# VAERS DETAIL

VAERS ID: 1055906

| Vaccine Type | Vaccine | Manufacturer | Lot | Dose | Route | Site |
|---|---|---|---|---|---|---|
| COVID19 | COVID19 (COVID19 (PFIZER-BIONTECH)) | PFIZER\BIONTECH | EK1768 | UNK | | |

| Event Information | | | |
|---|---|---|---|
| Patient Age | | Sex | M |
| State/Territory | FR | Date Report Completed | |
| Date Vaccinated | 1/18/2021 | Date Report Received | 2/26/2021 |
| Date of Onset | 1/20/2021 | Date Died | |
| Days to Onset | 2 | | |
| Vaccine Administered By | OTH | Vaccine Purchased By | |
| Mfr/Imm Project Number | | Split Type | GBPFIZER INC2021132097 |
| Recovered | N | Serious | |

| Event Categories | |
|---|---|
| Death | No |
| 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 |
|---|
| Cough |
| Creutzfeldt-Jakob disease |

## Adverse Event Description

'Sporadic Cough (Creutzfeldt-Jakob disease)'; Coughing/sporadic cough; This is a spontaneous report from a contactable consumer or non-health care professional. This is a report received from the RA. Regulatory authority report number GB-MHRA-WEBCOVID-20210206123823602O, Safety Report Unique Identifier GB-MHRA-ADR 24712993. A 79-years-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot Number: EK1768), via an unspecified route of administration on 18Jan2021 for COVID-19 immunization. The patient medical history was not reported. Concomitant medication included dutasteride (DUTASTERIDE). Patient had no symptoms associated with COVID-19 and have Not had a COVID-19 test. Patient has not tested positive for COVID-19 since having the vaccine. Patient is not enrolled in clinical trial. On an unspecified date, the patient experienced 'Sporadic Cough (Creutzfeldt-Jakob disease)' (medically significant). On20Jan2021 experienced coughing/Sporadic cough. Sporadic cough which has lasted for 10 days, Has not got any worse or better. No treatment given for cough. The clinical outcome of the event Creutzfeldt-Jakob disease was unknown while coughing/sporadic cough was not recovered. No follow-up attempts are possible. No further information is expected.

| Lab Data | Current Illness | Adverse Events After Prior Vaccinations |
|---|---|---|
| | | |

| Medications At Time of Vaccination | History/Allergies |
|---|---|
| DUTASTERIDE | |

# VAERS DETAIL

VAERS ID: 1181093

| Vaccine Type | Vaccine | Manufacturer | Lot | Dose | Route | Site |
|---|---|---|---|---|---|---|
| COVID19 | COVID19 (COVID19 (PFIZER-BIONTECH)) | PFIZER\BIONTECH | ER1741 | 1 | | |

| Event Information | | | |
|---|---|---|---|
| Patient Age | | Sex | F |
| State/Territory | FR | Date Report Completed | |
| Date Vaccinated | 3/18/2021 | Date Report Received | 4/8/2021 |
| Date of Onset | 3/21/2021 | Date Died | |
| Days to Onset | 3 | | |
| Vaccine Administered By | OTH | Vaccine Purchased By | |
| Mfr/Imm Project Number | | Split Type | GBPFIZER INC2021327131 |
| Recovered | N | Serious | |

| Event Categories | |
|---|---|
| Death | No |
| 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 |
|---|
| Creutzfeldt-Jakob disease |
| Headache |

## Adverse Event Description

sporadic; ice pick headache/Stabbing headache in left temple area on head. Sporadic; This is a spontaneous report from a contactable consumer or other non HCP. This is a report received from the Regulatory Authority. Regulatory authority report number is, Safety Report Unique Identifier.

A 46-year-old female patient received first dose of BNT162B2 (COVID-19 MRNA VACCINE BIONTECH; batch/Lot Number: ER1741; expiration date not provided), via an unspecified route of administration at single dose on 18Mar2021 for COVID-19 immunization. Medical history included lactation decreased from an unspecified date and unknown if ongoing and suspected covid-19 from 06Feb2020 to 09Feb2020. Patient has not had a COVID-19 test. Patient is not enrolled in clinical trial. Patient is not pregnant and is not currently breastfeeding. The patient's concomitant medications were not reported. The patient experienced Creutzfeldt-Jakob disease on an unspecified date and 'ice pick headache/Stabbing headache in left temple area on head. Sporadic' on 21Mar2021. Patient's clinical course is as follows: Stabbing headache in left temple area on head. Sporadic, can be seconds or minutes apart. Continues through night. The events were assessed as serious (medically significant). Outcome of the event Creutzfeldt-Jakob disease was unknown; outcome of the event 'ice pick headache/Stabbing headache in left temple area on head. Sporadic' was recovering.  No follow-up attempts are possible. No further information is expected.

| Lab Data | Current Illness | Adverse Events After Prior Vaccinations |
|---|---|---|
| | | |

| Medications At Time of Vaccination | History/Allergies |
|---|---|
| | Medical History/Concurrent Conditions: Lactation decreased; Suspected COVID-19 |

# VAERS DETAIL

VAERS ID: 1225030

| Vaccine Type | Vaccine | Manufacturer | Lot | Dose | Route | Site |
|---|---|---|---|---|---|---|
| COVID19 | COVID19 (COVID19 (PFIZER-BIONTECH)) | PFIZER\BIONTECH | EK9788 | 1 | OT | |

| Event Information | | | |
|---|---|---|---|
| Patient Age | 61 | Sex | F |
| State/Territory | FR | Date Report Completed | |
| Date Vaccinated | 2/3/2021 | Date Report Received | 4/18/2021 |
| Date of Onset | 2/18/2021 | Date Died | |
| Days to Onset | 15 | | |
| Vaccine Administered By | OTH | Vaccine Purchased By | |
| Mfr/Imm Project Number | | Split Type | DEPFIZER INC2021398806 |
| Recovered | N | Serious | |

| Event Categories | |
|---|---|
| Death | No |
| Life Threatening | Yes |
| Permanent Disability | Yes |
| 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 |
|---|
| Creutzfeldt-Jakob disease |
| CSF test |
| Investigation |
| Magnetic resonance imaging |
| Partial seizures |
| Psychomotor retardation |

## Adverse Event Description

pronounced psychomotor slowdown; Creutzfeld-Jakob disease; complex focal seizures; This is a spontaneous report received from a non-contactable physician downloaded from the Medicine Agency (MA) regulatory authority-WEB. The regulatory authority report number is DE-PEI-PEI2021003989. A 61-year-old female patient received the first dose of BNT162B2 (COMIRNATY, lot number: EK9788), intramuscular administered in the upper arm, on 03Feb2021, as single dose, for prophylaxis/COVID-19 immunisation. Medical history included hypertension arterial. The patient's concomitant medications were not reported. On 18Feb2021, (also reported as "16 days after the first vaccination"), the patient developed Creutzfeld-Jakob disease, complex focal seizures and pronounced psychomotor slowdown. The patient was hospitalized due to the events on an unspecified date. The events were reported as disabling/incapacitating and life-threatening. The patient underwent cerebrospinal fluid examination, MRI, and clinical examination on an unspecified date with unknown results. The patient received the second dose of COMIRNATY (lot number: EP2163) on 24Feb2021. The outcome of the events was not recovered. The health authority assessed relatedness of drug to reactions Psychomotor retardation, Creutzfeld-Jakob disease and Focal seizures as Unclassifiable (Source of assessment: Paul-Ehrlich-Institut). Health Authority Comment: Cerebrospinal fluid examination, MRI, clinical examination No follow-up attempts possible. No further information expected. Information on lot number already obtained.

| Lab Data | Current Illness | Adverse Events After Prior Vaccinations |
|---|---|---|
| Test Name: Cerebrospinal fluid examination; Result Unstructured Data: Test Result:Unknown result; Test Name: clinical examination; Result Unstructured Data: Test Result:Unknown result; Test Name: MRI; Result Unstructured Data: Test Result:Unknown result | | |

| Medications At Time of Vaccination | History/Allergies |
|---|---|
| | Medical History/Concurrent Conditions: Hypertension arterial |

