of myocarditis. In contrast, our case patient developed symptoms 5 days after the first dose of the BNT162b2 mRNA vaccine and died 7 hours later, and showed isolated atrial myocarditis with neutrophil and histiocyte predominance. The histopathological features described in their report did not include CBN or single-cell necrosis of myocytes. This suggests that myocarditis after COVID-19 mRNA vaccination is heterogenous, both clinically and histologically. The demographic and clinical characteristics of myocarditis after mRNA vaccination in previous reports are summarized. Vaccine-associated myocarditis has been reported predominantly in young males after the second vaccination. Myocarditis was mainly diagnosed clinically based on elevated serum troponin and cardiac magnetic resonance imaging, and all patients except our and the patient reported by Verma et al. recovered after receiving supportive care. The patient in this case showed similar clinical features, which supports a potential association between vaccination and myocarditis. However, given that other reported myocarditis cases were generally mild and the symptoms usually developed after the second vaccination, the clinical course of our case (sudden death 6 days after the first vaccination) is an extremely rare event. Considering the short time interval between the onset of the deceased patient's symptoms and his sudden death, the immediate cause of death was possibly an arrhythmia, rather than heart failure. This is the first case that the Centers for Disease Control and Prevention acknowledged the causality of COVID-19 vaccination and myocarditis. This unique case provides an example of a serious adverse event following COVID-19 mRNA vaccination. It is unknown whether this case is related to the vaccine type or to a specific vaccine component. It is also unclear whether the location (atrium), type of inflammation (neutrophils and histiocytes), CBN, and single-cell necrosis without inflammation are specific characteristics of COVID-19 vaccine-associated myocarditis. Comprehensive clinical and pathological evaluation of additional cases is needed to clarify the relationship between COVID-19 vaccination and myocarditis. Demographic and clinical features of previously reported myocarditis following coronavirus disease 2019 vaccination No follow-up attempts are needed; information about batch/lot number cannot be obtained.; Sender's Comments: Based on available information and the drug temporal relationship, the causality between the event myocarditis and the suspect drug BNT162B2 cannot be completely excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.; Reported Cause(s) of Death: myocarditis

Lab Data	Current Illness	Adverse Events After Prior Vaccinations
Test Date: 202106; Test Name: histology of heart; Result Unstructured Data: Test Result:massive inflammatory infiltration with neutrophil; Comments: (A) Hematoxylin and eosin stains of atrial septum shows massive inflammatory infiltration with neutrophil predominance. (B) The myocytes often show contraction band necrosis (yellow arrows), which were highlighted by Masson's trichrome staining. (C) The atrioventricular node area shows extension of atrial myocarditis to the superficial layer of the node. (D) The ventricular myocardium is free of inflammatory infiltrates, but there are multiple large foci of contraction band necrosis (yellow arrows) particularly in the left ventricular wall and the ventricular septum. Bars represent 100 um. The blue arrows in insets show where the section was taken from the low magnification views. Hematoxylin and eosin stain was used for the specimen shown in (A) and Masson's trichrome stain was used for the specimen shown in (B-D).; Test Date: 202106; Test Name: Immunohistochemistry of the heart.; Result Unstructured Data: Test Result:most of the inflammatory cells are histiocytes.; Comments: (A) Immunohistochemical staining for CD68 shows that most of the inflammatory cells are histiocytes. (B) Most of the inflammatory cells are negative for CD3 staining, indicating a paucity of lymphocytes. (C) Positive staining for C4d shows scattered single-cell necrosis of atrial myocytes. Bars represent 100 um.; Test Date: 202001; Test Name: blood pressure; Result Unstructured Data: Test Result:156/94 mmHg; Test Date: 202011; Test Name: blood pressure; Result Unstructured Data: Test Result:128/74 mmHg		

Medications At Time of Vaccination	History/Allergies
	Medical History/Concurrent Conditions: Blood pressure increased

VAERS DETAIL

VAERS ID: 1994389

Vaccine Type	Vaccine	Manufacturer	Lot	Dose	Route	Site
COVID19	COVID19 (COVID19 (PFIZER-BIONTECH))	PFIZER\BIONTECH		1		LA

Event Information			
Patient Age	13	Sex	F
State/Territory	FR	Date Report Completed	
Date Vaccinated	11/29/2021	Date Report Received	12/31/2021
Date of Onset	11/30/2021	Date Died	12/5/2021
Days to Onset	1		
Vaccine Administered By	OTH	Vaccine Purchased By	
Mfr/Imm Project Number			
Recovered	N	Serious	

Event Categories	
Death	Yes
Life Threatening	No
Permanent Disability	No
Congenital Anomaly/Birth Defect	No
Hospitalized	No
Days in Hospital	None
Existing Hospitalization Prolonged	No
Emergency Room/Office Visit	Yes
Emergency Room	No
Office Visit	No

Symptoms
Dyspnoea
Headache
Seizure
Somnolence

Adverse Event Description

seizure; difficulty breathing; mild headache; sleepy; This is a spontaneous report received from a contactable reporter(s) (Consumer or other non HCP). The reporter is the parent. A 13 year-old female patient (not pregnant) received bnt162b2 (BNT162B2), administered in arm left, administration date 29Nov2021 12:30 (Batch/Lot number: unknown) at the age of 13 years as dose 1, single for covid-19 immunisation. The patient's relevant medical history and concomitant medications were not reported. The following information was reported: SEIZURE (death, medically significant) with onset 05Dec2021 22:30, outcome fatal, described as seizure; DYSPNOEA (death) with onset 05Dec2021 22:30, outcome fatal, described as difficulty breathing; HEADACHE (non-serious) with onset 30Nov2021, outcome unknown, described as mild headache; SOMNOLENCE (non-serious) with onset 30Nov2021, outcome unknown, described as sleepy. Therapeutic measures were not taken as a result of headache, somnolence. The patient date of death was 05Dec2021. The reported cause of death was dyspnoea, seizure. First day after vaccine she had mild headache and sleepy only and after 6 days at 10.30 pm while she was sleeping, her mother waked up and saw the patient had seizure and had difficulty breathing and after almost 30 mins the patient declared dead on arrival in hospital. The patient had no comorbidities she was very healthy child. The mother knew in her heart that only vaccine killed her life. Autopsy remarks Consider adverse reaction to Pfizer covid vaccine. The autopsy was performed, and results were not provided. The lot number for bnt162b2 was not provided and will be requested during follow up.; Reported Cause(s) of Death: difficulty breathing; seizure

Lab Data	Current Illness	Adverse Events After Prior Vaccinations

Medications At Time of Vaccination	History/Allergies

VAERS DETAIL

VAERS ID: 1906671

Vaccine Type	Vaccine	Manufacturer	Lot	Dose	Route	Site
COVID19	COVID19 (COVID19 (MODERNA))	MODERNA		1		

Event Information			
Patient Age	26	Sex	M
State/Territory	FR	Date Report Completed	
Date Vaccinated	6/2/2021	Date Report Received	11/29/2021
Date of Onset	6/18/2021	Date Died	6/19/2021
Days to Onset	16		
Vaccine Administered By	UNK	Vaccine Purchased By	
Mfr/Imm Project Number			
Recovered	N	Serious	

Event Categories	
Death	Yes
Life Threatening	No
Permanent Disability	No
Congenital Anomaly/Birth Defect	No
Hospitalized	No
Days in Hospital	None
Existing Hospitalization Prolonged	No
Emergency Room/Office Visit	No
Emergency Room	No
Office Visit	No

Symptoms
Myocarditis

Adverse Event Description

Approx. 2 weeks after the first vaccination, my brother who was in perfect health died from myocarditis... he had no pre-existing conditions. Athletic and fit.; This case was received via a regulatory authority (Reference number: DE-PEI-202100224220) on 23-Nov-2021 and was forwarded to Moderna on 23-Nov-2021. This regulatory authority case was reported by a consumer and describes the occurrence of MYOCARDITIS (Approx. 2 weeks after the first vaccination, my brother who was in perfect health died from myocarditis... he had no pre-existing conditions. Athletic and fit.) in a 26-year-old male patient who received mRNA-1273 (Spikevax) for Prophylactic vaccination. No Medical History information was reported. On 02-Jun-2021, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 18-Jun-2021, the patient experienced MYOCARDITIS (Approx. 2 weeks after the first vaccination, my brother who was in perfect health died from myocarditis... he had no pre-existing conditions. Athletic and fit.) (seriousness criterion death). The patient died on 19-Jun-2021. The reported cause of death was Myocarditis. An autopsy was not performed. Approximately 2 weeks after the first vaccination, the reporter's brother who was in perfect health died from myocarditis. The patient had no pre-existing conditions, was athletic and fit. Patient had hay fever. Patient experienced cardiac arrest while swimming. Concomitant medication was not provided. Treatment information was not provided. Company comment: This regulatory case concerns a 26-year-old, male patient with no relevant medical history and was athletic and fit, who experienced the unexpected, serious AESI of myocarditis. The event, which resulted in a fatal outcome, occurred 16 days after administration of the first dose of the Moderna mRNA-1273. The patient died from myocarditis and cardiac arrest while swimming 1 day after experiencing the event. No further information was provided. No autopsy was done. The rechallenge was not applicable as the event resulted in a fatal outcome. The patient's gender remains a confounder. The benefit-risk relationship of the Moderna mRNA-1273 is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 23-Nov-2021: Translated document received on 25-Nov-2021: Event verbatim was translated and narrative updated.; Reporter's Comments: Do you or the person concerned have any known allergies? If yes, which? Only hay fever. Information on risk factors or pre-existing conditions: None. / Cardiac arrest while swimming.; Sender's Comments: This regulatory case concerns a 26-year-old, male patient with no relevant medical history and was athletic and fit, who experienced the unexpected, serious AESI of myocarditis. The event, which resulted in a fatal outcome, occurred 16 days after administration of the first dose of the Moderna mRNA-1273. The patient died from myocarditis and cardiac arrest while swimming 1 day after experiencing the event. No further information was provided. No autopsy was done. The rechallenge was not applicable as the event resulted in a fatal outcome. The patient's gender remains a confounder. The benefit-risk relationship of the Moderna mRNA-1273 is not affected by this report.; Reported Cause(s) of Death: Myocarditis

Lab Data	Current Illness	Adverse Events After Prior Vaccinations

Medications At Time of Vaccination	History/Allergies

VAERS DETAIL

VAERS ID: 1770625

Vaccine Type	Vaccine	Manufacturer	Lot	Dose	Route	Site
COVID19	COVID19 (COVID19 (PFIZER-BIONTECH))	PFIZER\BIONTECH	FK0112	UNK		

Event Information			
Patient Age	37	Sex	F
State/Territory	CA	Date Report Completed	
Date Vaccinated		Date Report Received	10/8/2021
Date of Onset		Date Died	
Days to Onset			
Vaccine Administered By	UNK	Vaccine Purchased By	
Mfr/Imm Project Number			
Recovered	N	Serious	

Event Categories	
Death	Yes
Life Threatening	No
Permanent Disability	No
Congenital Anomaly/Birth Defect	No
Hospitalized	No
Days in Hospital	None
Existing Hospitalization Prolonged	No
Emergency Room/Office Visit	No
Emergency Room	No
Office Visit	No

Symptoms
Death

Adverse Event Description

died; This is a spontaneous report from a contactable pharmacist. A 37-year-old female patient received bnt162b2 (COMIRNATY, Lot Number: FK0112; Expiration Date: 30Jan2022), via an unspecified route of administration on an unspecified date (37-year-old at time of vaccination) as single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient died on an unspecified date. Verbatim: The reporting pharmacist states that she is located in the (country A) but has patients in (country B) who travel back and forth for business. These patients are stuck in (country B) due to the high rates of the delta variant there the pharmacist explained. She states that Pfizer COVID 19 vaccines as well as Moderna COVID 19 vaccines are being donated by other countries to (country B) to help provide vaccination. She states that one of her patients who is in (country B) received one of these donated vaccine with lot number FK0112 and customer service was again to look up this lot number and provide the expiration date of (30Jan2022) stated the pharmacist. She relays that there have been multiple adverse events that have happened with this lot number and she would like to know if it is possible that there was something wrong with that lot. Her patient who was a 37-year-old healthy female received the vaccine from this lot and died 4 hours later. She would like to know why this could have occurred. What data is available on deaths being reported. It was unknown if an autopsy was performed. The cause of death was unknown.; Sender's Comments: Based on the information available and close temporal association, a possible contributory role of the suspect BNT162B2 cannot be excluded for the reported events . The case will be reassessed once new information is available The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.; Reported Cause(s) of Death: died

Lab Data	Current Illness	Adverse Events After Prior Vaccinations

Medications At Time of Vaccination	History/Allergies

VAERS DETAIL

VAERS ID: 1871772

Vaccine Type	Vaccine	Manufacturer	Lot	Dose	Route	Site
COVID19	COVID19 (COVID19 (PFIZER-BIONTECH))	PFIZER\BIONTECH	FF2595	1	OT	LA

Event Information			
Patient Age	33	Sex	M
State/Territory	FR	Date Report Completed	
Date Vaccinated	8/20/2021	Date Report Received	11/16/2021
Date of Onset	9/16/2021	Date Died	
Days to Onset	27		
Vaccine Administered By	OTH	Vaccine Purchased By	
Mfr/Imm Project Number			
Recovered	N	Serious	

Event Categories	
Death	Yes
Life Threatening	No
Permanent Disability	No
Congenital Anomaly/Birth Defect	No
Hospitalized	Yes
Days in Hospital	None
Existing Hospitalization Prolonged	No
Emergency Room/Office Visit	No
Emergency Room	No
Office Visit	No

Symptoms
Guillain-Barre syndrome
Paralysis

Adverse Event Description

Guillain-Barre syndrome; ACUTE FLACID PARALYSIS; This is a spontaneous report from a non-contactable other hcp. This is a report received from Regulatory Authority. Regulatory authority report number 17890-11. A 33-year-old male patient received bnt162b2 (BNT162B2), dose 1 intramuscular, administered in Arm Left on 20Aug2021 (Batch/Lot Number: FF2595) as DOSE 1, SINGLE for covid-19 immunisation (age at vaccination: 33-year-old). The patient medical history and concomitant medications were not reported. The patient was healthy before vaccination. No infectious diseases in the past 15 days before vaccination, no allergy. The patient experienced acute flacid paralysis and guillain-barre syndrome on 16Sep2021. It was unknown if the therapeutic measures were taken as a result of acute flacid paralysis, guillain-barre syndrome. The patient died on an unspecified date. It was not reported if an autopsy was performed. The case was reported as serious with criteria of death, hospitalization. The clinical course was reported as: begins on 16Sep2021, with paresia of the left arm, in less than 72 hrs the total paresia of the upper and lower limbs is installed. Follow-up is not possible. No further information is expected.; Sender's Comments: Based on known drug safety profile, there is reasonable possibility of causal association between the events Guillain-Barre syndrome (fatal) and Paralysis (fatal) and BNT162B2. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate. ; Reported Cause(s) of Death: ACUTE FLACID PARALYSIS; Guillain-Barre syndrome

Lab Data	Current Illness	Adverse Events After Prior Vaccinations

Medications At Time of Vaccination	History/Allergies

VAERS DETAIL

VAERS ID: 1927728

Vaccine Type	Vaccine	Manufacturer	Lot	Dose	Route	Site
COVID19	COVID19 (COVID19 (JANSSEN))	JANSSEN		1	OT	

Event Information			
Patient Age		Sex	F
State/Territory		Date Report Completed	
Date Vaccinated		Date Report Received	12/7/2021
Date of Onset		Date Died	
Days to Onset			
Vaccine Administered By	UNK	Vaccine Purchased By	
Mfr/Imm Project Number			
Recovered	N	Serious	

Event Categories	
Death	Yes
Life Threatening	No
Permanent Disability	No
Congenital Anomaly/Birth Defect	No
Hospitalized	No
Days in Hospital	None
Existing Hospitalization Prolonged	No
Emergency Room/Office Visit	No
Emergency Room	No
Office Visit	No

Symptoms
Death

Adverse Event Description

DIED 2 DAYS AFTER VACCINATION; This spontaneous report received from a consumer via social media via a company representative concerned a 24 year old female of unspecified race and ethnicity. The patient's height, and weight were not reported. Patient was healthy. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin, and batch number: unknown expiry: unknown) dose, 1 total, start therapy date were not reported for prophylactic vaccination (Dose number in series 1). The batch number was not reported. The Company is unable to perform follow-up to request batch/lot numbers. No concomitant medications were reported. On an unspecified date, the patient died 2 days after the vaccination from unknown cause of death. It was unspecified if an autopsy was performed. As per reporter, my daughters good friend of 24 years died 2 days after the J&J. She was healthy. Dr's aside there is a rare side effect between the J&J and women on hormonal birth control. Tragic The action taken with covid-19 vaccine ad26.cov2.s was not applicable. This report was serious (Death).; Sender's Comments: V0: 20211212284-Covid-19 vaccine ad26.cov2.s-Death. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).; Reported Cause(s) of Death: UNKNOWN CAUSE OF DEATH

Lab Data	Current Illness	Adverse Events After Prior Vaccinations

Medications At Time of Vaccination	History/Allergies
	Comments: Patient was healthy.

VAERS DETAIL

VAERS ID: 1878777

Vaccine Type	Vaccine	Manufacturer	Lot	Dose	Route	Site
COVID19	COVID19 (COVID19 (PFIZER-BIONTECH))	PFIZER\BIONTECH		2		

Event Information			
Patient Age		Sex	M
State/Territory	FR	Date Report Completed	
Date Vaccinated		Date Report Received	11/18/2021
Date of Onset		Date Died	
Days to Onset			
Vaccine Administered By	OTH	Vaccine Purchased By	
Mfr/Imm Project Number			
Recovered	N	Serious	

Event Categories	
Death	Yes
Life Threatening	No
Permanent Disability	No
Congenital Anomaly/Birth Defect	No
Hospitalized	No
Days in Hospital	None
Existing Hospitalization Prolonged	No
Emergency Room/Office Visit	No
Emergency Room	No
Office Visit	No

Symptoms
Physical deconditioning

Adverse Event Description

Physical deconditioning; This is a spontaneous report from a contactable consumer (the patient's childhood friend) received via Medical Information Team. A 38-year-old male patient received second dose of BNT162B2 (COMIRNATY, Solution for injection, Lot number and Expiration date was not reported), via an unspecified route of administration on an unspecified date (the day of vaccination) as dose 2, single for covid-19 immunisation. It was reported that patient had no underlying diseases and was healthy, and no other medical history was reported. Concomitant medications were not reported. The patient previously received first dose of BNT162B2 (COMIRNATY, Solution for injection, Lot Number and Expiration date was not reported) via an unspecified route of administration on unspecified date as dose 1, single for covid-19 immunization. On an unspecified date (it was reported as 2 hours after the 2nd dose of the vaccination), the patient developed physical deconditioning. On an unspecified date (next day of the 2nd dose of the vaccination), the patient died. It was reported that the patient developed physical deconditioning suddenly at the night of the second inoculation (2 hours after the 2nd dose of the vaccination) and died next day. It was unknown if an autopsy was performed. The reporter wondered why such a healthy person's condition suddenly changed after the vaccination. The reporter was told that there was no causal relationship with the vaccination (it was not reported who made the assessment). No follow-up attempts are possible; information about lot/batch number cannot be obtained. No further information is expected.; Reported Cause (s) of Death: Physical deconditioning

Lab Data	Current Illness	Adverse Events After Prior Vaccinations

Medications At Time of Vaccination	History/Allergies

VAERS DETAIL

VAERS ID: 1334527

Vaccine Type	Vaccine	Manufacturer	Lot	Dose	Route	Site
COVID19	COVID19 (COVID19 (PFIZER-BIONTECH))	PFIZER\BIONTECH	EW0173	2		

Event Information			
Patient Age	28	Sex	M
State/Territory	CA	Date Report Completed	
Date Vaccinated	5/4/2021	Date Report Received	5/20/2021
Date of Onset	5/10/2021	Date Died	5/15/2021
Days to Onset	6		
Vaccine Administered By	SCH	Vaccine Purchased By	
Mfr/Imm Project Number			
Recovered	N	Serious	

Event Categories	
Death	Yes
Life Threatening	No
Permanent Disability	No
Congenital Anomaly/Birth Defect	No
Hospitalized	Yes
Days in Hospital	1
Existing Hospitalization Prolonged	No
Emergency Room/Office Visit	Yes
Emergency Room	No
Office Visit	No

Symptoms
Abnormal behaviour
Blood potassium decreased
Blood test abnormal
Computerised tomogram
Cough
Death
Dyspnoea
Echocardiogram
Haemoptysis
Heart rate increased
Infection
Malaise
Mobility decreased
Pallor
Pulmonary oedema
SARS-CoV-2 test negative

Adverse Event Description

My brother got the Pfizer 5/4 and started getting sick with a cough on the 7th and by the 10th he was getting more and more sick and ye was taken to the ER on the 14th and he started coughing up blood, he was out of it and pale and not able to move much. On 5/15 in the hospital he was having a hard time breathing and they were trying to give him meds to make him better, they gave him antibiotics because his blood work showed infection, and Precedex to help him rest, and he passed away the same day, he was in good health before. They also said his heart rate was 201/123 and the doctors said pulmonary anema. It escalated so quickly.

Lab Data	Current Illness	Adverse Events After Prior Vaccinations
Yes, blood work, ECHO, CAT, and Covid test that was negative, potassium was low, HR was elevated to 200bpm Blood work showed infection.	may be high blood pressure	

Medications At Time of Vaccination	History/Allergies
No	No
	Seasonal allergies only

VAERS DETAIL

VAERS ID: 1846428

Vaccine Type	Vaccine	Manufacturer	Lot	Dose	Route	Site
COVID19	COVID19 (COVID19 (PFIZER-BIONTECH))	PFIZER\BIONTECH	FG3530	2	OT	LA

Event Information			
Patient Age	39	Sex	M
State/Territory	FR	Date Report Completed	
Date Vaccinated	9/28/2021	Date Report Received	11/5/2021
Date of Onset	9/28/2021	Date Died	10/11/2021
Days to Onset	0		
Vaccine Administered By	OTH	Vaccine Purchased By	
Mfr/Imm Project Number			
Recovered	N	Serious	

Event Categories	
Death	Yes
Life Threatening	No
Permanent Disability	No
Congenital Anomaly/Birth Defect	No
Hospitalized	No
Days in Hospital	None
Existing Hospitalization Prolonged	No
Emergency Room/Office Visit	Yes
Emergency Room	No
Office Visit	No

Symptoms
Cardiogenic shock
Cardio-respiratory arrest
Fatigue
Hyperhidrosis
Inappropriate schedule of product administration
Pallor
Pulmonary embolism

Adverse Event Description

cardiorespiratory arrest; pallor; tiredness; sweating; Pulmonary thromboembolism; cardiogenic shock; dose 1: 13Jul2021 / dose 2: 28Sep2021; This is a spontaneous report from a contactable nurse (patient's wife) received through COVAES portal. A 39-years-old male patient received bnt162b2 (COMIRNATY), dose 2 intramuscular, administered in Arm Left on 28Sep2021 09:30 (Lot Number: FG3530) at age of 39-years-old as dose 2, single for COVID-19 immunisation. Medical history and concomitant medication were none. No known allergies. The patient previously received bnt162b2 (COMIRNATY, Batch/Lot No: 9094), dose 1 intramuscular on 13Jul2021 08:30 AM at age of 39-years-old in Arm Left for COVID-19 immunisation. The patient had always been healthy and super full of life. The patient had massive pulmonary thromboembolism on 02Oct2021 and died 14 days after the vaccine, he presented symptoms such as tiredness, pallor and sweating from the 3rd day after the vaccine (2 dose) on 02Oct2021. Adverse events resulted in Go to the emergency department, Death. In the emergency room, with oxygen supply, but the patient progressed rapidly to cardiorespiratory arrest, with no success in the area. Death cause included Pulmonary thromboembolism and cardiogenic shock. Therapeutic measures were taken as a result of all events without cardiorespiratory arrest and Inappropriate schedule of vaccine administered. The patient died on 11Oct2021. An autopsy was not performed. The outcome of the event Pulmonary thromboembolism and cardiogenic shock was fatal, of other events was unknown. No COVID prior vaccination. No COVID tested post vaccination.; Sender's Comments: Based on the information in the case report, a possible causal association between the events and suspect drug BNT162B2 cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.; Reported Cause(s) of Death: Pulmonary thromboembolism; cardiogenic shock

Lab Data	Current Illness	Adverse Events After Prior Vaccinations

Medications At Time of Vaccination	History/Allergies
	Comments: List of non-encoded Patient Relevant History: Patient Other Relevant History 1: none

SAMPLE VAERS RECORDS FROM THE "20 AND UNDER" CATEGORY

CRITERIA:

1. 20 years of age or less (but excluding fetuses and babies)
2. Eliminate any record with most any comorbidity (including asthma, ADHD, obesity, but with the exception of very minor things such as allergies)

VAERS DETAIL

VAERS ID: 1971636

Vaccine Type	Vaccine	Manufacturer	Lot	Dose	Route	Site
COVID19	COVID19 (COVID19 (MODERNA))	MODERNA		1	OT	

Event Information			
Patient Age	14	Sex	F
State/Territory	FR	Date Report Completed	
Date Vaccinated	9/24/2021	Date Report Received	12/22/2021
Date of Onset	10/9/2021	Date Died	
Days to Onset	15		
Vaccine Administered By	UNK	Vaccine Purchased By	
Mfr/Imm Project Number			
Recovered	N	Serious	

Event Categories	
Death	Yes
Life Threatening	No
Permanent Disability	No
Congenital Anomaly/Birth Defect	No
Hospitalized	Yes
Days in Hospital	None
Existing Hospitalization Prolonged	No
Emergency Room/Office Visit	No
Emergency Room	No
Office Visit	No

Symptoms
Brain herniation
Brain injury
Cardiac arrest
Dizziness
Headache
Multiple organ dysfunction syndrome
Nausea
Pyrexia

Adverse Event Description

Brain injury; nausea; Cardiac arrest; Brain herniation; Multiple organ dysfunction syndrome; Dizziness; Headache; Pyrexia; This case was received via an unknown source (no reference has been entered for a health authority or license partner) on 14-Dec-2021 and was forwarded to Moderna on 14-Dec-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of CARDIAC ARREST (Cardiac arrest), BRAIN INJURY (Brain injury), BRAIN HERNIATION (Brain herniation) and MULTIPLE ORGAN DYSFUNCTION SYNDROME (Multiple organ dysfunction syndrome) in a 14-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No Medical History information was reported. On 24-Sep-2021, the patient received first dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 09-Oct-2021, the patient experienced DIZZINESS (Dizziness), HEADACHE (Headache) and PYREXIA (Pyrexia). On 10-Oct-2021, the patient experienced CARDIAC ARREST (Cardiac arrest) (seriousness criteria death and medically significant), BRAIN INJURY (Brain injury) (seriousness criteria death, hospitalization and medically significant), BRAIN HERNIATION (Brain herniation) (seriousness criteria death and medically significant) and MULTIPLE ORGAN DYSFUNCTION SYNDROME (Multiple organ dysfunction syndrome) (seriousness criteria death and medically significant). On an unknown date, the patient experienced NAUSEA (nausea). The patient died on an unknown date. The reported cause of death was Brain herniation, Brain injury, Cardiac arrest and Multiple organ dysfunction syndrome. It is unknown if an autopsy was performed. At the time of death, DIZZINESS (Dizziness) had resolved and NAUSEA (nausea), HEADACHE (Headache) and PYREXIA (Pyrexia) outcome was unknown. The action taken with mRNA-1273 (Spikevax) (Intramuscular) was unknown. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. On the 10th of October Patient complained to her father that she felt unwell and dizzy. CPR was performed and Patient was transported via ambulance to hospital where Patient was declared deceased. Treatment notes: 16 days post vaccine patient complained of headache and nausea prior to bed; the following morning she was found unconscious at 10:00. RoSC achieved after two shocks; LMA inserted and transported to Hospital; loss of output en route however RoSC achieved after adrenaline and CPR; at hospital. Lab Data: lactate 20 and pH <6.8; in resuscitation, patient had recurrent episodes of loss of cardiac output (non-shockable rhythm) followed by CPR and return of spontaneous circulation; CT brain performed and showed changes in keeping with global ischaemia; subsequently transferred to ICU, where patient sustained rapid development of multiorgan failure as well as hypoxic brain injury with tonsillar herniation; patient passed away morning of 11/10 This is a regulatory case concerning a 14-year-old female patient with no relevant medical history, who experienced the serious unexpected fatal AESI event of Cardiac arrest, serious unexpected fatal events of Brain injury, Brain herniation, Multiple organ dysfunction syndrome and non-serious expected events of Dizziness, Headache, Pyrexia and Nausea. The events occurred approximately 16-17 days after the first dose of mRNA-1273 vaccine administration. The events were considered as related to the product administration. The rechallenge was not applicable. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.; Sender's Comments: This is a regulatory case concerning a 14-year-old female patient with no relevant medical history, who experienced the serious unexpected fatal AESI event of Cardiac arrest, serious unexpected fatal events of Brain injury, Brain herniation, Multiple organ dysfunction syndrome and non-serious expected events of Dizziness, Headache, Pyrexia and Nausea. The events occurred approximately 16-17 days after the first dose of mRNA-1273 vaccine administration. The events were considered as related to the product administration. The rechallenge was not applicable. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.; Reported Cause(s) of Death: Brain herniation; Brain injury; Cardiac arrest; Multiple organ dysfunction syndrome

Lab Data	Current Illness	Adverse Events After Prior Vaccinations

Medications At Time of Vaccination	History/Allergies

VAERS DETAIL

VAERS ID: 1988217

Vaccine Type	Vaccine	Manufacturer	Lot	Dose	Route	Site
COVID19	COVID19 (COVID19 (JANSSEN))	JANSSEN		1	OT	

Event Information			
Patient Age		Sex	U
State/Territory		Date Report Completed	
Date Vaccinated		Date Report Received	12/29/2021
Date of Onset		Date Died	12/23/2021
Days to Onset			
Vaccine Administered By	UNK	Vaccine Purchased By	
Mfr/Imm Project Number			
Recovered	N	Serious	

Event Categories	
Death	Yes
Life Threatening	No
Permanent Disability	No
Congenital Anomaly/Birth Defect	No
Hospitalized	No
Days in Hospital	None
Existing Hospitalization Prolonged	No
Emergency Room/Office Visit	No
Emergency Room	No
Office Visit	No

Symptoms
Adverse event
Death
Off label use
Product administered to patient of inappropriate age