# VAERS DETAIL

VAERS ID: 1236510

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

| Event Information | | | |
|---|---|---|---|
| Patient Age | | Sex | F |
| State/Territory | FR | Date Report Completed | |
| Date Vaccinated | | Date Report Received | 4/21/2021 |
| Date of Onset | | Date Died | 4/7/2021 |
| Days to Onset | | | |
| Vaccine Administered By | OTH | Vaccine Purchased By | |
| Mfr/Imm Project Number | | Split Type | DEPFIZER INC2021415168 |
| 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 |
|---|
| Creutzfeldt-Jakob disease |
| Headache |

## Adverse Event Description

Creutzfeldt-Jakob disease; headache; This is a spontaneous report based on information received by Pfizer from Biontech [manufacturer control number: 39961], license party for Comirnaty. A non-contactable consumer (patient's neighbour) reported that a 61-year-old female patient received bnt162b2 (COMIRNATY) via an unspecified route of administration as single dose for covid-19 immunisation, dose 1 in Mar2021 (beginning of March) (Lot number was not reported), dose 2 on an unspecified date (one- three weeks after dose 1) (Lot number was not reported). The patient medical history and concomitant medications were not reported. The patient was healthy before the vaccination. The patient had headache, went to hospital and died of creutzfeldt-jakob disease 07Apr2021 (four weeks after the first dose). It was not reported if an autopsy was performed. The outcome of event creutzfeldt-jakob disease was fatal. The outcome of event headache was unknown. No follow-up attempts are possible, information about lot/batch number cannot be obtained.; Reported Cause(s) of Death: Creutzfeldt-Jakob disease

| Lab Data | Current Illness | Adverse Events After Prior Vaccinations |
|---|---|---|
| | | |

| Medications At Time of Vaccination | History/Allergies |
|---|---|
| | |

# VAERS DETAIL

VAERS ID: 1400779

| Vaccine Type | Vaccine | Manufacturer | Lot | Dose | Route | Site |
|---|---|---|---|---|---|---|
| COVID19 | COVID19 (COVID19 (PFIZER-BIONTECH)) | PFIZER\BIONTECH | ET3620 | 2 | OT | LA |

| Event Information | | | |
|---|---|---|---|
| Patient Age | | Sex | F |
| State/Territory | FR | Date Report Completed | |
| Date Vaccinated | 3/17/2021 | Date Report Received | 6/15/2021 |
| Date of Onset | | Date Died | 5/30/2021 |
| Days to Onset | | | |
| Vaccine Administered By | OTH | Vaccine Purchased By | |
| Mfr/Imm Project Number | | Split Type | FRPFIZER INC2021653387 |
| 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 |
|---|
| Creutzfeldt-Jakob disease |
| Electroencephalogram |
| Lumbar puncture |
| Magnetic resonance imaging head |

## Adverse Event Description

Creutzfeldt-Jakob disease; This is a spontaneous report from a contactable consumer downloaded from the Regulatory Authority-WEB, regulatory authority report number FR-AFSSAPS-PS20211178, Safety Report Unique Identifier FR-AFSSAPS-2021063339. An 83-year-old female patient received the second dose of BNT162B2 (COMIRNATY, Lot Number: ET3620) intramuscularly in left arm on 17Mar2021 at single dose for COVID-19 immunisation. Medical history included type 2 diabetes mellitus, hypertension arterial, hypercholesterolaemia, arthritis, cholecystectomy, pseudo-rhizomelic arthritis, thyroid nodule and early cognitive disorders. No history of COVID. Concomitant medications included saxagliptin hydrochloride (ONGLYZA), lercanidipine hydrochloride (ZANIDIP), rosuvastatin calcium (CRESTOR), rabeprazole sodium (PARIET), prednisone (CORTANCYL), potassium chloride (DIFFU-K), calcium carbonate, colecalciferol (OROCAL VITAMINE D3), boric acid, phenylmercuric borate, sodium borate (DACRYOSERUM) and levothyroxine(L-THYROXINE), all taken for an unspecified indication from an unspecified date. On 27Mar2021: hospitalization for about a week for the management of a pulmonary embolism (corresponding detailed information captured in AER#2021653376). Subsequently, the patient presented signs of mental confusion and paranoia (no longer recognizes her relatives, loss of speech and coordination of movements) => consultation in neurology on 05May2021, then hospitalization (May2021). Electroencephalogram of 06May2021: very altered, a little asymmetrical (probably more altered on the right) with periodic activity suggesting Creutzfeldt-Jakob disease. No crisis recorded. Brain MRI with injection on 07May2021: cortical hypersignal on the left hemispherical diffusion sequence, no central gray nuclei hypersignal. Lumbar puncture of 11May2021: rock water liquid, 1 element, 2 red blood cells, absence of germ on direct examination, culture in progress, proteinorachia at 0.32 g/L, glycorachia at 5.6mmol / L for blood glucose at 12.9 mmol/L, chlororurorachia at 150 mmol/L. Isofocusing in progress. Protein 14.3.3 in progress. In total: diagnosis of probable Creutzfeldt-Jakob disease in its sporadic form in an 83-year-old patient, presenting a dementia syndrome of rapid evolution in 1 month with typical abnormalities on the EEG as well as on the brain MRI. Evolution: rapid worsening with akinetic mutism. Transfer to palliative care for continuation of care on 20May2021. The patient died on 30May2021. It was not reported if an autopsy was performed. In total, occurrence of Creutzfeldt-Jakob disease diagnosed approximately 1.5 months after the second injection of the Comirnaty vaccine. The role of the vaccine in the onset of this disease is unlikely even if we cannot formally exclude it (onset of the first signs after vaccination).  No follow-up attempts are possible. No further information is expected.; Reported Cause(s) of Death: Creutzfeldt-Jakob disease

| Lab Data | Current Illness | Adverse Events After Prior Vaccinations |
|---|---|---|
| Test Date: 20210511; Test Name: Lumbar puncture; Result Unstructured Data: Test Result:rock water liquid, 1 element, 2 red blood cells, a; Comments: rock water liquid, 1 element, 2 red blood cells, absence of germ on direct examination, culture in progress, proteinorachia at 0.32 g / L, glycorachia at 5.6mmol / L for blood glucose at 12.9 mmol / L, chlororurorachia at 150 mmol / L. Isofocusing in progress. Protein 14.3.3 in progress.; Test Date: 20210507; Test Name: brain MRI; Result Unstructured Data: Test Result:cortical hypersignal on the left hemispherical dif; Comments: cortical hypersignal on the left hemispherical diffusion sequence, no central gray nuclei hypersignal.; Test Date: 20210506; Test Name: Electroencephalogram; Result Unstructured Data: Test Result:very altered, a little asymmetrical (probably more; Comments: very altered, a little asymmetrical (probably more altered on the right) with periodic activity suggesting Creutzfeldt-Jakob disease. No crisis recorded. | | |

| Medications At Time of Vaccination | History/Allergies |
|---|---|
| ONGLYZA; ZANIDIP; CRESTOR; PARIET; CORTANCYL; DIFFU-K; OROCAL VITAMINE D3 [CALCIUM CARBONATE;COLECALCIFEROL]; DACRYOSERUM [BORIC ACID;PHENYLMERCURIC BORATE;SODIUM BORATE]; L-THYROXINE [LEVOTHYROXINE] | Medical History/Concurrent Conditions: Arthritis; Cholecystectomy; Cognitive disorders; Hypercholesterolaemia; Hypertension arterial; Rhizomelic pseudopolyarthritis; Thyroid nodule; Type 2 diabetes mellitus |

# VAERS DETAIL

VAERS ID: 1411412

| Vaccine Type | Vaccine | Manufacturer | Lot | Dose | Route | Site |
|---|---|---|---|---|---|---|
| COVID19 | COVID19 (COVID19 (PFIZER-BIONTECH)) | PFIZER\BIONTECH | EW3143 | 1 | | |

| Event Information | | | |
|---|---|---|---|
| Patient Age | | Sex | M |
| State/Territory | FR | Date Report Completed | |
| Date Vaccinated | 5/31/2021 | Date Report Received | 6/18/2021 |
| Date of Onset | 6/1/2021 | Date Died | |
| Days to Onset | 1 | | |
| Vaccine Administered By | OTH | Vaccine Purchased By | |
| Mfr/Imm Project Number | | Split Type | GBPFIZER INC2021655496 |
| Recovered | N | Serious | |

| Event Categories | |
|---|---|
| Death | No |
| 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 |
|---|
| Creutzfeldt-Jakob disease |
| Fatigue |
| Feeling cold |
| Headache |
| Lymphadenopathy |
| Malaise |