Adverse Event Description

DEATH; ADVERSE REACTION TO THE JANSSEN AND JANSSEN VACCINE; OFF LABEL USE; PRODUCT ADMINISTERED TO PATIENT OF INAPPROPRIATE AGE; This spontaneous report received from a consumer via social media concerned a 4 year old of unspecified sex, race and ethnicity. The patient's height, and weight were not reported. No past medical history or concurrent conditions were reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin, and batch number: unknown and expiry: unknown) dose, start therapy date were not reported, 1 total administered for prophylactic vaccination (Dose number in series 1). The batch number was not reported. The Company is unable to perform follow-up to request batch/lot numbers. No concomitant medications were reported. It was reported that the patient was 4 year old (child), it was not a approved age to receive vaccine (coded as product administered to patient of inappropriate age and off label use). On an unspecified date, the patient experienced an adverse reaction to the JANSSEN AND JANSSEN vaccine. On 23-DEC-2021, the patient died from an unknown cause of death. It was unspecified if an autopsy was performed. Reporter also stated that ''My friend's neighbor's 4 year old cousin just passed away after an adverse reaction to the J&J vaccine. Absolutely devastated for them. Please pray for their family.''. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient died of death on 23-DEC-2021, and the outcome of adverse reaction to the JANSSEN AND JANSSEN vaccine, off label use and product administered to patient of inappropriate age was not reported. This report was serious (Death). This report was associated with product quality complaint: 90000208442.; Sender's Comments: V0:20211252331-COVID-19 VACCINE AD26.COV2.S- Death. This event is considered unassessable. The event has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event.; Reported Cause(s) of Death: UNKNOWN CAUSE OF DEATH

Lab Data	Current Illness	Adverse Events After Prior Vaccinations

Medications At Time of Vaccination	History/Allergies

VAERS DETAIL

VAERS ID: 1941909

Vaccine Type	Vaccine	Manufacturer	Lot	Dose	Route	Site
COVID19	COVID19 (COVID19 (PFIZER-BIONTECH))	PFIZER\BIONTECH		UNK		

Event Information			
Patient Age		Sex	M
State/Territory		Date Report Completed	
Date Vaccinated		Date Report Received	12/11/2021
Date of Onset		Date Died	
Days to Onset			
Vaccine Administered By	UNK	Vaccine Purchased By	
Mfr/Imm Project Number			
Recovered	N	Serious	

Event Categories	
Death	Yes
Life Threatening	No
Permanent Disability	No
Congenital Anomaly/Birth Defect	No
Hospitalized	No
Days in Hospital	None
Existing Hospitalization Prolonged	No
Emergency Room/Office Visit	No
Emergency Room	No
Office Visit	No

Symptoms
Death
Drug ineffective

Adverse Event Description

My son has died from a Pfizer vaccine; I have a dead child in my arms; I have a dead 6 years old in my arms; Vaccine doesn't work; This is a spontaneous report received from a non-contactable reporter(s) (Consumer or other non HCP). The reporter is the parent. A 6 year-old male patient received bnt162b2 (BNT162B2) (Batch/Lot number: unknown) as dose number unknown, single for covid-19 immunisation. The patient's relevant medical history and concomitant medications were not reported. The following information was reported: DEATH (death, medically significant), outcome fatal, described as My son has died from a Pfizer vaccine; I have a dead child in my arms; I have a dead 6 years old in my arms; DRUG INEFFECTIVE (medically significant), outcome unknown, described as Vaccine doesn't work. The patient date of death was unknown. The reported cause of death was My son has died from a Pfizer vaccine; I have a dead child in my arms; I have a dead 6 years old in my arms. No follow-up attempts are possible; information about lot/batch number cannot be obtained. No further information is expected.; Reported Cause (s) of Death: My son has died from a Pfizer vaccine; I have a dead child in my arms; I have a dead 6 years old in my arms

Lab Data	Current Illness	Adverse Events After Prior Vaccinations

Medications At Time of Vaccination	History/Allergies

VAERS DETAIL

VAERS ID: 1963633

Vaccine Type	Vaccine	Manufacturer	Lot	Dose	Route	Site
COVID19	COVID19 (COVID19 (PFIZER-BIONTECH))	PFIZER\BIONTECH		1	IM	LA
COVID19	COVID19 (COVID19 (PFIZER-BIONTECH))	PFIZER\BIONTECH		2	IM	LA

Event Information			
Patient Age	15	Sex	F
State/Territory	WI	Date Report Completed	
Date Vaccinated	6/19/2021	Date Report Received	12/20/2021
Date of Onset	12/2/2021	Date Died	12/19/2021
Days to Onset	166		
Vaccine Administered By	UNK	Vaccine Purchased By	
Mfr/Imm Project Number			
Recovered	N	Serious	

Event Categories	
Death	Yes
Life Threatening	No
Permanent Disability	No
Congenital Anomaly/Birth Defect	No
Hospitalized	Yes
Days in Hospital	17
Existing Hospitalization Prolonged	No
Emergency Room/Office Visit	Yes
Emergency Room	No
Office Visit	No

Symptoms
Acute respiratory failure
Alpha haemolytic streptococcal infection
Angiogram cerebral abnormal
Arterial catheterisation
Arterial spasm
Asthenia
Blood culture positive
Brain injury
Central venous catheterisation
Cerebral endovascular aneurysm repair
Cerebral haemorrhage
Cerebral mass effect
Cognitive disorder
Computerised tomogram head abnormal
COVID-19
Death
Decompressive craniectomy
Drug titration
Echocardiogram abnormal
Ejection fraction decreased
Electroencephalogram normal
Endotracheal intubation
Extubation
Gait inability
Gastrointestinal tube insertion
Headache
Heart rate decreased
Hypophagia
Hypotension
Infusion
Intensive care
Intracranial pressure increased
Intraventricular haemorrhage
Laboratory test abnormal

Adverse Event Description
In brief, patient is a previously healthy 15 year old who had acute headache and collapse at home, concern for posturing versus seizure, and ultimately found to have cerebral and intraventricular hemorrhage with mass effect secondary to ruptured aneurysm. S/p coiling of aneurysm, bilateral EVD placement and R decompressive craniectomy. She has acute respiratory failure, strep viridans bacteremia, and concurrent COVID-19 infection. Presented 12/2/21 with aneurysm and incidentally found to be COVID positive. NEURO: On arrival, she was somewhat responsive and by the time she arrived at ED she was posturing versus seizing. Head CT revealed hemorrhage 3x3x3 hemorrhagic focus anterior and inferior to the right basal ganglion with mass effect, also with intraventricular blood in lateral and third ventricles with acute subarachnoid hemorrhage in suprasellar cistern and bilateral sylvian fissures. At that time, reportedly pupils equal, 3-4, minimally reactive. At ED, received Mannitol bolus, and 4mg Ativan administered. Flight for Life activated and upon arrival to CW was admitted to the PICU with plan for emergent EVD placement. Neurosurgery placed EVD at bedside. Repeat head CT and CTA performed and demonstrated bilobed aneurysm arising from right ICA terminus with enlarging intraparenchymal hematoma along superior aspect mostly likely representing a ruptured aneurysm, increased intraventricular hemorrhage, similar subarachnoid hemorrhage, increased mass effect, effacement of basal cisterns, worsened midline shift. Optimized neuroprotection management with sedation, neuromuscular blockade, ventilator management, and hypertonic saline. R pupil became dilated and nonreactive and patient demonstrated persistently elevated ICPs >50. She underwent emergent IR coiling and R decompressive craniectomy with second right-sided EVD placement. Patient continued to demonstrate ICPs in 20s. Worked with Neurosurgery to optimize sedation. Repeat head CT demonstrated increased hypoattenuation in right frontal and parietal lobes, left parietal lobe, and splenium of corpus callosum. Loss of gray-white differentiation concerning for ischemic change. Increased right to left midline shift. TCDs demonstrated moderate spasm of the L MCA. EEG without seizure. Started Pentobarbital coma. On 12/9, an occurred episode while in transport to MRI and patient was noted to be obtunded. ICP 11 during episode, EVDs patent. She was not connected to LTM during episode, as she was in transport. She was started on epi drip and became more responsive, moving spontaneously and withdrawing to pain. On 12/10, her neurostorming medication regimen was optimized and no further changes were made. Given poor neurologic prognosis, patient was given adequate sedation for pain management during terminal extubation on 12/18. CV: Had periods of hypotension intraoperatively requiring initiation of Epinephrine and Norepinephrine infusions to maintain goal MAP > 80, SBP > 120. Returned to PICU with femoral CVL, arterial line, sedated with Fentanyl and Dexmedetomidine infusions, and on Vecuronium infusions, Nimodipine. On 12/4 echocardiogram report noted significant for left ventricular mid-inferoseptal hypokinesis and moderately diminished left ventricular systolic function, with an LVEF 41%. She required titration of pressors to maintain goal pressures. Added stress dose Hydrocortisone. Repeat echocardiogram demonstrated significant improvement in LV systolic function, consistent with the hypothesis that myocardium was neurologically stunned. 12/6-12/8 Patient weaned from sedation and pressors. On 12/9 she experienced a hypotensive episode while in transport to MRI. HR dropped to 40s-50s. 105 mcg Epi dwindle given, then started on Epi drip, given 500 mL NS push pull. HR and BP normalized. On 12/10, patient was weaned from pressors and stress dose steroids. She remained hemodynamically appropriate leading to terminal extubation on 12/18. RESP: Intubated in the OR. Notably, course complicated by significant pulmonary edema with poor compliance. On 12/10, her ventilator settings were weaned to CPAP/PS. She remained hemodynamically appropriate with CPAP/PS until terminal extubation on 12/18. FEN/GI: On 12/10 patient was started on enteral feeds which were discontinued after terminal extubation on 12/18. ID: At ED, she was incidentally found to be COVID positive. Blood cultures were drawn at that time positive for strep viridans. She started on empiric Cefepime and Vancomycin due to concern for septic shock given pressor requirements. Initiated thermoregulation. Patient continued to be intermittently febrile and remained on Ceftriaxone per family's wishes until 12/19. RENAL: Initially had significantly increased urine output. Labs concerning for DI, although could also be secondary to 3% boluses. Initiated DI protocol. This later resolved and she continued to have urine output appropriate for age leading to her terminal extubation on 12/18. OTHER: On 12/5 ,discussion took place between provider and mother and placed partial code status, including no bolus cardiac resuscitative medications, no defibrillation, no chest compressions. Care Conference took place on 12/10, during which mother voiced she would like to get MRI for further neuroprognostication before changing goals of care. Care conference on 12/14 to discuss MRI results with family. Neurology explained likely deficits patient will experience as a result of her brain injury including weakness of both sides of her body, inability to walk, inability to effectively eat PO, personality changes, cognitive dysfunction. Mother voices Patient would not want to live like this, but requests time to discuss these options with family before making any decisions. Another discussion between providers and family on 12/15 during which family voiced they would not want patient to be reintubated once extubated, would not want her to receive blood products, and would like to continue with enteral feeding. Tentative plans for extubation on 12/17 or 12/18 once family from out of state has come to say their goodbyes. Family later decided to move forward with terminal extubation on 12/18. She was extubated 12/18 to room air and passed away on 12/19/2021 @ 20:37 PM with mother, brother and step father at the bedside.

Lab Data	Current Illness	Adverse Events After Prior Vaccinations
Head CT, MRI, Echocardiogram, multiple ultrasounds, angiogram	Unknown	

Medications At Time of Vaccination	History/Allergies
Unknown	None
	No known allergies.

Left ventricular dysfunction
Magnetic resonance imaging head abnormal
Mechanical ventilation
Medical induction of coma
Mydriasis
Myocardial stunning
Pain
Personality change
Positive airway pressure therapy
Posturing
Pulmonary oedema
Pupillary light reflex tests abnormal
Pyrexia
Ruptured cerebral aneurysm
SARS-CoV-2 test positive
Seizure
Subarachnoid haemorrhage
Syncope
Ultrasound scan
Urine output increased
Ventricular drainage
Ventricular hypokinesia

VAERS DETAIL

VAERS ID: 2045402

Vaccine Type	Vaccine	Manufacturer	Lot	Dose	Route	Site
COVID19	COVID19 (COVID19 (PFIZER-BIONTECH))	PFIZER\BIONTECH	FF7481	2	OT	

Event Information			
Patient Age		Sex	F
State/Territory	FR	Date Report Completed	
Date Vaccinated	8/11/2021	Date Report Received	1/19/2022
Date of Onset	12/28/2021	Date Died	12/29/2021
Days to Onset	139		
Vaccine Administered By	OTH	Vaccine Purchased By	
Mfr/Imm Project Number			
Recovered	N	Serious	

Event Categories	
Death	Yes
Life Threatening	No
Permanent Disability	No
Congenital Anomaly/Birth Defect	No
Hospitalized	No
Days in Hospital	None
Existing Hospitalization Prolonged	No
Emergency Room/Office Visit	Yes
Emergency Room	No
Office Visit	No

Symptoms
Cerebral haemorrhage
Computerised tomogram
COVID-19
Hypertension
Pneumonia
Pupils unequal
SARS-CoV-2 test
Shock
Vaccination failure

Adverse Event Description

Vaccine ineffectiveness in a patient vaccinated with a double dose of Cominarty vaccine tested positive for SARS-COV2, bilateral pneumonia; Nasopharyngeal swab for Sars-Cov2 Positive; entered directly into the shock room for cerebral haemorrhage.; Bilateral pneumonia; Upon arrival in emergency room, appearance of anisocores; Upon arrival in emergency room, appearance of hypertension; entered directly into the shock room for cerebral haemorrhage.; This is a spontaneous report received from a contactable reporter(s) (Pharmacist) from the Regulatory Authority and product quality group. Regulatory number: IT-MINISAL02-829587. A 16 year-old female patient received bnt162b2 (COMIRNATY), intramuscular, administration date 11Aug2021 (Lot number: FF7481) as dose 2, single and intramuscular, administration date 02Jul2021 (Lot number: FE2625) as dose 1, single for covid-19 immunisation. The patient's relevant medical history and concomitant medications were not reported. The following information was reported: VACCINATION FAILURE (death) with onset 28Dec2021, outcome fatal, described as Vaccine ineffectiveness in a patient vaccinated with a double dose of Cominarty vaccine tested positive for SARS-COV2, bilateral pneumonia; COVID-19 (death) with onset 28Dec2021, outcome fatal, described as Nasopharyngeal swab for Sars-Cov2 Positive; SHOCK (death), CEREBRAL HAEMORRHAGE (death, medically significant) all with onset 28Dec2021, outcome fatal and all described as entered directly into the shock room for cerebral haemorrhage.; PNEUMONIA (death, medically significant) with onset 28Dec2021, outcome fatal, described as Bilateral pneumonia; PUPILS UNEQUAL (death) with onset 28Dec2021, outcome fatal, described as Upon arrival in emergency room, appearance of anisocores; HYPERTENSION (death) with onset 28Dec2021, outcome fatal, described as Upon arrival in emergency room, appearance of hypertension. The events vaccine ineffectiveness in a patient vaccinated with a double dose of cominarty vaccine tested positive for sars-cov2, bilateral pneumonia, nasopharyngeal swab for sars-cov2 positive, entered directly into the shock room for cerebral haemorrhage., bilateral pneumonia, upon arrival in emergency room, appearance of anisocores, upon arrival in emergency room, appearance of hypertension and entered directly into the shock room for cerebral haemorrhage. were evaluated at the emergency room visit. The patient underwent the following laboratory tests and procedures: computerised tomogram: (unspecified date) right frontal intraparenchymal hemorrhage, notes: is found with significant reduction of right hemispheric flow; sars-cov-2 test: (28Dec2021) positive. Therapeutic measures were taken as a result of vaccination failure, covid-19, shock, pneumonia, pupils unequal, hypertension, cerebral haemorrhage. The patient date of death was 29Dec2021. The reported cause of death was cerebral haemorrhage. It was not reported if an autopsy was performed. Clinical course: Invasive ventilation begins from 28Dec2021, central venous catheter positioning, arterial and bladder catheter since 28Dec2021. The patient died on 29Dec2021 in front of the very serious situation Reporter Comment: The patient had completed the vaccination course with a double dose Cominarty vaccine. First dose on 02Jul2021 lot FE2625, second dose on 11Aug2021 lot FF7481, is positive for the nasopharyngeal molecular swab performed on 28Dec2021 during access to the emergency room due to cerebral haemorrhage caused the death. The vaccine does not appear to be related to cause of death. No follow-up attempts are possible. No further information is expected.; Reporter's Comments: The patient had completed the vaccination course with a double dose Cominarty vaccine. First dose on 02Jul2021 lot FE2625, second dose on 11Aug2021 lot FF7481, is positive for the nasopharyngeal molecular swab performed on 28Dec2021 during access to the emergency room due to cerebral haemorrhage caused the death. The vaccine does not appear to be related to cause of death.; Reported Cause(s) of Death: cerebral haemorrhage

Lab Data	Current Illness	Adverse Events After Prior Vaccinations
Test Name: ct scan; Result Unstructured Data: Test Result:right frontal intraparenchymal hemorrhage; Comments: is found with significant reduction of right hemispheric flow.; Test Date: 20211228; Test Name: Nasopharyngeal swab for Sars-Cov2; Test Result: Positive		

Medications At Time of Vaccination	History/Allergies

VAERS DETAIL

VAERS ID: 2041038

Vaccine Type	Vaccine	Manufacturer	Lot	Dose	Route	Site
COVID19	COVID19 (COVID19 (PFIZER-BIONTECH))	PFIZER\BIONTECH	Unknown	2		

Event Information			
Patient Age		Sex	M
State/Territory	FR	Date Report Completed	
Date Vaccinated	11/1/2021	Date Report Received	1/18/2022
Date of Onset		Date Died	
Days to Onset			
Vaccine Administered By	OTH	Vaccine Purchased By	
Mfr/Imm Project Number			
Recovered	N	Serious	

Event Categories	
Death	Yes
Life Threatening	No
Permanent Disability	No
Congenital Anomaly/Birth Defect	No
Hospitalized	No
Days in Hospital	None
Existing Hospitalization Prolonged	No
Emergency Room/Office Visit	No
Emergency Room	No
Office Visit	No

Symptoms
Blood test
Cardiomyopathy
Thrombosis

Adverse Event Description

multiple thrombosis in the lower limbs; Cardiomyopathy; This is a spontaneous report received from contactable reporter(s) (Physician) from a sales representative. A 18 year-old male patient received bnt162b2 (COMIRNATY), administration date Nov2021 (Lot number: Unknown) as dose 2, single for covid-19 immunisation. The patient's relevant medical history and concomitant medications were not reported. Vaccination history included: Covid-19 vaccine (DOSE 1; MANUFACTURER UNKNOWN), for COVID-19 immunisation. The following information was reported: THROMBOSIS (death), outcome fatal, described as multiple thrombosis in the lower limbs; CARDIOMYOPATHY (medically significant) with onset 2021, outcome recovered, described as Cardiomyopathy. The patient underwent the following laboratory tests and procedures: blood test: not good. Therapeutic measures were taken as a result of thrombosis, cardiomyopathy. Clinical course: 15 days after the second dose, he presented with myocardiopathy, which was treated, and whose outcome was favorable. Then, he had a clinical presentation of multiple thrombosis of lower limbs: he underwent surgery (no more precision). The patient died. Autopsy was performed (no more precision). The patient date of death was unknown. The reported cause of death was multiple thrombosis in the lower limbs. The lot number for bnt162b2 was not provided and will be requested during follow up.; Sender's Comments: The information available in this report is limited and the reported events thrombosis, cardiomyopathy cannot be totally excluded/assessed. This case will be reassessed when additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.; Reported Cause(s) of Death: multiple thrombosis in the lower limbs

Lab Data	Current Illness	Adverse Events After Prior Vaccinations
Test Name: Blood work-up; Result Unstructured Data: Test Result:not good		

Medications At Time of Vaccination	History/Allergies

VAERS DETAIL

VAERS ID: 1960942

Vaccine Type	Vaccine	Manufacturer	Lot	Dose	Route	Site
COVID19	COVID19 (COVID19 (PFIZER-BIONTECH))	PFIZER\BIONTECH	PCB0002	UNK	OT	

Event Information			
Patient Age	15	Sex	M
State/Territory	FR	Date Report Completed	
Date Vaccinated	11/15/2021	Date Report Received	12/18/2021
Date of Onset	11/16/2021	Date Died	
Days to Onset	1		
Vaccine Administered By	OTH	Vaccine Purchased By	
Mfr/Imm Project Number			
Recovered	N	Serious	

Event Categories	
Death	Yes
Life Threatening	No
Permanent Disability	No
Congenital Anomaly/Birth Defect	No
Hospitalized	Yes
Days in Hospital	None
Existing Hospitalization Prolonged	No
Emergency Room/Office Visit	No
Emergency Room	No
Office Visit	No

Symptoms
Abdominal pain
Asthenia
Decreased appetite
Diarrhoea
Dyspnoea
Pyrexia
Vomiting

Adverse Event Description

vomiting non projectile/Vomiting x10 episodes; undocumented low grade fever; loss of appetite; generalized abdominal pain; difficulty of breathing; LBM watery non mucoid, non bloody/LBM x3 episodes; generalized body weakness; This is a spontaneous report received from a contactable reporter(s) (Other HCP) from Regulatory Authority. Regulatory number: PH-PHFDA-300122591. A 15 year-old male patient received bnt162b2 (COMIRNATY), intramuscular, administration date 15Nov2021 (Lot number: PCB0002) at the age of 15 years as dose number unknown, single for covid-19 immunisation. The patient's relevant medical history and concomitant medications were not reported. The following information was reported: ASTHENIA (death, hospitalization) with onset 16Nov2021, outcome fatal, described as generalized body weakness; VOMITING (death, hospitalization) with onset 18Nov2021, outcome fatal, described as vomiting non projectile/Vomiting x10 episodes; PYREXIA (death, hospitalization) with onset 18Nov2021, outcome fatal, described as undocumented low grade fever; DECREASED APPETITE (death, hospitalization) with onset 18Nov2021, outcome fatal, described as loss of appetite; ABDOMINAL PAIN (death, hospitalization) with onset 18Nov2021, outcome fatal, described as generalized abdominal pain; DYSPNOEA (death, hospitalization) with onset 18Nov2021, outcome fatal, described as difficulty of breathing; DIARRHOEA (death, hospitalization) with onset 18Nov2021, outcome fatal, described as LBM watery non mucoid, non bloody/LBM x3 episodes. On 19Nov2021, Persistence vomiting, (+) abdominal pain, (+) DOB. The patient date of death was unknown. The reported cause of death was asthenia, vomiting, pyrexia, decreased appetite, abdominal pain, dyspnoea, diarrhoea. It was not reported if an autopsy was performed. No follow-up attempts are possible. No further information is expected.; Reported Cause(s) of Death: generalized abdominal pain; LBM watery non mucoid, non bloody; difficulty of breathing; generalized body weakness; vomiting non projectile; undocumented low grade fever; loss of appetite

Lab Data	Current Illness	Adverse Events After Prior Vaccinations

Medications At Time of Vaccination	History/Allergies

VAERS DETAIL

VAERS ID: 1964146

Vaccine Type	Vaccine	Manufacturer	Lot	Dose	Route	Site
COVID19	COVID19 (COVID19 (PFIZER-BIONTECH))	PFIZER\BIONTECH	FE3591	1		LA

Event Information			
Patient Age		Sex	F
State/Territory	FR	Date Report Completed	
Date Vaccinated	8/16/2021	Date Report Received	12/20/2021
Date of Onset	8/19/2021	Date Died	8/25/2021
Days to Onset	3		
Vaccine Administered By	OTH	Vaccine Purchased By	
Mfr/Imm Project Number			
Recovered	N	Serious	

Event Categories	
Death	Yes
Life Threatening	No
Permanent Disability	No
Congenital Anomaly/Birth Defect	No
Hospitalized	No
Days in Hospital	None
Existing Hospitalization Prolonged	No
Emergency Room/Office Visit	Yes
Emergency Room	No
Office Visit	No

Symptoms
Blood test
Chills
Death
Dehydration
Eye pain
Headache
Pharyngitis
Pyrexia
SARS-CoV-2 test
Swelling

Adverse Event Description

they said she was dehydrated; death; enormous chill; started swelling a lot; a lot of headache; pain in the eyes; fever; inflamed throat; This is a spontaneous report received from a contactable consumer via Regulatory Authority. A 20 year-old female patient (not pregnant) received BNT162B2 (COMIRNATY), administered in arm left, on 16Aug2021 (Lot number: FE3591) as first single dose for covid-19 immunization. The patient had no relevant medical history. There were no concomitant medications. The following information was reported: death (death) with onset 25Aug2021, outcome fatal, described as death; headache (medically significant) with onset 19Aug2021, outcome not recovered, described as a lot of headache; eye pain (medically significant) with onset 19Aug2021, outcome not recovered, described as pain in the eyes; pyrexia (medically significant) with onset 19Aug2021, outcome not recovered, described as fever; pharyngitis (medically significant) with onset 19Aug2021, outcome not recovered, described as inflamed throat; Chills (medically significant) with onset 23Aug2021, outcome not recovered, described as enormous chill; swelling (medically significant) with onset 23Aug2021, outcome not recovered, described as started swelling a lot; dehydration (medically significant), outcome not recovered, described as they said she was dehydrated. The events a lot of headache, pain in the eyes, fever, inflamed throat, started swelling a lot and they said she was dehydrated were evaluated at the emergency room visit. The patient underwent the following laboratory tests and procedures: blood test: (23Aug2021) all normal; Nasal Swab: (22Aug2021) inconclusive. Therapeutic measures were not taken as a result of death. Therapeutic measures were taken as a result of headache, eye pain, pyrexia, pharyngitis, chills, swelling, dehydration. The patients date of death was 25Aug2021. Additional information: The patients sister noted that the 20-year-old girl who died on 25Aug2021. She was vaccinated in 16Aug2021, three days later, the complaints started, an included, a lot of headache, pain in the eyes, fever and sore throat. She continued complaining during the week, the fever increased. On 22Aug2021, she couldn't stand it anymore; she went to the emergency room, where covid test and dengue test were performed. The patient was administered saline in the vein, and an injection for fever. She was released from the hospital, but she was still bad. On the following day, 23Aug2021, the symptoms persisted, but with a huge chill, and she started to swell a lot. She returned to the emergency room, but the doctors said there was nothing to do; they administered saline again and said that she was dehydrated. Some unspecified blood tests were performed; the results were all normal. The patient returned home. She was unable to be alone; she contacted the reporter, who went to her house; the reporter noted that her health condition was very bad.; Reported Cause(s) of Death: patent died on 25Aug2021

Lab Data	Current Illness	Adverse Events After Prior Vaccinations
Test Date: 20210823; Test Name: blood tests; Result Unstructured Data: Test Result:all normal; Test Date: 20210822; Test Name: Nasal Swab; Result Unstructured Data: Test Result:Inconclusive		

Medications At Time of Vaccination	History/Allergies
	Comments: List of non-encoded Patient Relevant History: Patient Other Relevant History 1: None

VAERS DETAIL

VAERS ID: 1871945

Vaccine Type	Vaccine	Manufacturer	Lot	Dose	Route	Site
COVID19	COVID19 (COVID19 (PFIZER-BIONTECH))	PFIZER\BIONTECH	1G042A-CDC	UNK	OT	

Event Information			
Patient Age		Sex	F
State/Territory	FR	Date Report Completed	
Date Vaccinated	9/24/2021	Date Report Received	11/16/2021
Date of Onset	10/15/2021	Date Died	10/15/2021
Days to Onset	21		
Vaccine Administered By	OTH	Vaccine Purchased By	
Mfr/Imm Project Number			
Recovered	N	Serious	

Event Categories	
Death	Yes
Life Threatening	No
Permanent Disability	No
Congenital Anomaly/Birth Defect	No
Hospitalized	No
Days in Hospital	None
Existing Hospitalization Prolonged	No
Emergency Room/Office Visit	No
Emergency Room	No
Office Visit	No

Symptoms
Cardiac arrest
Feeling abnormal
Nervous system disorder
Respiratory arrest
Respiratory failure
Sudden death
Syncope

Adverse Event Description

SYNCOPE; FEEL UNCOMFORTABLE; LOST BREATHING; LOST HEARTBEAT; RESPIRATORY FAILURE; SUDDEN DEATH; BRAIN NEUROPATHY; This is a spontaneous report from a non-contactable healthcare professional via Agency Regulatory Authority (Regulatory authority report number: TW-TFDA-TVS-1100010930), based on information received by Pfizer from BioNTech (manufacturer control number: TW-Fosun-2021FOS004726), license party for bnt162b2 (COMIRNATY). This is a spontaneous report received from a non-contactable HCP received via Regulatory Authority for Disease Control. The regulatory authority report number is TW-TFDA-TVS-1100010930. A 15-year-old female patient started to receive a dose of (COMIRNATY) (batch number: 1G042A-CDC) on 24-Sep-2021 via unknown route at unknown dose with unspecified dosing frequency for COVID-19 immunization. Medical history, concomitant medication and past product were not reported. The patient experienced syncope, feel uncomfortable, lost breathing, lost heartbeat, respiratory failure, sudden death and brain neuropathy on 15-Oct-2021. On 24-Sep-2021, the patient inoculated the BNT vaccination in school, and there was no discomfort in the school or home. In the morning of 15-Oct-2021, the patient went to the school, and ran on the corridor in the sports class. When the patient was in a hiking, she felt uncomfortable. The teacher made the patient sit down, but the patient suddenly fainted and lost her breathing and heartbeat. It was reported that notify the nursing to the scene, discover the head or above, the nursing was on the spot, and the Automated External Defibrillator (AED) first aid, and at the same time contacted 119 and the patient's parents. At 9:53 of 15-Oct-2021, the rescue personnel came to pick up the patient, and sent to hospital first aid. At 10:17 of 15-Oct-2021, the patient arrived at the hospital. It was reported that the first death in the hospital, the first aid is invalid. At 10:51 of 15-Oct-2021, it was reported that the patient's families had been discovered after the speech explanation, and the family agreed to give up first aid. At 11:04 of 15-Oct-2021, the patient was announced death. The family was not willing to anatomy. Upon the judicial test, the diagnosis of death was the respiratory failure and sudden death. The death causes B was brain neuropathy, death facts. Syncope, feel uncomfortable, lost breathing, lost heartbeat, respiratory failure, sudden death and brain neuropathy met the seriousness criterion of results in death. The actions taken for (COMIRNATY) regarding the event were not applicable. At the time of the report, the outcomes of the events were death. The patient died on 15-Oct-2021. An autopsy was not performed and the reported cause of death was the respiratory failure, sudden death and brain neuropathy. Initial report was received on 03-Nov-2021. Follow-up closed, no further information is possible BIONTECH comment: The medical review comments of RA Department on the report of syncope, feel uncomfortable, lost breathing, lost heartbeat, respiratory failure and sudden death is as follows: The seriousness of syncope, feel uncomfortable, lost breathing, lost heartbeat, respiratory failure and sudden death is: death. Syncope, feel uncomfortable, lost breathing, lost heartbeat, respiratory failure and sudden death are not common adverse events in the package insert of COMIRNATY, so the expectedness is: unexpected. Given the limited information available to date, it is difficult to exclude a causal relationship, and the relationships between syncope, feel uncomfortable, lost breathing, lost heartbeat, respiratory failure and sudden death and COMIRNATY is considered as possible. Causality assessment Syncope; Feels poorly; Breathing arrested; Standstill cardiac; Respiratory failure; Sudden death; Central nervous system disorder Per Reporter=Possible Per Company=Possible; Reported Cause(s) of Death: respiratory failure; sudden death; brain neuropathy

Lab Data	Current Illness	Adverse Events After Prior Vaccinations

Medications At Time of Vaccination	History/Allergies

VAERS DETAIL

VAERS ID: 1826903

Vaccine Type	Vaccine	Manufacturer	Lot	Dose	Route	Site
COVID19	COVID19 (COVID19 (PFIZER-BIONTECH))	PFIZER\BIONTECH		1		