## Adverse Event Description

Swollen lymph nodes/ day 2 onward slightly enlarged axillary lymph nodes; tiredness; sporadic headache/ Creutzfeldt-Jakob disease; Headache; Feeling cold; Malaise; This is a spontaneous report from a contactable consumer received from the regulatory authority report number is GB-MHRA-WEBCOVID-202106030902134560-EVTYL, Safety Report Unique Identifier GB-MHRA-ADR 25410639. A 26-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 31May2021 (Lot Number: EW3143) as 1ST DOSE, SINGLE for COVID-19 immunisation. Medical history included suspected COVID-19 from 18Mar2020 to 01Apr2020. Not had a COVID-19 test and patient was not enrolled in clinical trial. Concomitant medications were not reported. On 01Jun2021, day 1 after vaccination, the patient experienced general malaise and feeling of cold, headache, sporadic headache/Creutzfeldt-Jakob disease, tiredness. Symptoms were short-lasting and responding to treatment with paracetamol. On 02Jun2021, patient experienced swollen lymph nodes/ day 2 onward slightly enlarged axillary lymph nodes, single sided, side of injection, palpable, not painful. The events were considered serious, medically significant. Patient has not tested positive for COVID-19 since having the vaccine. The outcome of the event tiredness, sporadic headache/Creutzfeldt-Jakob disease, swollen lymph nodes/ day 2 onward slightly enlarged axillary lymph nodes was recovering; feeling cold and malaise was recovered on 01Jun2021, while headache was recovered on 02Jun2021. No follow-up attempts are needed. No further information is expected.

| Lab Data | Current Illness | Adverse Events After Prior Vaccinations |
|---|---|---|
| | | |

| Medications At Time of Vaccination | History/Allergies |
|---|---|
| | Medical History/Concurrent Conditions: Suspected COVID-19 |

# VAERS DETAIL

VAERS ID: 1479205

| Vaccine Type | Vaccine | Manufacturer | Lot | Dose | Route | Site |
|---|---|---|---|---|---|---|
| COVID19 | COVID19 (COVID19 (PFIZER-BIONTECH)) | PFIZER\BIONTECH | ER9470 | 2 | OT | LA |

| Event Information | | | |
|---|---|---|---|
| Patient Age | | Sex | M |
| State/Territory | FR | Date Report Completed | |
| Date Vaccinated | 3/31/2021 | Date Report Received | 7/16/2021 |
| Date of Onset | 4/1/2021 | Date Died | |
| Days to Onset | 1 | | |
| Vaccine Administered By | OTH | Vaccine Purchased By | |
| Mfr/Imm Project Number | | Split Type | FRPFIZER INC2021824247 |
| Recovered | N | Serious | |

| Event Categories | |
|---|---|
| Death | No |
| Life Threatening | Yes |
| 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 |
|---|
| Alexia |
| Aphasia |
| Cardiovascular examination |
| Creutzfeldt-Jakob disease |
| Dyslexia |
| Echocardiogram |
| Electrocardiogram ambulatory |
| Electroencephalogram |
| Fatigue |
| HIV test |
| Immunoglobulins |
| Lumbar puncture |
| Lymphocyte count |
| Magnetic resonance imaging head |
| Microbiology test |
| Neurological examination |
| Prostatic specific antigen |
| Protein total |
| SARS-CoV-2 test |
| Visual agnosia |

## Adverse Event Description

Creutzfeld-Jacob disease; visual agnosia; aphasia; dyslexia; fatigue; alexia; This is a spontaneous report from a contactable physician downloaded from the Agency regulatory authority report number FR-AFSSAPS-2021082801. A 72-year-old male patient received BNT162B2 (COMIRNATY, Lot Number: ER9470), dose 2 intramuscularly, administered in left arm on 31Mar2021 (at an unspecified age) as dose 2, single for COVID-19 immunisation. Medical history included aortic valve replacement from an unknown date and not ongoing (aortic valve bioprosthesis on aneurysm), Colonic neoplasm NOS from an unknown date and not ongoing, ongoing cancer of prostate (Prostate adenocarcinoma: treated with total prostatectomy (2003) then radiation therapy in 2004 following a PSA increase, then chemotherapy in 2007 following a PSA re-increase), Sigmoid adenocarcinoma treated by left hemi-colectomy (2016) and chemotherapy (2016), vertebral fracture from 2019 (L1 vertebral fracture on metastasis (2019) treated by hormone therapy), vagal discomfort. Patient was undergoing radiotherapy for bone metastases of a prostate cancer. Patient was considered at risk of developing a severe form of COVID-19. No history of COVID-19. Patient was tested (SARS-CoV-2 test): negative on an unspecified date. Concomitant medications included acetylsalicylate lysine (KARDEGIC); bisoprolol. The patient experienced creutzfeld-jacob disease (hospitalization, life threatening) on 10Apr2021, visual agnosia (medically significant) on 26May2021, dyslexia on 10Apr2021, fatigue on 10Apr2021, alexia on Apr2021, aphasia on 26May2021. Clinical details: Around 10Apr2021 small dyslexia and difficulty in deciphering even simple writings put on the account of a temporary fatigue (note that the patient was undergoing radiotherapy for bone metastases of a prostate cancer). At the end of Apr2021, appearance of alexia for which a 1st cerebral MRI is performed on 27Apr2021, described as normal but, after rereading, evocation of an ischemic lesion in the territory of the left posterior cerebral artery (very cortical) and of the left Postero-inferior cerebellar artery (PICA). Normal cardiological etiological work-up (ETT, ECG holter). On 15May2021, appearance of phasic disorders. Hospitalization, brain MRI (17May2021 then 25May2021): right fronto-temporo-occipital and left occipital cortical hypersignal in DWI, more marked on the MRI of 25May2021. On 15May2021: TEE: left atrium "bent" without thrombus. Otherwise normal. Biology without particularity. LP: absence of cells, normo-proteinorachy. Negative multiplex PCR. EEG: slowed theta wakefulness trace, moderately organized. No malignant state. Increase in diffuse slow abnormalities with aspect of diffuse cerebral suffering. Clinical worsening during this hospitalization with observation of visual agnosia. Trial of a treatment with KEPPRA 500 mg X 2 as a diagnostic test, without effectiveness. At the diagnostic level, in view of the clinical aggravation and the paraclinical elements (MRI and EEG), a Creutzfeldt Jakob disease is evoked. On 26May2021 clinical examination: Neurological examination: severe motor aphasia with lack of the word, decrease in verbal fluency, agrammatism, executes simple and complex commands, partial awareness of disorders, temporo-spatial disorientation, also alexia and visual agnosia. No spontaneous or reflex myoclonus. No balance disorder, normal walking. The rest of the clinical examination, especially the general examination, was unremarkable. Paraclinical examinations on an unspecified date: Biology: The blood count shows lymphopenia at 0.35 G/L and the lymphocyte immuno-phenotyping shows an overall decrease in lymphocytes, both CD3, CD4 and CD8. HIV serology is negative. There is a slight hypo-gammaglobulinemia at 6 g/liter on serum protein electrophoresis. EEG: Recording of numerous diffuse delta slow waves, larger in the posterior leads, rarely taking a triphasic aspect. These abnormalities seem to regress with drowsiness and eye opening. Intermittent light stimulation has no effect. Absence of epileptic seizure. In conclusion: Encephalopathy pattern, compatible in the context with a prion disease, although the appearance is not specific. Absence of epileptic anomaly. Spinal tap: < 1 WBC/mm3, normal protein count 0.3 g/L, Tau protein 2000pg/mL, phosphorylated Tau 34 pg/mL, i.e., an isolated and very significant increase in Tau protein with a Tau/Phosphorylated Tau ratio > 20, in favor of a diagnosis of sporadic human Prion disease (Creutzfeldt-Jakob disease). Conclusions: Rapidly progressive cognitive impairment associated with cortical diffusion abnormalities on MRI, isolated and very significant elevation of Tau protein in CSF, and EEG abnormalities supporting a diagnosis of Creutzfeldt-Jakob disease. The outcome of the event creutzfeld-jacob disease was not recovered, outcome of the other events was unknown.  No follow-up attempts are possible. No further information is expected.