Event Information			
Patient Age		Sex	F
State/Territory	FR	Date Report Completed	
Date Vaccinated	10/3/2021	Date Report Received	10/29/2021
Date of Onset	10/8/2021	Date Died	10/8/2021
Days to Onset	5		
Vaccine Administered By	OTH	Vaccine Purchased By	
Mfr/Imm Project Number			
Recovered	N	Serious	

Event Categories	
Death	Yes
Life Threatening	No
Permanent Disability	No
Congenital Anomaly/Birth Defect	No
Hospitalized	No
Days in Hospital	None
Existing Hospitalization Prolonged	No
Emergency Room/Office Visit	No
Emergency Room	No
Office Visit	No

Symptoms
Cardiac disorder
Ovarian enlargement

Adverse Event Description

growth on her ovaries and anomalies in her heart; growth on her ovaries and anomalies in her heart; This is a spontaneous report from a non-contactable consumer. A 14-years-old female patient received bnt162b2 (COMIRNATY), dose 1 via an unspecified route of administration on 03Oct2021 (Batch/Lot number was not reported) as DOSE 1, SINGLE for COVID-19 immunisation. The patient medical history and concomitant medications were not reported. Patient did not have any allergies or disease. Her health was in good condition post vaccination. She did not experience any fever, runny nose, joint pains or difficulty in breathing and could continue her routine as usual. The patient died on 08Oct2021. A post-mortem conducted on the patient found that there was a growth on her ovaries and anomalies in her heart following a post-mortem on 08Oct2021. No follow up activities are possible. No further information is expected.; Reported Cause(s) of Death: growth on her ovaries and anomalies in her heart; growth on her ovaries and anomalies in her heart; Autopsy-determined Cause(s) of Death: growth on her ovaries and anomalies in her heart; growth on her ovaries and anomalies in her heart

Lab Data	Current Illness	Adverse Events After Prior Vaccinations

Medications At Time of Vaccination	History/Allergies

VAERS DETAIL

VAERS ID: 1913198

Vaccine Type	Vaccine	Manufacturer	Lot	Dose	Route	Site
COVID19	COVID19 (COVID19 (PFIZER-BIONTECH))	PFIZER\BIONTECH		UNK		

Event Information			
Patient Age	13	Sex	F
State/Territory	TX	Date Report Completed	
Date Vaccinated	8/1/2021	Date Report Received	12/1/2021
Date of Onset	9/1/2021	Date Died	12/1/2021
Days to Onset	31		
Vaccine Administered By	UNK	Vaccine Purchased By	
Mfr/Imm Project Number			
Recovered	N	Serious	

Event Categories	
Death	Yes
Life Threatening	No
Permanent Disability	No
Congenital Anomaly/Birth Defect	No
Hospitalized	Yes
Days in Hospital	30
Existing Hospitalization Prolonged	No
Emergency Room/Office Visit	No
Emergency Room	No
Office Visit	No

Symptoms
Acute kidney injury
Airway peak pressure increased
Asthenia
Back pain
Bradycardia
Cardiac output decreased
Cardiac tamponade
Chemotherapy
Chest pain
Death
Debridement
Diarrhoea
Dyspnoea
Endotracheal intubation
Epithelioid sarcoma
Exploratory operation
Fatigue
Fluid retention
General symptom
Haemofiltration
Hypotension
Influenza virus test negative
Intracardiac mass
Lactic acidosis
Loss of personal independence in daily activities
Low lung compliance
Multiple organ dysfunction syndrome
Neoplasm malignant
Oedema
Oropharyngeal pain
Pericardial excision
Pericardial rub
Pneumonia
Pulmonary oedema
Pyrexia
SARS-CoV-2 test negative
Sedation
Streptococcus test negative
Tachycardia
Tumour excision

Adverse Event Description

Patient received Pfizer vaccine in 8/2021. In 9/2021 she began to have some vague complaints of upper back pain. Patient ultimately diagnosed with epitheliod sarcoma. Parents requested that this information be sent to VAERS in case her cancer was related to Vaccine. Physicians caring for the child do not feel her death or her cancer was related to the covid vaccine. Presented to the local Medical Center on 10/30/21 after having received care closer to home. Pt is a 13 y.o. female with no past medical history who presents with fever, chest pain, and diarrhea. About two weeks PTA, she began complaining of sternal chest pain. She had fatigue and sore throat so was taken to an urgent care where she was negative for strep, flu, and COVID. She was prescribed bromfed. She then progressed to a dry mild that started about 10 days PTA. On Tuesday, 10/26, she was seen at an outside ER and was diagnosed with pneumonia. She was started on azithromycin and augmentin. She has continued to have chest pain, SOB, and fatigue. The day of presentation, she stayed home from school. She developed nonbloody diarrhea, tachycardia, and weakness so she was taken back to the ER for evaluation. Found to have a pericardial friction rub. Admitted to hospitalist service.

Lab Data	Current Illness	Adverse Events After Prior Vaccinations
Admitted to local HCF 10/30/21. See the following from her death note summary related to hospital course: Pt is a 13 y.o. female admitted for Left atrial mass and has been hospitalized for 30 days. she had her left atrial mass resection on 11/11/21, pericardial window creation, and mediastinal exploration with debridement. Her mass continued to grow and increase in size and Rhee invading the left atrium and possibly the right atrium along with creation of tamponade physiology on the ventricles. She was started on chemotherapy by hematology team, Nephrology team started her her on CRRT since she developed acute kidney injury along was multi organ failure and severe lactic acidosis. Patient was on multiple inotropics support with progressively increasing inotropics support epinephrine up to 0.3 micrograms/kilogram per minute, norepinephrine up to 0.3 micrograms/kilogram per minute along with 2 milliunits per kg per minute vasopressin. Over the past 48 hours prior to patient staff she was getting multiple fluid boluses and she was few L positive every day with severe 3rd spacing and progressively worsening cardiac output. She has had evidence of progressive tamponade physiology despite aggressive chemotherapy. she remained intubated and sedated with extremely high lung peak pressures and very poor compliance with severe pulmonary edema. On 12/1/2021 family expressed the wishes of stop giving fluids to her since she looks very edematous, parents understand that this will lead to cardiac arrest and ending her life within the next few hours, father expressed he is willing to do everything for her but he wants to end her suffering, mom and dad were at the bedside, IV fluid replacement was stopped. Patient vasopressin was weaned along with other inotropic support, family agreed on extubating the patient so that they can spend some time with her prior to the off. Patient continue to progressively having low cardiac output, hypotension and bradycardia, time of death was 7:00 a.m..	unknown	

Medications At Time of Vaccination	History/Allergies
None known	none
	No known allergies

VAERS DETAIL

VAERS ID: 1952747

Vaccine Type	Vaccine	Manufacturer	Lot	Dose	Route	Site
COVID19	COVID19 (COVID19 (PFIZER-BIONTECH))	PFIZER\BIONTECH	FF0884	1		

Event Information			
Patient Age		Sex	M
State/Territory	FR	Date Report Completed	
Date Vaccinated	11/27/2021	Date Report Received	12/15/2021
Date of Onset	12/1/2021	Date Died	12/1/2021
Days to Onset	4		
Vaccine Administered By	OTH	Vaccine Purchased By	
Mfr/Imm Project Number			
Recovered	N	Serious	

Event Categories	
Death	Yes
Life Threatening	No
Permanent Disability	No
Congenital Anomaly/Birth Defect	No
Hospitalized	No
Days in Hospital	None
Existing Hospitalization Prolonged	No
Emergency Room/Office Visit	No
Emergency Room	No
Office Visit	No

Symptoms
Death

Adverse Event Description

Found dead at 01 o'clock at night without prior symptoms of any kind; This is a spontaneous report received from contactable reporter(s) (Consumer or other non HCP and Physician) from the regulatory authority. Regulatory number: DK-DKMA-ADR 26295617 (DKMA). A 12 year-old male patient received bnt162b2 (COMIRNATY), administration date 27Nov2021 (Lot number: FF0884) as dose 1, single for covid-19 immunisation. The patient's relevant medical history and concomitant medications were not reported. The following information was reported: DEATH (death, medically significant) with onset 01Dec2021, outcome fatal, described as Found dead at 01 o'clock at night without prior symptoms of any kind. The patient date of death was 01Dec2021. The reported cause of death was Found dead at 01 o'clock at night without prior symptoms of any kind. The autopsy was performed, and results were not provided. Clinical course: On 01Dec2021, 4 days after vaccination, he was found dead at 01 o'clock at night without prior symptoms of any kind. The patient had been happy and playing computer games online with his friends until he went to bed at 23:00 on 30Nov2021. Reported cause of death was not reported. An autopsy had been performed but the result was not expected to be available until 3 months. The ADR was by the reporter reported as being Fatal. There was no information regarding test results. Causality: The relative reports as the child has been vaccinated 4 days earlier and he therefore believes it should be reported. The patient's general practitioner confirms that the patient is dead but will not comment on whether there is a connection with the vaccine, as there is no result from the autopsy. The forensic pathologist comments that it is being investigated whether it is related to the vaccine, but comments that it may be natural causes. The autopsy is an urgent matter, and the result is awaited (expected in 3 months). No follow-up attempts are possible. No further information is expected; Reported Cause(s) of Death: Found dead at 01 o'clock at night without prior symptoms of any kind

Lab Data	Current Illness	Adverse Events After Prior Vaccinations

Medications At Time of Vaccination	History/Allergies

SAMPLE VAERS RECORDS FROM THE "CAUSAL LINK LIKELY" CATEGORY

CRITERIA:

1. Description mentions that a physician or other health care-related professional believes that a causal link is suspected, likely, or confirmed.

VAERS DETAIL

VAERS ID: 1578593

Vaccine Type	Vaccine	Manufacturer	Lot	Dose	Route	Site
COVID19	COVID19 (COVID19 (PFIZER-BIONTECH))	PFIZER\BIONTECH	EW0191	1	IM	RA

Event Information			
Patient Age	34	Sex	M
State/Territory	WA	Date Report Completed	
Date Vaccinated	6/15/2021	Date Report Received	8/17/2021
Date of Onset	6/23/2021	Date Died	6/25/2021
Days to Onset	8		
Vaccine Administered By	OTH	Vaccine Purchased By	
Mfr/Imm Project Number			
Recovered	N	Serious	

Event Categories	
Death	Yes
Life Threatening	No
Permanent Disability	No
Congenital Anomaly/Birth Defect	No
Hospitalized	Yes
Days in Hospital	3
Existing Hospitalization Prolonged	No
Emergency Room/Office Visit	Yes
Emergency Room	No
Office Visit	No

Symptoms
Autopsy
Cardiac arrest
Death
Vaccination complication

Adverse Event Description

Died June 25th after cardiac arrest on June 23rd, 8 days after his vaccine.

Lab Data	Current Illness	Adverse Events After Prior Vaccinations
Forensic Pathologist after full autopsy determined patient was a healthy adult with no heart disease, no liver disease, and no pnemomia. Coroner determined after toxicology report that covid 19 vaccine was the only contributing factor. Everything else was ruled out.	N/A	Pertussis reaction as newborn

Medications At Time of Vaccination	History/Allergies
Gabapentin Clonazepam Baclofen Cimetidine	Depression and anxiety
	Penicillin

VAERS DETAIL

VAERS ID: 1778557

Vaccine Type	Vaccine	Manufacturer	Lot	Dose	Route	Site
COVID19	COVID19 (COVID19 (PFIZER-BIONTECH))	PFIZER\BIONTECH	FF9942	1		

Event Information			
Patient Age	72	Sex	F
State/Territory	FR	Date Report Completed	
Date Vaccinated	8/25/2021	Date Report Received	10/12/2021
Date of Onset	8/25/2021	Date Died	8/25/2021
Days to Onset	0		
Vaccine Administered By	OTH	Vaccine Purchased By	
Mfr/Imm Project Number			
Recovered	N	Serious	

Event Categories	
Death	Yes
Life Threatening	No
Permanent Disability	No
Congenital Anomaly/Birth Defect	No
Hospitalized	No
Days in Hospital	None
Existing Hospitalization Prolonged	No
Emergency Room/Office Visit	No
Emergency Room	No
Office Visit	No

Symptoms
Body temperature
Malaise
Myocarditis
Nausea

Adverse Event Description

malaise; queasy; Acute myocarditis; This is a spontaneous report from a contactable physician received from the Regulatory Agency. Regulatory authority report number is v21128690. The patient was a 72-year and 5-month-old female. Body temperature before vaccination was 35.0 degrees centigrade. The family history was not provided. The patient had medical history of allergy to antibiotic. On 25Aug2021 at 09:00 (the day of vaccination), the patient received the first dose of BNT162b2 (COMIRNATY, Solution for injection, Lot number FF9942, Expiration date 30Nov2021) via an unspecified route of administration as DOSE 1, SINGLE for COVID-19 immunization. On 25Aug2021 (the day of the vaccination), the patient died with acute myocarditis. On 25Aug2021, although the patient complained of physical deconditioning while she was waiting after the vaccination, since she recovered, she went home. On 25Aug2021 16:00 (7 hours later), the patient was complained of physical deconditioning to her family member (malaise and queasy), and the family member came to see how the patient was doing. On 26Aug2021, the family member was not in contact with the patient, and when the family member came to see how the patient was doing, the patient was found dead at her home. Based on the results of the administrative autopsy under the act on the investigation of cause of death, severe and acute myocarditis accompanied by microthrombus was observed in the heart of this dead body, and no underlying diseases such as bacteria or virus which generally caused myocarditis were observed. In addition, the time of onset of the event which was assumed from the tissue image was not inconsistent with after the vaccination. Moreover, no other diseases or injuries which could be the causes of death were observed. Thus, it was hard to avoid thinking that the acute myocarditis in this dead body was a side reaction caused by the vaccination. The reporting physician classified the event as serious (death) and assessed that the event was related to BNT162b2. There was no other possible cause of the event such as any other diseases. The reporting physician commented as follows: As the results of the autopsy, it was hard to avoid thinking that the acute myocarditis in this dead body was a side reaction caused by the vaccination. Outcome of the events malaise and queasy was unknown.; Reported Cause(s) of Death: Acute myocarditis; Autopsy-determined Cause(s) of Death: It was hard to avoid thinking that the acute myocarditis in this dead body was a side reaction caused by the vaccination.

Lab Data	Current Illness	Adverse Events After Prior Vaccinations
Test Date: 20210825; Test Name: body temperature; Result Unstructured Data: Test Result:35.0 Centigrade; Comments: Before vaccination		

Medications At Time of Vaccination	History/Allergies
	Medical History/Concurrent Conditions: Allergy to antibiotic

VAERS DETAIL

VAERS ID: 1325541

Vaccine Type	Vaccine	Manufacturer	Lot	Dose	Route	Site
COVID19	COVID19 (COVID19 (PFIZER-BIONTECH))	PFIZER\BIONTECH	ER7449	1		

Event Information			
Patient Age	47	Sex	F
State/Territory	FR	Date Report Completed	
Date Vaccinated	4/27/2021	Date Report Received	5/18/2021
Date of Onset	4/1/2021	Date Died	5/2/2021
Days to Onset			
Vaccine Administered By	OTH	Vaccine Purchased By	
Mfr/Imm Project Number			
Recovered	N	Serious	

Event Categories	
Death	Yes
Life Threatening	No
Permanent Disability	No
Congenital Anomaly/Birth Defect	No
Hospitalized	No
Days in Hospital	None
Existing Hospitalization Prolonged	No
Emergency Room/Office Visit	Yes
Emergency Room	No
Office Visit	No

Symptoms
Body temperature
Cardio-respiratory arrest
Computerised tomogram head
Computerised tomogram thorax
Echocardiogram
Fibrin D dimer
Genital haemorrhage
Physical deconditioning
Pulmonary embolism
Sudden death

Adverse Event Description

Sudden death; cardio-respiratory arrest; pulmonary embolism; genital haemorrhage; physical deconditioning; This is a spontaneous report from a contactable physician received from the regulatory authority. The regulatory authority report number is v21105963. A 47-year-old female patient received the first dose of BNT162B2 (COMIRNATY; Lot Number: ER7449; Expiration Date: 30Jun2021), via an unspecified route of administration, on 27Apr2021 at 10:00 (at the age of 47-years-old) as a single dose for COVID-19 immunisation. Medical history included adenomyosis uteri. The patient had no particular family history. The patient's concomitant medications were not reported. The patient previously took leuprorelin (MANUFACTURER UNKNOWN) from 28May2020 to 30Oct2020 (a total of 6 times, once per month). The patient experienced sudden death on 02May2021 at 06:00, reported as 5 days after the vaccination. The patient also experienced genital haemorrhage and physical deconditioning in Apr2021 (reported as 2 to 3 days before death) and cardio-respiratory arrest and pulmonary embolism on 02May2021. The clinical course was reported as follows: The body temperature before vaccination was 36.3 degrees Centigrade on 27Apr2021. On 02May2021, in the early morning, the patient began to suffer, and she had cardio-respiratory arrest in the restroom, and she was emergently transferred to the hospital. The heart rate was restored with administration of adrenaline (MANUFACTURER UNKNOWN). The patient repeatedly had cardiac arrest, and she was confirmed to be dead at 09:18 (as reported) on the same day. It was reported that 2 to 3 days before the death, the patient had genital haemorrhage and physical deconditioning. A head and chest computerised tomogram (CT) showed no finding which was the cause of death within the skull, and no findings such as aortic dissection were observed on 02May2021. The echocardiography showed findings of right heart strain on 02May2021, and the patient was suspected to have pulmonary embolism based on the clinical course. The D-dimer was high at 41.9 mcg/mL on 02May2021. Therapeutic measures were taken as a result of sudden death and cardio-respiratory arrest as aforementioned. The clinical outcome of genital haemorrhage and physical deconditioning was unknown and of cardio-respiratory arrest and pulmonary embolism was fatal. The patient died on 02May2021. The cause of death was reported as sudden death and assessed as due to cardio-respiratory arrest and pulmonary embolism. It was not reported if an autopsy was performed. The reporting physician assessed that the event was related to BNT162B2. There was no other possible cause of the event such as any other diseases reported. The reporting physician reported that: a 47-year-old healthy female without serious underlying diseases died 5 days after receiving the vaccination. Thus, the side reaction was considered highly likely, and this case was reported.; Reported Cause(s) of Death: sudden death; cardio-respiratory arrest; pulmonary embolism

Lab Data	Current Illness	Adverse Events After Prior Vaccinations
Test Date: 20210427; Test Name: body temperature; Result Unstructured Data: Test Result:36.3 Centigrade; Comments: Before vaccination; Test Date: 20210502; Test Name: head CT; Result Unstructured Data: Test Result:no finding which was the cause of death within the; Comments: skull, and no findings such as aortic dissection; Test Date: 20210502; Test Name: chest CT; Result Unstructured Data: Test Result:no finding which was the cause of death within the; Comments: skull, and no findings such as aortic dissection; Test Date: 20210502; Test Name: echocardiography; Result Unstructured Data: Test Result:findings of right heart strain; Test Date: 20210502; Test Name: D-dimer; Result Unstructured Data: Test Result:41.9 ug/ml; Comments: high		

Medications At Time of Vaccination	History/Allergies
	Medical History/Concurrent Conditions: Adenomyosis uteri

VAERS DETAIL

VAERS ID: 1784381

Vaccine Type	Vaccine	Manufacturer	Lot	Dose	Route	Site
COVID19	COVID19 (COVID19 (PFIZER-BIONTECH))	PFIZER\BIONTECH	FF0843	2		

Event Information			
Patient Age	43	Sex	M
State/Territory	FR	Date Report Completed	
Date Vaccinated	8/30/2021	Date Report Received	10/14/2021
Date of Onset	9/8/2021	Date Died	9/8/2021
Days to Onset	9		
Vaccine Administered By	OTH	Vaccine Purchased By	
Mfr/Imm Project Number			
Recovered	N	Serious	

Event Categories	
Death	Yes
Life Threatening	No
Permanent Disability	No
Congenital Anomaly/Birth Defect	No
Hospitalized	No
Days in Hospital	None
Existing Hospitalization Prolonged	No
Emergency Room/Office Visit	No
Emergency Room	No
Office Visit	No

Symptoms
Autopsy
Body temperature
Cardiac arrest
Myocarditis

Adverse Event Description

Acute myocarditis; cardiac arrest; This is a spontaneous report from a contactable physician received from the Regulatory Agency. Regulatory authority report number is v21128812. A 43-year-old male patient received BNT162B2 (COMIRNATY, Solution for injection, Lot Number: FF0843; Expiration Date: 31Oct2021), via an unspecified route of administration on 30Aug2021 14:00 (at the age of 43-year-old) as dose 2, single for COVID-19 immunization. Medical history included acute leukaemia from an unknown date and there was tendency toward recovery. The patient's concomitant medications and family history were not reported. Historical vaccine included first dose of BNT162B2 (COMIRNATY, Solution for injection, Lot: FC3661, Expiration date 30Sep2021), via an unspecified route of administration on 26Jul2021 14:00, as single dose for COVID-19 immunization. Body temperature before vaccination was 36.8 degrees Centigrade. On 08Sep2021(8 days after the vaccination), the patient suddenly developed cardiac arrest and died. Pathological autopsy indicated a large amount of cardiac effusion which had not been noted until the previous day, and it was considered that the patient developed acute myocarditis on 08Sep2021 08:15. The reporting physician classified the event as serious (fatal outcome) and assessed that the event was related to BNT162b2. There was no other possible cause of the event such as any other diseases. The reporting physician commented as follows: Acute myocarditis suddenly developed and no other possible cause was considered. Therefore, the vaccination was considered to be the cause of the event.; Reported Cause(s) of Death: cardiac arrest; Acute myocarditis; Autopsy-determined Cause(s) of Death: Cardiac effusion

Lab Data	Current Illness	Adverse Events After Prior Vaccinations
Test Name: Pathological autopsy; Result Unstructured Data: Test Result: a large amount of cardiac effusion; Test Date: 20210830; Test Name: Body temperature; Result Unstructured Data: Test Result: 36.8 Centigrade; Comments: before vaccination.		

Medications At Time of Vaccination	History/Allergies
	Medical History/Concurrent Conditions: Acute leukaemia.

VAERS DETAIL

VAERS ID: 1862975

Vaccine Type	Vaccine	Manufacturer	Lot	Dose	Route	Site
COVID19	COVID19 (COVID19 (PFIZER-BIONTECH))	PFIZER\BIONTECH	FF9944	2		

Event Information			
Patient Age	36	Sex	M
State/Territory	FR	Date Report Completed	
Date Vaccinated	8/28/2021	Date Report Received	11/12/2021
Date of Onset	8/29/2021	Date Died	8/31/2021
Days to Onset	1		
Vaccine Administered By	OTH	Vaccine Purchased By	
Mfr/Imm Project Number			
Recovered	N	Serious	

Event Categories	
Death	Yes
Life Threatening	No
Permanent Disability	No
Congenital Anomaly/Birth Defect	No
Hospitalized	No
Days in Hospital	None
Existing Hospitalization Prolonged	No
Emergency Room/Office Visit	No
Emergency Room	No
Office Visit	No

Symptoms
Autopsy
Body temperature
Malaise
Myocarditis
Pyrexia

Adverse Event Description

Acute myocarditis; malaise; the body temperature was 37.4 degrees Centigrade; This is a spontaneous report from a contactable physician received from the Regulatory Authority. Regulatory authority report number is v21130695. The patient was a 36-year and 10-month-old male. Body temperature before vaccination was 36.5 degrees Centigrade. Medical history included adenomatous goitre and hypothyroidism (in Apr2019, the patient regularly visited a different hospital for the treatment). Concomitant medications and family history were not reported. On 07Aug2021, the patient previously received the first dose of BNT162b2 (COMIRNATY, Solution for injection, Lot# FF4204, Expiration date 31Jan2022) via an unspecified route of administration as a single dose for COVID-19 immunization. On 28Aug2021 at 10:00, (the day of vaccination), the patient received the second dose of BNT162b2 (COMIRNATY, Solution for injection, Lot# FF9944, Expiration date 28Feb2022) via an unspecified route of administration as a single dose for COVID-19 immunization (at the age of 36 years old). On 31Aug2021 at 01:00 (3 days after the vaccination), the patient died of acute myocarditis. An autopsy was performed (the cause of death confirmed by autopsy was acute myocarditis). The course of the events was as follows: On 29Aug2021(1 day after the vaccination), the body temperature was 37.4 degrees Centigrade. On that day, he worked from 04:00 a.m. to 07:00 (not clear if it was a.m. or p.m.). After he returned home, as he did not feel well, he ate Japanese thin wheat noodles only. On 30Aug2021(2 days after the vaccination), the patient had a day off from work. From that morning, he had malaise and stayed in his room all day. On 31Aug2021 at 06:23 (3 days after the vaccination), his mother found him lying on the floor in his room. On the same day, a postmortem examination was performed. On 01Sep2021, an administrative autopsy was carried out at the department of legal medicine of the university. A diagnosis of acute myocarditis was made. The reporting physician classified the event as serious (fatal outcome) and assessed that the event was related to BNT162b2. There was no other possible cause of the event such as any other diseases. The reporting physician commented as follows: According to the anatomist, the reasons for the presence of a causal relationship with the vaccination were that i) the patient carried on normal life before the vaccination and ii) the relatedness between the vaccination and myocarditis has been reported by the press. No follow-up attempts possible. No further information expected.; Reported Cause(s) of Death: Acute myocarditis; Autopsy-determined Cause(s) of Death: Acute myocarditis

Lab Data	Current Illness	Adverse Events After Prior Vaccinations
Test Date: 20210901; Test Name: administrative autopsy; Result Unstructured Data: Test Result:acute myocarditis; Test Date: 20210828; Test Name: Body temperature; Result Unstructured Data: Test Result:36.5 Centigrade; Comments: before vaccination; Test Date: 20210829; Test Name: Body temperature; Result Unstructured Data: Test Result:37.4 Centigrade		

Medications At Time of Vaccination	History/Allergies
	Medical History/Concurrent Conditions: Adenomatous goitre (the patient regularly visited a different hospital for the treatment); Hypothyroidism (the patient regularly visited a different hospital for the treatment)

VAERS DETAIL

VAERS ID: 1576804

Vaccine Type	Vaccine	Manufacturer	Lot	Dose	Route	Site
COVID19	COVID19 (COVID19 (PFIZER-BIONTECH))	PFIZER\BIONTECH	EY0583	2		

Event Information			
Patient Age		Sex	M
State/Territory	FR	Date Report Completed	
Date Vaccinated	7/29/2021	Date Report Received	8/17/2021
Date of Onset	7/31/2021	Date Died	7/31/2021
Days to Onset	2		
Vaccine Administered By	OTH	Vaccine Purchased By	
Mfr/Imm Project Number			
Recovered	N	Serious	

Event Categories	
Death	Yes
Life Threatening	No
Permanent Disability	No
Congenital Anomaly/Birth Defect	No
Hospitalized	No
Days in Hospital	None
Existing Hospitalization Prolonged	No
Emergency Room/Office Visit	No
Emergency Room	No
Office Visit	No

Symptoms
Blood pressure decreased
Blood pressure measurement
Body temperature
Imaging procedure
Respiratory disorder

Adverse Event Description

respiratory status suddenly aggravated; blood pressure decreased; This is a spontaneous report from a contactable physician received from the Regulatory Authority. Regulatory authority report number is v21122605. The patient was an 86-year and 8-month-old male. Body temperature before vaccination was 36.8 degrees centigrade. Family history was not reported. Medical history included emphysema, atelectasis, and pneumonia from 06Jul2021 which was treated with antibiotics and tended to improve. On an unspecified date, the patient previously received the first dose of BNT162b2 (COMIRNATY, Lot# and expiration date were not reported) for COVID-19 immunisation. On 27Jul2021, the antibiotics for pneumonia was suspended. On 29Jul2021 at 15:30 (the day of vaccination), the patient received the second dose of BNT162b2 (COMIRNATY, Solution for injection, Lot number EY0583, Expiration date 31Oct2021) via an unspecified route of administration as the second single dose for COVID-19 immunization. Imaging revealed residual pleural effusion and atelectasis on 29Jul2021, but vital signs were stable and consciousness level and complexion were good; thus, the patient received BNT162b2. On 31Jul2021 at 16:50 (2 days 1 hour and 20 minutes after the vaccination), the patient experienced respiratory status suddenly aggravated and blood pressure decreased. The condition did not improve, and the patient died on the same date (31Jul2021). It was not reported if an autopsy was performed. The reporting physician classified the events as serious (fatal) and assessed that the events were related to BNT162b2. Other possible causes of the event such as any other diseases were emphysema, pleural effusion, and atelectasis, which were observed. The reporting physician commented as follows: General condition before the vaccination was good and there was no particular change in condition immediately after the vaccination. Since there was no other pathological condition that resulted in sudden change, causality between the events and the vaccine could not be denied. ; Reported Cause(s) of Death: respiratory status suddenly aggravated; blood pressure decreased; emphysema; pleural effusion; atelectasis

Lab Data	Current Illness	Adverse Events After Prior Vaccinations
Test Date: 20210731; Test Name: blood pressure; Result Unstructured Data: Test Result: decreased; Comments: at 16:50; Test Date: 20210729; Test Name: Body temperature; Result Unstructured Data: Test Result:36.8 Centigrade; Comments: before vaccination; Test Date: 20210729; Test Name: Imaging; Result Unstructured Data: Test Result: residual pleural effusion and atelectasis.		

Medications At Time of Vaccination	History/Allergies
	Medical History/Concurrent Conditions: Atelectasis; Emphysema; Pneumonia (treated with antibiotics and tended to improve).