| Lab Data | Current Illness | Adverse Events After Prior Vaccinations |
|---|---|---|

| | | |
|---|---|---|
| Test Date: 20210427; Test Name: cardiovascular examination; Result Unstructured Data: Test Result:normal; Comments: Normal cardiological etiological work-up (ETT, ECG holter); Test Date: 20210427; Test Name: echocardiography; Result Unstructured Data: Test Result:normal; Comments: Normal cardiological etiological work-up (ETT, ECG holter); Test Date: 20210515; Test Name: echocardiography; Result Unstructured Data: Test Result:left atrium bent; Comments: left atrium bent without thrombus. Otherwise normal; Test Date: 20210427; Test Name: ecg; Result Unstructured Data: Test Result:normal; Comments: Normal cardiological etiological work-up (ETT, ECG holter); Test Name: eeg; Result Unstructured Data: Test Result:Recording of numerous diffuse delta slow waves; Comments: Recording of numerous diffuse delta slow waves, larger in the posterior leads, rarely taking a triphasic aspect. These abnormalities seem to regress with drowsiness and eye opening. Intermittent light stimulation has no effect. Absence of epileptic seizure.; Test Date: 20210515; Test Name: eeg; Result Unstructured Data: Test Result:slowed theta wakefulness trace; Comments: slowed theta wakefulness trace, moderately organized. No malignant state. Increase in diffuse slow abnormalities with aspect of diffuse cerebral suffering. Clinical worsening during this hospitalization with observation of visual agnosia.; Test Name: HIV; Test Result: Negative ; Test Name: hypo-gammaglobulinemia; Result Unstructured Data: Test Result:6 g/l; Comments: slight hypo-gammaglobulinemia at 6 g/liter on serum protein electrophoresis; Test Date: 20210515; Test Name: LP; Result Unstructured Data: Test Result:absence of cells, normo-proteinorachy; Comments: absence of cells, normo-proteinorachy. Negative multiplex PCR.; Test Name: Spinal tab; Result Unstructured Data: Test Result:less than WBC/mm3, normal protein count 0.3 g/L; Comments: less than WBC/mm3, normal protein count 0.3 g/L, Tau protein 2000pg/mL, phosphorylated Tau 34 pg/mL, i.e., an isolated and very significant increase in Tau protein with a Tau/Phosphorylated Tau ratio > 20, in favor of a diagnosis of sporadic human Prion disease (Creutzfeldt-Jakob disease); Test Name: lymphopenia; Result Unstructured Data: Test Result:0.35 g/l; Comments: the lymphocyte immuno-phenotyping shows an overall decrease in lymphocytes, both CD3, CD4 and CD8; Test Date: 20210427; Test Name: MRI; Result Unstructured Data: Test Result:normal; Comments: normal but, after rereading, evocation of an ischemic lesion in the territory of the left posterior cerebral artery (very cortical) and of the left PICA.; Test Date: 20210517; Test Name: MRI; Result Unstructured Data: Test Result:right fronto-temporo-occipital; Comments: right fronto-temporo-occipital and left occipital cortical hypersignal in DWI; Test Date: 20210525; Test Name: MRI; Result Unstructured Data: Test Result:right fronto-temporo-occipital; Comments: right fronto-temporo-occipital and left occipital cortical hypersignal in DWI, more marked on the MRI of 25May2021; Test Date: 20210515; Test Name: Biology; Result Unstructured Data: Test Result:without particularity; Test Date: 20210526; Test Name: neurological examination; Result Unstructured Data: Test Result:severe motor aphasia; Comments: severe motor aphasia with lack of the word, decrease in verbal fluency, agrammatism, executes simple and complex commands, partial awareness of disorders, temporo-spatial disorientation, also alexia and visual agnosia. No spontaneous or reflex myoclonus. No balance disorder, normal walking. The rest of the clinical examination, especially the general examination, was unremarkable.; Test Date: 2004; Test Name: PSA; Result Unstructured Data: Test Result:increase; Test Date: 2007; Test Name: PSA; Result Unstructured Data: Test Result:re-increase; Test Name: protein count; Result Unstructured Data: Test Result:0.3 g/l; Test Name: SARS-CoV-2 test; Test Result: Negative | Bone metastases (undergoing radiotherapy for bone metastases of a prostate cancer); Cancer of prostate (Prostate adenocarcinoma) | |

| Medications At Time of Vaccination | History/Allergies |
|---|---|
| KARDEGIC; BISOPROLOL | Medical History/Concurrent Conditions: Adenocarcinoma (Sigmoid adenocarcinoma treated by left hemi-colectomy (2016) and chemotherapy (2016)); Aortic valve replacement (aortic valve bioprosthesis on aneurysm); Chemotherapy; Colonic neoplasm NOS; Left hemicolectomy; Lumbar vertebral fracture L1 (- L1 vertebral fracture on metastasis (2019) treated by hormone therapy); Prostatectomy; Radiation therapy; Vagal reaction |

# VAERS DETAIL

VAERS ID: 1487386

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

| Event Information | | | |
|---|---|---|---|
| Patient Age | 60 | Sex | M |
| State/Territory | CA | Date Report Completed | |
| Date Vaccinated | 4/24/2021 | Date Report Received | 7/20/2021 |
| Date of Onset | 5/7/2021 | Date Died | |
| Days to Onset | 13 | | |
| Vaccine Administered By | UNK | Vaccine Purchased By | |
| Mfr/Imm Project Number | | Split Type | |
| Recovered | N | Serious | |

| Event Categories | |
|---|---|
| Death | No |
| Life Threatening | Yes |
| Permanent Disability | Yes |
| 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 | Yes |

| Symptoms |
|---|
| Anxiety |
| Aphasia |
| Asthenia |
| Computerised tomogram head normal |
| Creutzfeldt-Jakob disease |
| CSF test abnormal |
| Delirium |
| Disturbance in attention |
| Hypoxic-ischaemic encephalopathy |
| Loss of personal independence in daily activities |
| Lumbar puncture abnormal |
| Magnetic resonance imaging head abnormal |
| Paranoia |

## Adverse Event Description

60 yo M who developed delirium and was in ER 5/7/21 for this. Described by son/boss as difficulty focusing x 2-3 weeks, diffuse body weakness, paranoia, anxiety.  CT head was neg, pt was discharged home. outpatient MRI brain suggested Creutzfeldt Jakob disease CJD. He was seen by neurology, who confirmed CJD by LP, he is now nonverbal and dependent on all ADL's, going into hospice

| Lab Data | Current Illness | Adverse Events After Prior Vaccinations |
|---|---|---|
| CT  head w/o contrast 5/7/21 negative.  MRI brain 5/16/21 showed Bilateral frontal, parietal and temporal lobes cortical reduced diffusion is most suggestive of sporadic Creutzfeldt Jacob disease. The imaging appearance is not felt to be artifactual. The differential diagnosis includes a recent episode of hypoxic ischemic injury, please correlate with clinical history. 6/16/21 LP/CSF RT-QuIC positive | | |

| Medications At Time of Vaccination | History/Allergies |
|---|---|
| metoprolol XL 50mg daily, prilosec 20mg bid prn | hypertension, prediabetes |
| | vancomycin |

# VAERS DETAIL

VAERS ID: 1502914

| Vaccine Type | Vaccine | Manufacturer | Lot | Dose | Route | Site |
|---|---|---|---|---|---|---|
| COVID19 | COVID19 (COVID19 (PFIZER-BIONTECH)) | PFIZER\BIONTECH | FC8889 | 1 | OT | |

| Event Information | | | |
|---|---|---|---|
| Patient Age | 55 | Sex | F |
| State/Territory | FR | Date Report Completed | |
| Date Vaccinated | 6/1/2021 | Date Report Received | 7/26/2021 |
| Date of Onset | 6/1/2021 | Date Died | |
| Days to Onset | 0 | | |
| Vaccine Administered By | OTH | Vaccine Purchased By | |
| Mfr/Imm Project Number | | Split Type | DKPFIZER INC2021848005 |
| Recovered | N | Serious | |

| Event Categories | |
|---|---|
| Death | No |
| Life Threatening | Yes |
| 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 |
|---|
| Ballismus |
| Blood cholesterol |
| Blood pressure measurement |
| Blood test |
| Blood triglycerides |
| Body temperature |
| Cerebral infarction |
| Confusional state |
| Creutzfeldt-Jakob disease |
| Electrocardiogram |
| Electroencephalogram |
| Fall |
| Heart rate |
| Lumbar puncture |
| Magnetic resonance imaging head |
| Muscle twitching |
| Nasopharyngitis |
| Oxygen saturation |
| Respiratory rate |

## Adverse Event Description

This is a spontaneous report from a contactable physician downloaded from the Regulatory Authority-WEB, regulatory authority number DK-DKMA-WBS-0074944. A 55-year-old female patient received bnt162b2 (COMIRNATY, Batch/Lot Number: FC8889; Expiration Date: 30Sep2021), dose 1 intramuscular on 01Jun2021 (at the age of 55years) as dose 1, single for Covid-19 immunization. Medical history included ongoing ischemic cardiomyopathy.  The patient's concomitant medications were not reported. The physician described the occurrence of Creutzfeld-Jacob disease, cold symptoms (mild Cold symptoms lasting 4 days), confusion (Increasing confusion), Hemiballismus (hemiballism/sudden onset of right arm steering difficulty) and twitching (The patient falls and focal twitching in right hand was observed twice) in the patient vaccinated with Comirnaty. On 01Jun2021, same day as first vaccination, the patient developed cold symptoms lasting 4 days. On 11Jun2021, 10 days after the vaccination, the patient developed increasing confusion and Hemiballismus (sudden onset of right arm steering difficulty). On 12Jun2021, 11 days after the vaccination, the patient developed Creutzfeld-Jacob disease. On 21Jun2021, 20 days after the vaccination, the patient falls and focal twitching in right hand was observed twice. The adverse events were by the reporter reported as being life threatening. The patient was hospitalized on the 12Jun2021. No specific treatment is known, and the prognosis is very poor, with typically rapid progression with terminal exit within weeks to months. On 27Jun2021, the patient is transferred to palliative care. Test results on 12Jun2021: Blood pressure: 129/72 mmHg, Pulse rate: 94, Body temperature: 37.5 C, Respiration rate: 16, Oxygen saturation: 99 % without oxygen, Lumbar puncture: Blank, Blood cholesterol: 5.1, Blood triglycerides: 2.03, Blood test: Other blood test were normal, EKG: sinus rhythm, frequency 82; No ischemia signs or block; MRI brain (14Jun2021): Diffuse cortical bilateral ischemic changes in cerebral hemispheres as well as thalamus, especially cortical parietooccipital bilateral, as well as left frontal lobe. Fragmented infarcts and the changes are most compatible with either ictal or infectious changes. MRI brain (19Jun2021): Confirms small infarcts, cortical changes and charging in left ICA. EEG (several, dates unknown): Creutzfeldt-Jacob disease (Subacute spongiform encephalopathy). The outcome of Creutzfeld-Jacob disease was not recovered; cold symptoms recovered after 4 days on 05Jun2021; outcome of other events was unknown. Causality: On 23Jun2021, the patient was discussed on conference where the diagnosis of Creutzfeldt-Jacob Disease (CJD) was verified. The overall clinical picture, MRI scans and EEG are considered typical of CJD. The patient is from Slovakia, which is a high-incidence area for Creutzfeldt-Jacob Disease. There have been cerebellar, visual and diffuse holocephalas symptoms, which is typical. 10 percent of CJD cases start with stroke-like episodes as in this case. Difficult to get a medical history from the patient, partly due to language barrier. Senders comments: Additional test information: MRI brain (14Jun2021): Diffuse cortical bilateral ischemic changes in cerebral hemispheres as well as thalamus, especially cortical parietooccipital bilateral, as well as left frontal lobe. Fragmented infarcts and the changes are most compatible with either ictal or infectious changes. MRI brain (19Jun2021): Confirms small infarcts, cortical changes and charging in left ICA. No follow-up attempts are possible. No further information is expected.

| Lab Data | Current Illness | Adverse Events After Prior Vaccinations |
|---|---|---|
| Test Date: 20210612; Test Name: Blood cholesterol; Result Unstructured Data: Test Result:5.1 No unit disclosed; Test Date: 20210612; Test Name: Blood pressure; Result Unstructured Data: Test Result:129/72 mmHg; Test Date: 20210612; Test Name: Blood test; Result Unstructured Data: Test Result:Other blood tests normal; Test Date: 20210612; Test Name: Blood triglycerides; Result Unstructured Data: Test Result:2.03 No unit disclosed; Test Date: 20210612; Test Name: Body temperature; Result Unstructured Data: Test Result:37.5 Centigrade; Test Date: 20210612; Test Name: EKG; Result Unstructured Data: Test Result:sinus rhythm, frequency 82.; Test Date: 20210612; Test Name: EKG; Result Unstructured Data: Test Result:No ischemia signs or block; Test Date: 202106; Test Name: EEG; Result Unstructured Data: Test Result:CJD (Subacute spongiform encephalopathy); Test Date: 20210612; Test Name: Pulse rate; Result Unstructured Data: Test Result:94 No unit disclosed; Test Date: 20210612; Test Name: Lumbar puncture; Result Unstructured Data: Test Result:Blank; Test Date: 20210614; Test Name: MRI brain; Result Unstructured Data: Test Result:Diffuse cortical bilateral ischemic changes; Comments: Diffuse cortical bilateral ischemic changes in cerebral hemispheres as well as thalamus, especially cortical parietooccipital bilateral, as well as left frontal lobe. Fragmented infarcts and the changes are most compatible with either ictal or infectious changes.; Test Date: 20210619; Test Name: MRI brain; Result Unstructured Data: Test Result:Confirms small infarcts, cortical changes; Comments: Confirms small infarcts, cortical changes and charging in left ICA.; Test Date: 20210612; Test Name: Oxygen saturation; Result Unstructured Data: Test Result:99 without oxygen %; Test Date: 20210612; Test Name: Respiratory rate; Result Unstructured Data: Test Result:16 No unit disclosed | Ischemic cardiomyopathy | |

| Medications At Time of Vaccination | History/Allergies |
|---|---|
| | |

# VAERS DETAIL

VAERS ID: 1517906

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

| Event Information | | | |
|---|---|---|---|
| Patient Age | | Sex | F |
| State/Territory | NC | Date Report Completed | |
| Date Vaccinated | | Date Report Received | 7/31/2021 |
| Date of Onset | 3/29/2021 | Date Died | |
| Days to Onset | | | |
| Vaccine Administered By | OTH | Vaccine Purchased By | |
| Mfr/Imm Project Number | | Split Type | USJNJFOC20210760791 |
| Recovered | N | Serious | |

| Event Categories | |
|---|---|
| Death | No |
| 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 |
|---|
| Blood test |
| Brain neoplasm |
| Computerised tomogram |
| Creutzfeldt-Jakob disease |
| Lumbar puncture |
| Magnetic resonance imaging |
| Sleep terror |