VAERS DETAIL

VAERS ID: 1946421

Vaccine Type	Vaccine	Manufacturer	Lot	Dose	Route	Site
COVID19	COVID19 (COVID19 (PFIZER-BIONTECH))	PFIZER\BIONTECH		1		

Event Information			
Patient Age	29	Sex	F
State/Territory	FR	Date Report Completed	
Date Vaccinated	6/29/2021	Date Report Received	12/14/2021
Date of Onset	6/29/2021	Date Died	
Days to Onset	0		
Vaccine Administered By	OTH	Vaccine Purchased By	
Mfr/Imm Project Number			
Recovered	N	Serious	

Event Categories	
Death	Yes
Life Threatening	No
Permanent Disability	No
Congenital Anomaly/Birth Defect	No
Hospitalized	Yes
Days in Hospital	None
Existing Hospitalization Prolonged	No
Emergency Room/Office Visit	Yes
Emergency Room	No
Office Visit	No

Symptoms
Condition aggravated
Dizziness
Headache
Malaise
Myocarditis
Tremor

Adverse Event Description

Myocarditis; Giddiness; Shaking of hands; Giddiness and shaking of hands worsened; headache/headache aggravated/the possibility of Migraine was high; General malaise; This is a spontaneous report received from a contactable reporter(s) (Pharmacist) from Regulatory Authority. Regulatory number: v21131940. A 29-year and 3-month-old female patient received first single dose of bnt162b2 (COMIRNATY, Solution for injection), administration date 29Jun2021 15:00 (the day of vaccination), (Batch/Lot number: unknown) via an unspecified route of administration at the age of 29-year and 3-month-old as dose 1, single for covid-19 immunisation. Relevant medical history included: had allergies to chicken, pork (unspecified if ongoing); had allergies alcohol (unspecified if ongoing), notes: The patient had allergies to chicken, pork and alcohol. The patient's concomitant medications were not reported. The following information was reported: MYOCARDITIS (death, hospitalization, medically significant) with onset 03Jul2021, outcome fatal, described as Myocarditis; MALAISE (non-serious) with onset 29Jun2021 15:00, outcome unknown, described as General malaise; HEADACHE (non-serious) with onset 30Jun2021, outcome recovered, described as headache/headache aggravated/the possibility of Migraine was high; DIZZINESS (non-serious), outcome unknown, described as Giddiness; TREMOR (non-serious), outcome unknown, described as Shaking of hands; CONDITION AGGRAVATED (non-serious) with onset 05Jul2021, outcome unknown, described as Giddiness and shaking of hands worsened. The patient was hospitalized for myocarditis (start date: 25Sep2021). The events myocarditis, general malaise, headache/headache aggravated/the possibility of migraine was high, giddiness, shaking of hands and giddiness and shaking of hands worsened were evaluated at the emergency room visit. Therapeutic measures were taken as a result of malaise, headache, dizziness, tremor, condition aggravated. The patient date of death was unknown. The reported cause of death was myocarditis. It was not reported if an autopsy was performed. On 25Sep2021 (88 days after the vaccination), the patient was admitted to the hospital. On an unspecified date, the outcome of the event, myocarditis, was fatal. The course of the event was as follows: On 29Jun2021 at 15:00, the patient had general malaise. From 30Jun2021 in the morning, headache occurred, from 01Jul2021, the headache aggravated. The headache worsened due to body motion, then the patient rested quietly in her bed, but symptom did not improve. Since the patient had giddiness, general malaise, and shaking of hands, so she went to the emergency department of the reporting hospital. From the medical record, the possibility of migraine was high. The patient was prescribed medicines (TRIPTAN medicine, nonsteroidal anti-inflammatory drugs (NSAIDs), antiemetic and peptic ulcer medicine), and went to home. After taking the medicines, the headache disappeared, but the other symptoms persisted. On 05Jul2021, giddiness and shaking of hands worsened, then the patient went to the emergency department of the reporting hospital on 06Jul2021. There was a denial of benign paroxysmal positional vertigo, orthostatic hypotension or cerebellar lesion. Considering that the symptoms were form the existing pain, the patient was prescribed medicines (NSAIDs and peptic ulcer medicine), and she was scheduled to revisit the doctor on 12Jul2021, then went to home. Outcome of the event, myocarditis, was fatal. It was unknown if an autopsy was performed. The reporting pharmacist classified the event as serious (hospitalization from 25Sep2021) and assessed that the event was related to BNT162b2. The lot number for bnt162b2 was not provided and will be requested during follow up.; Reported Cause(s) of Death: Myocarditis

Lab Data	Current Illness	Adverse Events After Prior Vaccinations

Medications At Time of Vaccination	History/Allergies
	Medical History/Concurrent Conditions: Alcohol allergy (The patient had allergies to chicken, pork and alcohol.); Food allergy

VAERS DETAIL

VAERS ID: 1789608

Vaccine Type	Vaccine	Manufacturer	Lot	Dose	Route	Site
COVID19	COVID19 (COVID19 (PFIZER-BIONTECH))	PFIZER\BIONTECH	FK0108	2		

Event Information			
Patient Age	36	Sex	M
State/Territory	FR	Date Report Completed	
Date Vaccinated	10/4/2021	Date Report Received	10/16/2021
Date of Onset	10/5/2021	Date Died	10/7/2021
Days to Onset	1		
Vaccine Administered By	OTH	Vaccine Purchased By	
Mfr/Imm Project Number			
Recovered	N	Serious	

Event Categories	
Death	Yes
Life Threatening	No
Permanent Disability	No
Congenital Anomaly/Birth Defect	No
Hospitalized	No
Days in Hospital	None
Existing Hospitalization Prolonged	No
Emergency Room/Office Visit	No
Emergency Room	No
Office Visit	No

Symptoms
Body temperature
Malaise
Pyrexia
Respiratory arrest

Adverse Event Description

Respiratory arrest; pyrexia of 39 degrees centigrade; malaise; This is a spontaneous report from a contactable other healthcare professional received from the Regulatory Authority; report number is v21129155. A 36-year-old male patient received BNT162B2 (COMIRNATY, Solution for injection, Lot number FK0108, Expiration date 31Jan2022), via an unspecified route of administration on 04Oct2021 14:20 (at the age of 36-year and 4-month old) as dose 2, single for COVID-19 immunisation. Body temperature before vaccination was 36.8 degrees centigrade on 04Oct2021. The patient medical history was none. There were no points to be considered on the vaccine screening questionnaire (primary diseases, allergies, vaccinations and illnesses within the last one month, medications the patient was taking, past adverse effect history, growth status). Family history was unknown. The patient's concomitant medications were not reported. On 13Sep2021, the patient previously received the first dose of BNT162B2 (COMIRNATY, Lot# FD0349, Expiration date 31Oct2021) at single dose for COVID-19 immunisation (at the age of 36-year-old) and the patient had no allergy or physical deconditioning. On 04Oct2021 at 14:20 (the day of vaccination), the patient received the second dose of COMIRNATY. On 07Oct2021 in the morning (3 days after the vaccination), the patient experienced respiratory arrest. On 07Oct2021 (3 days after the vaccination), the outcome of the event was fatal. The course of the event was as follows: On 05Oct2021 in the late afternoon, the patient developed pyrexia of 39 degrees centigrade and malaise and took antipyretic. On 06Oct2021, body temperature became 37.0 degrees centigrade. Subsequently, the patient went to bed. On 07Oct2021 in the morning, family member found the patient in respiratory arrest. The reporting other healthcare professional classified the event as serious (fatal) and assessed that the event was related to BNT162b2. There was no other possible cause of the event such as any other diseases. The patient died on 07Oct2021. It was unknown if an autopsy was performed. The outcome of the event pyrexia of 39 degrees centigrade was recovering, of the event malaise was unknown.; Reported Cause(s) of Death: Respiratory arrest

Lab Data	Current Illness	Adverse Events After Prior Vaccinations
Test Date: 20211004; Test Name: Body temperature; Result Unstructured Data: Test Result:36.8 Centigrade; Comments: before vaccination; Test Date: 20211005; Test Name: Body temperature; Result Unstructured Data: Test Result:39 Centigrade; Test Date: 20211006; Test Name: Body temperature; Result Unstructured Data: Test Result:37 Centigrade		

Medications At Time of Vaccination	History/Allergies
	Comments: List of non-encoded Patient Relevant History: Patient Other Relevant History 1: none

VAERS DETAIL

VAERS ID: 1937980

Vaccine Type	Vaccine	Manufacturer	Lot	Dose	Route	Site
COVID19	COVID19 (COVID19 (MODERNA))	MODERNA	3005240	1	OT	

Event Information			
Patient Age	31	Sex	F
State/Territory	FR	Date Report Completed	
Date Vaccinated	8/26/2021	Date Report Received	12/10/2021
Date of Onset	10/30/2021	Date Died	10/30/2021
Days to Onset	65		
Vaccine Administered By	UNK	Vaccine Purchased By	
Mfr/Imm Project Number			
Recovered	N	Serious	

Event Categories	
Death	Yes
Life Threatening	No
Permanent Disability	No
Congenital Anomaly/Birth Defect	No
Hospitalized	No
Days in Hospital	None
Existing Hospitalization Prolonged	No
Emergency Room/Office Visit	No
Emergency Room	No
Office Visit	No

Symptoms
Sudden cardiac death

Adverse Event Description

Sudden cardiac death; This case was received via Pharmaceuticals (Reference number: 2021TJP127428) on 01-Dec-2021 and was forwarded to Moderna on 07-Dec-2021. This case was received via Pharmaceuticals (Reference number: 2021TJP127428) on 01-Dec-2021 and was forwarded to Moderna on 07-Dec-2021. This case, initially reported to the Regulatory Authority by a (physician), was received via the Regulatory Authority (Ref, v21131907). The patient visited a hospital regularly for epilepsy. On 26-Aug-2021, the patient received the 1st dose of this vaccine. On 23-Sep-2021, the patient received the 2nd dose of this vaccine. On 30-Oct-2021, the patient spent the time with her family member until around 15:00 and returned to her room to take a nap. Around 16:00, it is presumed that sudden cardiac death developed. At 19:00, when the family member went to wake the patient up, she was found dead. On an unknown date, the autopsy revealed sudden cardiac death. The outcome of sudden cardiac death was reported as fatal. Follow-up investigation will be made. Company Comment: The event developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.; Reporter's Comments: The event developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship. Reporter's comment: An autopsy was performed. It is possible that the patient had an epileptic seizure while sleeping in bed, but the patient experienced not asphyxia but sudden cardiac death; therefore, it is judged that the event was related to this vaccine.; Sender's Comments: This fatal regulatory authority case concerns a 31-year-old female patient with relevant medical history of epilepsy who experienced serious unexpected event of Death The event occurred 37 days after the second dose of mRNA-1273 vaccine. Autopsy was performed which showed sudden cardiac death Rechallenge was not applicable as the events occurred after the second dose so no rechallenge was done and recurrence was not applicable. The benefit-risk relationship of drug is not affected by this report; Reported Cause(s) of Death: Sudden cardiac death

Lab Data	Current Illness	Adverse Events After Prior Vaccinations
	Epilepsy	

Medications At Time of Vaccination	History/Allergies

VAERS DETAIL

VAERS ID: 1892281

Vaccine Type	Vaccine	Manufacturer	Lot	Dose	Route	Site
COVID19	COVID19 (COVID19 (PFIZER-BIONTECH))	PFIZER\BIONTECH	FF9942	2		

Event Information			
Patient Age		Sex	F
State/Territory	FR	Date Report Completed	
Date Vaccinated	8/28/2021	Date Report Received	11/23/2021
Date of Onset	9/15/2021	Date Died	9/16/2021
Days to Onset	18		
Vaccine Administered By	OTH	Vaccine Purchased By	
Mfr/Imm Project Number			
Recovered	N	Serious	

Event Categories	
Death	Yes
Life Threatening	No
Permanent Disability	No
Congenital Anomaly/Birth Defect	No
Hospitalized	No
Days in Hospital	None
Existing Hospitalization Prolonged	No
Emergency Room/Office Visit	Yes
Emergency Room	No
Office Visit	No

Symptoms
Cardiac disorder
Cardiac valve sclerosis
Carotid artery disease
Coronary artery disease
C-reactive protein
Haemoglobin
Haemorrhage subcutaneous
Headache
Investigation
Kidney congestion
Myocardial ischaemia
Myocardial necrosis
Petechiae
Platelet count
Platelet count decreased
Red blood cell count
Renal failure
Renal tubular necrosis
Shock
Syncope
White blood cell count

Adverse Event Description

Ischaemic heart disease; Petechiae in the inner surface of the scalp occurred; Subcutaneous haemorrhage in the right anterior chest was observed; collapse; headache; Mild intimal thickening was observed in the carotid artery; cortico-medullary junction was congestive in the kidneys; moderate intimal thickening in the coronary artery; platelet count of 95000; Dark red fluidity bloods were accumulated in the heart; shock; necrosis of the proximal tubular epithelium; shock kidney; In the cardiac muscle, fibrosis; contraction band necrosis; This is a spontaneous report from a contactable physician received from the Regulatory Authority. Regulatory authority report number is v21131323. A 53-year-old female patient received bnt162b2 (COMIRNATY), dose 2 via an unspecified route of administration on 28Aug2021 (Batch/Lot Number: FF9942; Expiration Date: 28Feb2022) as DOSE 2, SINGLE for covid-19 immunisation. The patient medical history and concomitant medications were not reported. Body temperature before vaccination was not provided. The family history was not provided. On 07Aug2021, the patient previously received the first dose of BNT162b2 (COMIRNATY, Lot# EW0207, Expiration date 31Dec2021) for COVID-19 immunization. On 16Sep2021 at 00:00 (19 days after the vaccination), the patient experienced ischaemic heart disease. On 16Sep2021 (19 days after the vaccination), the outcome of the event was fatal. The course of the event was as follows: On 07Aug2021, the patient received the first dose of BNT162b2 vaccination. On 28Aug2021 (the day of vaccination), the patient received the second dose of BNT162b2 vaccination. On 15Sep2021 (18 days after vaccination), at night, the patient complained of headache. On 16Sep2021 (19 days after vaccination), in the morning, the patient was found to collapse at her home. Although the patient was emergently transferred, she was confirmed to die at the hospital. Autopsy findings: (1) Petechiae in the inner surface of the scalp occurred. (2) Subcutaneous haemorrhage in the right anterior chest was observed. (3) The cardiac weight was 41.0 g. The thickness of the left ventricle was 1.3 cm and the thickness of the right ventricle was 0.25 cm. No morphologic abnormalities were observed. No obvious arteriosclerosis and stenosis were observed in the coronary artery. Dark red fluidity bloods were accumulated in the heart. (4) No appreciable abnormalities were observed other than congestion in other organs. The laboratory findings: (1) The examination of hematological value using cardiac blood showed WBC of 5100, RBC of 4310000, the hemoglobin content of 12.7 g/dL, the platelet count of 95000, and CRP of 0.1 mg/dL. (2) Alcohol in the cardiac blood and in the urine was negative. (3) The test of drug toxicity in the urine using drug toxicity simple test was negative. (4) The histopathological examination showed moderate intimal thickening in the coronary artery. Fibrotic lesions were scattered in the left ventricular posterior wall of the heart. Micro fibrosis around the micro coronary artery was observed in the left ventricular outflow tract and the left ventricular septum. Extensive contraction band necrosis and wavy appearance were observed in the right ventricular outflow tract. The cortico-medullary junction was congestive in the kidneys, and necrosis of the proximal tubular epithelium was observed (the findings of shock kidney). Mild intimal thickening was observed in the carotid artery. No appreciable abnormalities were observed other than congestion in other organs. The reporting physician classified the event as serious (death) and assessed that the event was related to BNT162b2. Other possible cause of the event such as any other diseases was as follows: The cause of death of this dead body was considered as ischaemic heart disease. The effect of side reactions to the vaccination was suspected. The outcome of events ischemic heart disease, petechiae, hemorrhage subcutaneous, Dark red fluidity bloods were accumulated in the heart, shock was fatal while for other events was unknown. The reporting physician commented as follows: The findings which were observed in acute death such as the onset of petechiae, accumulation of dark red fluidity bloods in the heart, and congestive change of various organs were observed in this dead body. In addition, since the histological examination showed findings of shock, acute death was suggested. In the cardiac muscle, fibrosis, contraction band necrosis, and wavy appearance were observed. Other injury which could affect the cause of death was not observed in this dead body, and no toxicological abnormalities were observed. Thus, the cause of death of this dead body was considered as ischaemic heart disease. Since a 53-year-old female without medical history suddenly dead, the effect of side reactions to the vaccination was suspected. No follow-up attempts are possible. No further information expected.; Reporter's Comments: Summary of reporter comment: The findings which were observed in acute death such as petechiae, accumulation of dark red fluidity bloods in the heart, congestive change, shock, fibrosis, contraction band necrosis, and wavy appearance. The cause of death of this dead body was considered as ischaemic heart disease. Since a 53-year-old female without medical history suddenly dead, the effect of side reactions to the vaccination was suspected.; Reported Cause(s) of Death: shock; Ischaemic heart disease; Autopsy-determined Cause(s) of Death: Dark red fluidity bloods were accumulated in the heart; Petechiae in the inner surface of the scalp occurred; Subcutaneous haemorrhage in the right anterior chest was observed