## Adverse Event Description

CREUTZFELDT-JAKOB DISEASE; TINY TUMOR IN THE FRONT OF BRAIN; AFRAID AT NIGHT TO STAY ALONE; This spontaneous report received from a consumer concerned a 62 year old female. The patient's weight was 230 pounds, and height was 67 inches. The patient's concurrent conditions included high blood pressure, non alcoholic, and non smoker. Patient had no known allergies, no drug abuse or illicit drug usage. Patient had always been independent, intelligent with outstanding memory The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number and expiration date was unknown) dose was not reported,1 total, administered on 08-MAR-2021 for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported.  After 3 weeks receiving the vaccine, patient went downhill. On 29-MAR-2021, the patient had, complained of arm being numb and started forgetting things. She started having very bad memory issue, was afraid at night to stay on her own and was agitated and emotional. She also had coordination issues, could not get into the car on her own, could barely stand up from the sitting position and would go side by side when walking. She could not form an understandable sentence so she was taken to the hospital and hospitalized from 31-MAY-2021 to 17-JUN-2021. Then she was taken to Psychiatric unit and sent her home with an appointment to see a neurologist. On 03-JUL-2021, patient was found naked on the kitchen floor, she could not remember anything and nothing made sense.  She was taken back to the hospital with the ambulance and later on (unknown date) the hospital transferred her to the another hospital, at the time of reporting patient was hospitalized there. They did computerized tomography scan, Magnetic resonance imaging, lumbar puncture and blood  works but did not have any results. During hospitalization they found a tiny tumor in the front of the brain and diagnosed Creutzfeldt-Jakob disease. The hospital also said no dementia and no Alzheimer's disease. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient had not recovered from tiny tumor in the front of brain, and creutzfeldt-jakob disease, and the outcome of afraid at night to stay alone was not reported. This report was serious (Hospitalization Caused / Prolonged).; Sender's Comments: V0: 20210760791-covid-19 vaccine ad26.cov2.s-Creutzfeldt-jakob disease and tiny tumor in the front of brain. This event(s) is considered un-assessable. 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).

| Lab Data | Current Illness | Adverse Events After Prior Vaccinations |
|---|---|---|
| Test Date: 202107; Test Name: CT scan; Result Unstructured Data: Unknown; Test Date: 202107; Test Name: Blood test; Result Unstructured Data: unknown; Test Date: 202107; Test Name: Lumbar puncture; Result Unstructured Data: unknown; Test Date: 202107; Test Name: Magnetic resonance imaging; Result Unstructured Data: unknown | Abstains from alcohol; Blood pressure high; Non-smoker | |

| Medications At Time of Vaccination | History/Allergies |
|---|---|
| | Comments: Patient had no known allergies, no drug abuse or illicit drug usage. The patient had always been independent, intelligent with outstanding memory. |

# VAERS DETAIL

VAERS ID: 1520794

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

| Event Information | | | |
|---|---|---|---|
| Patient Age | 51 | Sex | F |
| State/Territory | FR | Date Report Completed | |
| Date Vaccinated | 6/19/2021 | Date Report Received | 8/2/2021 |
| Date of Onset | 6/19/2021 | Date Died | |
| Days to Onset | 0 | | |
| Vaccine Administered By | OTH | Vaccine Purchased By | |
| Mfr/Imm Project Number | | Split Type | GBPFIZER INC202100909065 |
| Recovered | N | Serious | |

| Event Categories | |
|---|---|
| Death | No |
| 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 |
|---|
| Creutzfeldt-Jakob disease |
| Diarrhoea |
| Fatigue |
| Headache |
| Investigation |
| Lethargy |
| Pain |
| Vaginal haemorrhage |

## Adverse Event Description

Vaginal bleeding; Diarrhea; Headache dull/dull sporadic headaches; lethargic; body aches; Creutzfeldt-Jakob disease; Fatigue; This is a spontaneous report from a contactable consumer (patient) received from the regulatory authority. The regulatory authority report number is GB-MHRA-WEBCOVID-202107161026325680-HGUYS, Safety Report Unique Identifier is GB-MHRA-ADR 25662547. A 51-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE, Solution for injection, Lot number and expiration date unknown), via an unspecified route of administration on 19Jun2021 (at the age of 51 years old) as dose 1, single for COVID-19 immunization. Medical history lactation decreased and not had a period for over 10 years. Patient has not had symptoms associated with COVID-19, not had a COVID-19 test, was not pregnant, and not currently breastfeeding. The patient's concomitant medications were not reported. The patient experienced Creutzfeldt-Jakob disease, fatigue and cervical cancer on an unspecified date in 2021; lethargic on 19Jun2021, vaginal bleeding on 22Jun2021, diarrhea on 21Jun2021, headache dull/dull sporadic headaches on 19Jun2021, and body aches on 19Jun2021. The events were reported as non-serious. The clinical course was reported as follows: Within 24 hours of the jab, the patient began having dull sporadic headaches, she also had body aches and felt lethargic all the time. A couple of days later, the patient started having vaginal bleeding, having not had a period for over 10 years. She also started having diarrhea every day. The patient was having investigations for cervical cancer (2021, Unknown results), had to go into hospital. Patient has not tested positive for COVID-19 since having the vaccine. Patient was not enrolled in clinical trial. The outcome of the event Creutzfeldt-Jakob disease and lethargic was recovering. The outcome of the events vaginal bleeding, diarrhea, headache dull and fatigue was not recovered. The outcome of the remaining events was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.

| Lab Data | Current Illness | Adverse Events After Prior Vaccinations |
|---|---|---|
| Test Date: 2021; Test Name: investigations; Result Unstructured Data: Test Result:Unknown results | | |

| Medications At Time of Vaccination | History/Allergies |
|---|---|
| | Medical History/Concurrent Conditions: Absence of menstruation; Lactation decreased |

# VAERS DETAIL

VAERS ID: 1535217

| Vaccine Type | Vaccine | Manufacturer | Lot | Dose | Route | Site |
|---|---|---|---|---|---|---|
| COVID19 | COVID19 (COVID19 (PFIZER-BIONTECH)) | PFIZER\BIONTECH | EW0172 | 2 | SYR | UN |

| Event Information | | | |
|---|---|---|---|
| Patient Age | 64 | Sex | F |
| State/Territory | FL | Date Report Completed | |
| Date Vaccinated | 4/25/2021 | Date Report Received | 8/8/2021 |
| Date of Onset | 5/6/2021 | Date Died | |
| Days to Onset | 11 | | |
| Vaccine Administered By | SCH | Vaccine Purchased By | |
| Mfr/Imm Project Number | | Split Type | |
| Recovered | N | Serious | |

| Event Categories | |
|---|---|
| Death | Yes |
| Life Threatening | Yes |
| 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 |
| Confusional state |
| Creutzfeldt-Jakob disease |
| Death |
| Extrapyramidal disorder |
| Feeling abnormal |
| Headache |
| Locked-in syndrome |
| Lumbar puncture abnormal |
| Memory impairment |
| Motor dysfunction |
| Myoclonus |
| Pyramidal tract syndrome |
| Speech disorder |

## Adverse Event Description

After 2nd dose of Pfizer 4/25/21, by 5/6/2021 complaining of severe headache and showing major symptons of something neurologically wrong- extreme memory fog, confusion, headache.Was hospitalized on 5/31 for about 10 days after a 911 call complaining of a headche. Released in a worsened state. Spent 10 days at home, regressing daily. On 06/19/2021 hospitalized again, doing tests eliminating possibilities.Rapidly regressing, unable to speak full sentences, Myoclonus, loss of motor skills, Pyramidal & extrapyramidal symptoms as well as akinetic mutism. After 3 weeks undiagnosed, on 07/12/2021 LP results confirmed positive for CJD. Was released to hospice on 07/19/2021 and death on 07/22/21.

| Lab Data | Current Illness | Adverse Events After Prior Vaccinations |
|---|---|---|
| Lumbar pucture, 07/12/2021 result, CJD. | none | |

| Medications At Time of Vaccination | History/Allergies |
|---|---|
| | none |
| | none |

# VAERS DETAIL

VAERS ID: 1582190

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

| Event Information | | | |
|---|---|---|---|
| Patient Age | | Sex | F |
| State/Territory | FR | Date Report Completed | |
| Date Vaccinated | 5/10/2021 | Date Report Received | 8/18/2021 |
| Date of Onset | 5/13/2021 | Date Died | |
| Days to Onset | 3 | | |
| Vaccine Administered By | OTH | Vaccine Purchased By | |
| Mfr/Imm Project Number | | Split Type | ATPFIZER INC202101026219 |
| Recovered | N | Serious | |

| Event Categories | |
|---|---|
| Death | No |
| Life Threatening | Yes |
| 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 upper |
| Ataxia |
| Autonomic nervous system imbalance |
| Cognitive disorder |
| Coma |
| Creutzfeldt-Jakob disease |
| CSF test |
| Dementia |
| Generalised anxiety disorder |
| Magnetic resonance imaging |
| Panic attack |
| Psychiatric symptom |
| Tachycardia |

## Adverse Event Description

psychiatric symptoms (panic attacks and generalized anxiety disorder); Panic attacks; Generalised anxiety disorder; vegetative derailments / Vegetative dystonia; Tachycardia; Abdominal pain/stomach pain; dementia; cognitive deficits/ Cognitive impairment; Ataxia; Comatose; Creutzfeldt-Jakob disease; This is a spontaneous report from a contactable physician downloaded from the Regulatory Authority Report WEB AT-BASGAGES-2021-39613. A 51-years-old female patient received first dose of BNT162b2 (COMIRNATY, Solution for injection, Lot Number: unknown), via intramuscularly on 10May2021 as dose 1, single for COVID-19 immunisation. Medical history and concomitant medication were not reported. On 13May2021 (after 3 days of vaccination), the patient developed psychiatric symptoms (panic attacks and generalized anxiety disorder), vegetative derailments/ vegetative dystonia, tachycardia, and abdominal pain/stomach pain. She went to psychiatry first, but no therapies helped. She was then taken to the psychosomatic ward and when she developed ataxias there. She was taken over by the neurological ward with cognitive deficits/dementia and comatose. On an unspecified date in 2021, patient had dementia, cognitive deficits/ cognitive impairment, ataxia and comatose. Patient was hospitalized in 2021. On 11Jun2021 (after one month of vaccination), patient was diagnosed with Creutzfeldt Jakob Syndrome (assessed as life threatening by reporter) and no therapy possible with this diagnosis. On 16Jul2021 (admission to neurology), lab test included the lumbar puncture which showed the CSF findings (14/3/3 pos in the CSF findings), autoimmune antibodies were also examined in the CSF, the result was negative for autoimmune antibodies and MRI with unknown result. The outcome for events tachycardia and abdominal pain was unknown and for all other events was not resolved. The Health Care Professional assessed the causal relationship between bnt162b2 (COMIRNATY) and all the reported events as Probable/Likely. No follow-up Information on batch/lot number cannot be obtained attempts are possible. No further information expected.

| Lab Data | Current Illness | Adverse Events After Prior Vaccinations |
|---|---|---|
| Test Date: 20210716; Test Name: Lumbar puncture / CSF findings; Result Unstructured Data: Test Result:14/3/3; Comments: (pos in the CSF findings), autoimmune antibodies in the CSF was negative; Test Date: 20210716; Test Name: MRT; Result Unstructured Data: Test Result:unknown results | | |

| Medications At Time of Vaccination | History/Allergies |
|---|---|
| | |

# VAERS DETAIL

VAERS ID: 1700415

| Vaccine Type | Vaccine | Manufacturer | Lot | Dose | Route | Site |
|---|---|---|---|---|---|---|
| COVID19 | COVID19 (COVID19 (MODERNA)) | MODERNA | | 2 | SYR | RA |

| Event Information | | | |
|---|---|---|---|
| Patient Age | 69 | Sex | F |
| State/Territory | LA | Date Report Completed | |
| Date Vaccinated | 3/8/2021 | Date Report Received | 9/15/2021 |
| Date of Onset | 4/1/2021 | Date Died | 7/17/2021 |
| Days to Onset | 24 | | |
| Vaccine Administered By | PVT | Vaccine Purchased By | |
| Mfr/Imm Project Number | | Split Type | |
| 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 |
| Cerebrovascular accident |
| Computerised tomogram |
| Creutzfeldt-Jakob disease |
| Death |
| Diplopia |
| Dizziness |
| Electroencephalogram |
| Endotracheal intubation |
| Gait disturbance |
| Gait inability |
| Insomnia |
| Intensive care |
| Lumbar puncture abnormal |
| Magnetic resonance imaging |
| Memory impairment |
| Restless legs syndrome |
| Seizure |
| Speech disorder |

## Adverse Event Description

DEVELOPED RESTLESS LEG SYNDROME, INSOMNIA, DOUBLE VISION, DIZZINESS WITHIN 3 WEEKS OF LAST SHOT. DIAGNOSED WITH A STROKE ON 05/24/21. WITHIN 24 HOURS OF DISCHARGE, SHE COULD NOT WALK PROPERLY AND HAD TO USE A CANE. RE ENTERED THE HOSPITAL ON 06/7/21 TO REHAB CONTINUED TO DECLINE WITH ADVANCED SYMPTOMS OF GAIT DIFFICULTY, MEMORY AND SPEECH PROBLEMS AND STILL INSOMNIA, ULTIMATELY BEGAN TO HAVE SEIZURES AND WAS INTUBATED AND SEDATED ON 06/21/21. TRANSFERRED TO HOSPITAL 9TH FLOOR NEUROLOGICAL ICU ON 06/25/21 AND BEGAN PROCESS OF DIAGNOSIS WITH A LUMBAR PUNCTURE. RECEIVED THE CJD DIAGNOSIS ON 07/14/21 AND SHE PASSED AWAY ON 07/17/21. MY MOTHER WAS COMPLETELY HEALTHY, WENT TO THE DOCTOR EVERY 6 MONTHS WITH GREAT CHECK UPS , WORKED OUT EVERY DAY, AND LOVED LIFE.

| Lab Data | Current Illness | Adverse Events After Prior Vaccinations |
|---|---|---|
| NUMEROUS BLOOD WORK, CAT SCANS, MRI , EEG , LUMBER PUNCTURES | NONE | |

| Medications At Time of Vaccination | History/Allergies |
|---|---|
| LEVOTHYROXINE | NONE |
| | NONE |

# VAERS DETAIL

VAERS ID: 1699517

| Vaccine Type | Vaccine | Manufacturer | Lot | Dose | Route | Site |
|---|---|---|---|---|---|---|
| COVID19 | COVID19 (COVID19 (PFIZER-BIONTECH)) | PFIZER\BIONTECH | ET1831 | 2 | OT | LA |

| Event Information | | | |
|---|---|---|---|
| Patient Age | 79 | Sex | M |
| State/Territory | FR | Date Report Completed | |
| Date Vaccinated | 3/18/2021 | Date Report Received | 9/15/2021 |
| Date of Onset | 5/18/2021 | Date Died | 8/12/2021 |
| Days to Onset | 61 | | |
| Vaccine Administered By | OTH | Vaccine Purchased By | |
| Mfr/Imm Project Number | | Split Type | ITPFIZER INC202101135850 |
| Recovered | N | Serious | |

| Event Categories | |
|---|---|
| Death | Yes |
| Life Threatening | No |
| Permanent Disability | No |
| Congenital Anomaly/Birth Defect | No |
| Hospitalized | Yes |
| Days in Hospital | 6 |
| Existing Hospitalization Prolonged | No |
| Emergency Room/Office Visit | No |
| Emergency Room | No |
| Office Visit | No |

| Symptoms |
|---|
| Creutzfeldt-Jakob disease |
| CSF test |
| Magnetic resonance imaging |