Lab Data	Current Illness	Adverse Events After Prior Vaccinations
Test Date: 2021; Test Name: CRP; Test Result: 0.1 mg/dl; Test Date: 2021; Test Name: Haemoglobin; Result Unstructured Data: Test Result:12.7 g/dl; Test Date: 2021; Test Name: The histopathological examination; Result Unstructured Data: Test Result:moderate intimal thickening in the coronary artery; Test Date: 2021; Test Name: The test of drug toxicity in the urine using drug toxicity simple test; Test Result: Negative ; Test Date: 2021; Test Name: Platelet count; Result Unstructured Data: Test Result:95000; Test Date: 2021; Test Name: Red blood cell count; Result Unstructured Data: Test Result:4310000; Test Date: 2021; Test Name: White blood cell count; Result Unstructured Data: Test Result:5100		

Medications At Time of Vaccination	History/Allergies

VAERS DETAIL

VAERS ID: 1492484

Vaccine Type	Vaccine	Manufacturer	Lot	Dose	Route	Site
COVID19	COVID19 (COVID19 (PFIZER-BIONTECH))	PFIZER\BIONTECH	FA2453	1		

Event Information			
Patient Age		Sex	F
State/Territory	FR	Date Report Completed	
Date Vaccinated	6/10/2021	Date Report Received	7/22/2021
Date of Onset	6/12/2021	Date Died	7/4/2021
Days to Onset	2		
Vaccine Administered By	OTH	Vaccine Purchased By	
Mfr/Imm Project Number			
Recovered	N	Serious	

Event Categories	
Death	Yes
Life Threatening	No
Permanent Disability	No
Congenital Anomaly/Birth Defect	No
Hospitalized	Yes
Days in Hospital	None
Existing Hospitalization Prolonged	No
Emergency Room/Office Visit	No
Emergency Room	No
Office Visit	No

Symptoms
Blood pressure measurement
Breath sounds
Cerebral artery embolism
Computerised tomogram
Decreased appetite
Deep vein thrombosis
Echocardiogram
Endoscopy upper gastrointestinal tract
Haemorrhagic cerebral infarction
Headache
Heart rate
Magnetic resonance imaging head
Malaise
Myocardial infarction
Platelet count
Seizure
Thrombocytopenia
Thrombosis
Ultrasound scan

Adverse Event Description

haemorrhagic venous infarction; multiple cerebral microembolism; myocardial infarction; thrombosis accompanied by thrombocytopenia; thrombosis accompanied by thrombocytopenia; Deep vein thrombosis; seizure; headache; malaise; appetite impaired; This is a spontaneous report from a contactable physician received from the Regulatory Authority. Regulatory authority report number is v21117930. The patient was a 77-year and 8-month-old female. Body temperature before vaccination was uncertain. Medical history included gastric cancer. Concomitant medications and family history were not provided. On 10Jun2021 (the day of vaccination), the patient received the first dose of BNT162b2 (COMIRNATY, Solution for injection, Lot# FA2453, Expiration date 31Aug2021) via an unspecified route of administration as a single dose for COVID-19 immunization. On 12Jun2021 (2 days after the vaccination), appetite impaired appeared. On 16Jun2021 (6 days after the vaccination), headache and malaise appeared. On 24Jun2021, (14 days after the vaccination), haemorrhagic venous infarction, multiple cerebral microembolism, myocardial infarction and thrombosis accompanied by thrombocytopenia occurred. On that day, the patient was hospitalized. On 30Jun2021 (20 days after the vaccination), seizure occurred. On 01Jul2021 (21 days after the vaccination), deep vein thrombosis occurred. On 04Jul2021 at 07:01 (24 days after the vaccination), the patient died. It was not reported if an autopsy was performed. The course of the events was as follows: On 12Jun2021, appetite impaired appeared. On 16Jun2021, headache and malaise appeared. On 24Jun2021, cerebral infarction was found at a different hospital, and the patient was transferred to the reporter's hospital. She was hospitalized under diagnosis of haemorrhagic venous infarction in the right parietal occipital lobe, multiple cerebral microembolism and myocardial infarction. Administration of ARGATROBAN and anticonvulsant drugs was started. Blood test showed decreased platelets. Thrombosis accompanied by thrombocytopenia caused by vaccination was suspected. On 25Jun2021, as coagulopathy due to cancer was suggested as differential diagnoses, CT scan of the whole body was performed, and the result showed suspected breast cancer and multiple metastases to liver. On 28Jun2021, coronary artery CT scan showed neither obstruction nor marked stenosis. Head CT scan showed extension of cerebral infarction in the right occipital lobe. On 30Jun2021, anginal pain was noted but it disappeared in 2 hours. Seizure was noted. The dosage of anticonvulsant drugs was increased. From the result of head CT scan, it was found that cerebral infarction in the left occipital lobe occurred concurrently. On 01Jul2021, brain MRI (magnetic resonance imaging) showed right middle cerebral artery occlusion and cerebral infarction in that area. Further extension of myocardial infarction was not recognized on echocardiography. Lower extremity ultrasound showed the presence of deep vein thrombosis. Consciousness disturbed progressed. Appetite impaired was present. Nasogastric tube was inserted, and then regurgitation of blood was noted. Endoscopy upper gastrointestinal tract was urgently performed, which showed advanced gastric carcinoma. Since anaemia gradually advanced, red blood cell transfusion was performed. On 02Jul2021, head CT scan showed extensive brain swelling in the right cerebrum and cerebral infarction in a part of left frontal lobe and a part of the parietal lobe. On 03Jul2021, consciousness disturbed worsened and it led to severe consciousness disturbed. On 04Jul2021 at 06:00 in the morning, heart rate was 30 bpm. Decreased breath sounds were noted, and thereafter blood pressure decreased. Resuscitation was started. Head CT scan showed further worsening of brain swelling and this was determined to be brain herniation. At 07:01, the patient's death was confirmed. The reporting physician classified the events as serious (fatal) and assessed that the events were related to BNT162b2. Gastric cancer was considered as another possible cause of the events. The reporting physician commented as follows: The patient experienced multi-organ thrombus accompanied by thrombocytopenia. As for cerebral infarction, after 2 weeks passed, extremely severe cerebral infarction (it would not be an exaggeration to say that this was status epilepticus) concurrently occurred. It was most likely to consider that the patient was susceptible to have abnormal coagulation due to gastric cancer, and then refractory thrombosis occurred as an adverse reaction of BNT162b2. The outcome of events haemorrhagic venous infarction, multiple cerebral microembolism, myocardial infarction and thrombosis accompanied by thrombocytopenia was fatal; outcome of the other events was unknown. No follow-up attempts are possible. No further information is expected.; Reported Cause(s) of Death: haemorrhagic venous infarction; multiple cerebral microembolism; myocardial infarction; thrombosis accompanied by thrombocytopenia; thrombosis accompanied by thrombocytopenia

Lab Data	Current Illness	Adverse Events After Prior Vaccinations
Test Date: 20210704; Test Name: blood pressure; Result Unstructured Data: Test Result:decreased; Test Date: 20210704; Test Name: breath sounds; Result Unstructured Data: Test Result:decreased; Test Date: 20210628; Test Name: coronary artery CT scan; Result Unstructured Data: Test Result:neither obstruction nor marked stenosis; Comments: neither obstruction nor marked stenosis; Test Date: 20210625; Test Name: CT scan of the whole body; Result Unstructured Data: Test Result:suspected breast cancer and metastases; Comments: suspected breast cancer and multiple metastases to liver; Test Date: 20210628; Test Name: Head CT scan; Result Unstructured Data: Test Result:extension of cerebral infarction; Comments: extension of cerebral infarction in the right occipital lobe; Test Date: 20210630; Test Name: Head CT scan; Result Unstructured Data: Test Result:cerebral infarction; Comments: cerebral infarction in the left occipital lobe; Test Date: 20210702; Test Name: Head CT scan; Result Unstructured Data: Test Result:extensive brain swelling; Comments: extensive brain swelling in the right cerebrum and cerebral infarction in a part of left frontal lobe and a part of the parietal lobe; Test Date: 20210704; Test Name: Head CT scan; Result Unstructured Data: Test Result:further worsening of brain swelling; Test Date: 20210701; Test Name: echocardiography; Result Unstructured Data: Test Result:no further extension of cerebral infarction; Comments: no further extension of cerebral infarction; Test Date: 20210701; Test Name: Endoscopy upper gastrointestinal tract; Result Unstructured Data: Test Result:advanced gastric carcinoma; Test Date: 20210704; Test Name: heart rate; Result Unstructured Data: Test Result:30; Comments: Unit:bpm; Test Date: 20210701; Test Name: brain MRI; Result Unstructured Data: Test Result:right middle cerebral artery occlusion; Comments: right middle cerebral artery occlusion and cerebral infarction in that area; Test Date: 20210624; Test Name: platelet; Result Unstructured Data: Test Result:decreased; Test Date: 20210701; Test Name: Lower extremity ultrasound; Result Unstructured Data: Test Result:deep vein thrombosis		

Medications At Time of Vaccination	History/Allergies
	Medical History/Concurrent Conditions: Gastric cancer

VAERS DETAIL

VAERS ID: 1660620

Vaccine Type	Vaccine	Manufacturer	Lot	Dose	Route	Site
COVID19	COVID19 (COVID19 (PFIZER-BIONTECH))	PFIZER\BIONTECH	EY2173	1		

Event Information			
Patient Age	71	Sex	M
State/Territory	FR	Date Report Completed	
Date Vaccinated	5/24/2021	Date Report Received	9/1/2021
Date of Onset	5/26/2021	Date Died	7/8/2021
Days to Onset	2		
Vaccine Administered By	OTH	Vaccine Purchased By	
Mfr/Imm Project Number			
Recovered	N	Serious	

Event Categories	
Death	Yes
Life Threatening	No
Permanent Disability	No
Congenital Anomaly/Birth Defect	No
Hospitalized	Yes
Days in Hospital	3
Existing Hospitalization Prolonged	No
Emergency Room/Office Visit	No
Emergency Room	No
Office Visit	Yes

Symptoms
Body temperature
Pulmonary embolism

Adverse Event Description

Pulmonary thromboembolism with shortness of breath/dyspnoea and pain in the left lumbar and the left thigh. The pain in the left chest and pain on coughing were severe; This is a spontaneous report from a contactable physician. This is a report received from the Regulatory Agency, Regulatory authority report number v21124681. A 71-year-old male patient received BNT162B2 (COMIRNATY), via an unspecified route of administration on 24May2021 16:00 (at the age of 71 years) (Lot Number: EY2173; Expiration Date: 31Aug2021) as dose 1, single for covid-19 immunization. The patient medical history and family history was not reported. Concomitant medications included enalapril maleate tablet 5mg, 5mg (1 tablet) once daily in morning taken for an unspecified indication, start and stop date were not reported. The body temperature before vaccination was reported as 36.3 degree centigrade. On 26May2021 in the morning (2 days after vaccination), the patient had severe shortness of breath, and pain in the left lumbar and the left thigh. The pain in the left chest and pain on coughing were severe. On 26May2021 at 18:00 (2 days and 2 hours after the vaccination), the patient experienced dyspnoea. Since these symptoms did not resolve after one week, the patient visited the reporting clinic (on 31May2021). On 01Jun2021 (discrepantly reported as 7 days after the vaccination), the patient was admitted to another hospital for detailed examination. On 04Jun2021 (discrepantly reported as 10 days after vaccination), the patient was discharged. Thereafter, the patient rested at his home. On 08Jul2021 (discrepantly reported as one month and 13 days after vaccination), the patient suddenly died at his home. It was unknown if an autopsy was performed. The reporting physician classified the dyspnoea as serious (hospitalization) and pulmonary thromboembolism as serious (hospitalization and death). Causality was assessed that the events were related to BNT162B2. It was not reported if there were other possible causes of the events such as any other diseases. The reporting physician commented as follows: Eventually, the cause of death was pulmonary thromboembolism.; Reported Cause(s) of Death: pulmonary thromboembolism

Lab Data	Current Illness	Adverse Events After Prior Vaccinations
Test Date: 20210524; Test Name: body temperature; Result Unstructured Data: Test Result:36.3 Centigrade; Comments: Before vaccination		

Medications At Time of Vaccination	History/Allergies
ENALAPRIL MALEAT	

VAERS DETAIL

VAERS ID: 1862946

Vaccine Type	Vaccine	Manufacturer	Lot	Dose	Route	Site
COVID19	COVID19 (COVID19 (PFIZER-BIONTECH))	PFIZER\BIONTECH	FK0108	2		

Event Information			
Patient Age	13	Sex	M
State/Territory	FR	Date Report Completed	
Date Vaccinated	10/30/2021	Date Report Received	11/12/2021
Date of Onset	10/30/2021	Date Died	10/30/2021
Days to Onset	0		
Vaccine Administered By	OTH	Vaccine Purchased By	
Mfr/Imm Project Number			
Recovered	N	Serious	

Event Categories	
Death	Yes
Life Threatening	No
Permanent Disability	No
Congenital Anomaly/Birth Defect	No
Hospitalized	No
Days in Hospital	None
Existing Hospitalization Prolonged	No
Emergency Room/Office Visit	Yes
Emergency Room	No
Office Visit	No

Symptoms
Cardio-respiratory arrest
Drowning

Adverse Event Description

Cardio-respiratory arrest; the patient found submerged in the bathtub; This is a spontaneous report from a contactable pharmacist received via COVID-19 Adverse Event Self-Reporting Solution. A 13-year and 6-month-old male patient received second single dose of bnt162b2 (COMIRNATY: Solution for injection; Batch/Lot Number: FK0108; Expiration Date: 30Apr2022), via an unspecified route of administration on 30Oct2021 16:55 (the day of vaccination, at the age of 13-year old) as dose 2, single for covid-19 immunisation. Medical history included bronchial asthma from an unknown date and unknown if ongoing. The patient had no allergies to medications, food, or other products. It was unknown if the patient received other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient has not been tested for COVID-19. The patient's concomitant medications were not reported. The patient previously received first single dose of BNT162b2 (COMIRNATY, Solution for injection, Lot number FJ1763, Expiration date 30Apr2022) via an unspecified route of administration on an unspecified date in Oct2021 as dose 1 ,single for COVID-19 immunization. The onset date/time of the event was reported as 30Oct2021 at 21:20. On 30Oct 2021 at 21:20, (day of vaccination), the patient developed cardio-respiratory arrest and died. An autopsy was performed, but the cause of death confirmed by the autopsy was unknown. The event required emergency room visit. On 30Oct2021 at around 21:00, about 4 hours after the second dose of the vaccination, the patient found submerged in the bathtub. The course of the events was as follows: On 30Oct2021, after receiving the second dose of the vaccination, the patient returned home. At around 19:00, the patient had a meal. At 20:30, he took a bath, but he did not get out of the bathroom. At around 21:20, his parents found that he was in cardio-respiratory arrest. They called an ambulance and at 21:34, an emergency team arrived. At 21:40, they arrived at the reporting hospital where cardiopulmonary resuscitation was performed, but his death was confirmed. The reporting physician classified the event as serious (fatal outcome) and assessed the causality between the event and BNT162b2 as unassessable. From the findings from the macroscopic anatomy, no possible cause of the event was found. The reporting pharmacist commented as follows: The fatal case of COVID-19 vaccine was reported from the emergency medical care center. The patient had past medical history of bronchial asthma, however, considering that he was a healthy child and suddenly died, the possibility of BNT162b2 being related to the adverse event was considered to be high. After his death was confirmed, an autopsy was performed by the police. The reporting physician commented as follows: On 02Nov2021, judicial autopsy was performed. From the results, the cause of drowning could not be macroscopically detected. No follow-up attempts are needed; No further information is expected.; Reported Cause(s) of Death: Drowning; Cardio-respiratory arrest

Lab Data	Current Illness	Adverse Events After Prior Vaccinations

Medications At Time of Vaccination	History/Allergies
	Medical History/Concurrent Conditions: Bronchial asthma