## Adverse Event Description

Jakob-Creutzfeldt disease; This is a spontaneous report from a contactable physician downloaded from the  Regulatory Authority number IT-MINISAL02-775458. A 79-years-old male patient received bnt162b2 (COMIRNATY,Formulation:Solution for injection,Batch/Lot Number: ET1831), via intramuscularly administered in Arm Left on 18Mar2021  as Dose 2, 0.3mL, Single for covid-19 immunization. Medical history included supraventricular tachycardia from an unknown date and unknown if ongoing, two remote episodes of paroxysmal supraventricular tachycardia, radical prostatectomy from 01Jan2016 to an unknown date Robotic radical prostatectomy for carcinoma in 2016, T1 N0 Gleason 6. annual follow-up, always, glaucoma from an unknown date and unknown if ongoing, non-hodgkin's lymphoma from an unknown date and unknown if ongoing, large cell non-Hodgkin's lymphoma, 8 cycles of CT, complete remission since 2004 (follow up annual). Historical vaccination included the patient received bnt162b2 (COMIRNATY, Formulation: Solution for injection, Batch/Lot Number: EJ6790) via unspecified route on 25Feb2021 as Dose 1, Single for covid-19 immunization.Concomitant medication(s) included verapamil hydrochloride (ISOPTINE) taken for an unspecified indication, start and stop date were not reported; acetylsalicylic acid (ACETYLSALICYLIC ACID) taken for an unspecified indication, start and stop date were not reported; atorvastatin (ATORVASTATIN) taken for an unspecified indication, start and stop date were not reported; timolol (TIMOLOL) taken for an unspecified indication, start and stop date were not reported; zolpidem tartrate (STILNOX) taken for an unspecified indication, start and stop date were not reported. The patient experienced jakob-creutzfeldt disease (creutzfeldt-jakob disease) (death, hospitalization) on 18May2021.  The patient was hospitalized for jakob-creutzfeldt disease (creutzfeldt-jakob disease) from 03Jun2021 to 09Jun2021. The patient underwent lab tests and procedures which included CSF test: waiting for the results of the csf tests on 27Aug2021, magnetic resonance imaging: mri abnormal on 31May2021. Signal changes in the right parietal cortex diffusion-weighted imaging / FLAIR of non-univocal iteration. Therapeutic measures were taken as a result of jakob-creutzfeldt disease (creutzfeldt-jakob disease). The patient died on 12Aug2021. An autopsy was not performed.  Reporter's comment:  probable Creutzfeldt Jakob disease detection from mRNA vaccines - Actions taken (hydration-morphine-anticholinergic-anticonvulsants) - Ethnic origin (PRIVACY) - COVID 19 COMIRNATY VACCINE (PFIZER): Administration site (left shoulder) Booster dose number (2) second dose Pfizer 18Mar2021 (Lot ET1831) from April 2021. general malaise and dyspraxia, from May: ataxia. hallucinations. taste alterations, dysarthria, akinetic mutism, total dysphagia. First dose performed on 25Feb202 Sender's comment:  Regional Pharmacovigilance: Pending Lot Number. 25Aug2021 Regional Center for Pharmacovigilance : requests for follow-up information from the reporter regarding doc. medical case. 26Aug2021 hospital of PRIVACY: Pending final discharge letter, including the results of the CSF tests made 27Aug2021 Regional Center for Pharmacovigilance: the form is updated with the additional information provided by the reporter and the clinical report is attached. The autopsy was not done.  LOT: ET1831 No follow-up attempts are possible. No further information is expected.; Reporter's Comments: probable Creutzfeldt Jakob disease detection from mRNA vaccines - Actions taken (hydration-morphine-anticholinergic-anticonvulsants) - Ethnic origin (PRIVACY) - COVID 19 COMIRNATY VACCINE (PFIZER): Administration site (left shoulder) Booster dose number (2) second dose Pfizer 18Mar2021 (Lot ET1831) from April 2021. general malaise and dyspraxia, from May: ataxia. hallucinations. taste alterations, dysarthria, akinetic mutism, total dysphagia. First dose performed on 25Feb202; Reported Cause(s) of Death: Jakob-Creutzfeldt disease

| Lab Data | Current Illness | Adverse Events After Prior Vaccinations |
|---|---|---|
| Test Date: 20210827; Test Name: CSF; Result Unstructured Data: Test Result:Waiting for the results of the CSF tests; Test Date: 20210531; Test Name: MRI; Result Unstructured Data: Test Result:MRI abnormal; Comments: Signal changes in the right parietal cortex diffusion-weighted imaging / FLAIR of non-univocal iteration | | |

| Medications At Time of Vaccination | History/Allergies |
|---|---|
| ISOPTINE; ACETYLSALICYLIC ACID; ATORVASTATIN; TIMOLOL; STILNOX | Medical History/Concurrent Conditions: Glaucoma; Non-Hodgkin's lymphoma (large cell non-Hodgkin's lymphoma, 8 cycles of CT, complete remission since 2004 (follow up annu); Paroxysmal supraventricular tachycardia (two remote episodes of paroxysmal supraventricular tachycardia); Radical prostatectomy (Robotic radical prostatectomy for carcinoma in 2016: T1 N0 Gleason 6. annual follow-up, always) |

# VAERS DETAIL

VAERS ID: 1729954

| Vaccine Type | Vaccine | Manufacturer | Lot | Dose | Route | Site |
|---|---|---|---|---|---|---|
| COVID19 | COVID19 (COVID19 (PFIZER-BIONTECH)) | PFIZER\BIONTECH | EJ6134 | 2 | | |

| Event Information | | | |
|---|---|---|---|
| Patient Age | | Sex | F |
| State/Territory | FR | Date Report Completed | |
| Date Vaccinated | 2/2/2021 | Date Report Received | 9/24/2021 |
| Date of Onset | 5/1/2021 | Date Died | |
| Days to Onset | 88 | | |
| Vaccine Administered By | OTH | Vaccine Purchased By | |
| Mfr/Imm Project Number | | Split Type | SEPFIZER INC202101216306 |
| Recovered | N | Serious | |

| Event Categories | |
|---|---|
| Death | No |
| Life Threatening | Yes |
| Permanent Disability | Yes |
| 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 |
|---|
| Abnormal dreams |
| Cognitive disorder |
| Creutzfeldt-Jakob disease |
| Dizziness |
| Dysstasia |
| Electroencephalogram |
| Frontotemporal dementia |
| Hallucination, visual |
| Investigation |
| Memory impairment |
| Mental disorder |
| Motor dysfunction |
| Positron emission tomogram |
| Protein total |

## Adverse Event Description

Creutzfeldt-Jakob disease; dizziness; hallucinations/visual hallucinations where she had seen horses and dogs; frontal lobe dementia; impaired memory; anxious dreams; gradually deteriorates during the care period motorically and cognitively; gradually deteriorates during the care period motorically and cognitively; Could no longer stand up; had difficulty following instructions and closed her eyes most of the time; This is a spontaneous report from a contactable pharmacist downloaded from the regulatory agency-WEB, regulatory authority number SE-MPA-2021-083041. This pharmacist reported events for two vaccine doses, this is first of two reports for second dose. A 76-year-old female patient received second dose of BNT162B2 (COMIRNATY), via an unspecified route of administration on 02Feb2021 (Lot Number: EJ6134) as single dose for covid-19 immunisation. Medical history included polymyalgia rheumatica, hypertension, osteoporosis, glaucoma, hyperlipidaemia and chronic obstructive lung disease, all ongoing. Concomitant medications included metoprolol tartrate (METOPROLOL SANDOZ) from 2008 to 04Aug2021; acetylsalicylic acid (TROMBYL) from 2008 to Sep2021; amlodipine besilate (AMLODIPIN SANDOZ) from 2011 to Sep2021; calcium carbonate, colecalciferol (KALCIPOS-D) from 2014 to Sep2021; enalapril maleate (ENALAPRIL KRKA) from 2010 to 03Sep2021; simvastatin (SIMVASTATIN KRKA) from 2008 to Sep2021; omeprazole (OMEPRAZOL TEVA) taken for an unspecified indication from 2012 to 30Aug2021. The patient previously took first dose of BNT162B2 (COMIRNATY), via an unspecified route of administration on 12Jan2021 (batch/lot: EJ6795), as single dose for covid-19 immunisation and experienced reduced general condition (had a reduced general condition since Jan2021, debuted in connection with covid vaccination). Reported suspect adverse events were Creutzfeldt-Jakob disease on 20Jul2021. According to medical records, the woman had been hospitalized due to dizziness and hallucinations since mid-May2021. The woman confirmed visual hallucinations where she had seen horses and dogs. During the past month developed impaired memory. The dizziness was not described as nautical or rotational in nature, but occurs when standing up and increases after about one minute. Had anxious dreams and visual hallucinations, seen dead relatives talking to her. The woman had no heredity for dementia or malignancy. The woman undergoes most investigations without an explanation for the symptoms and finally an investigation was started for Creutzfeldt Jakob's disease. Electroencephalogram (EEG) showed no typical complexes as in Creutzfeldt-Jakob disease. Protein 14-3-3 analysis was ordered and was positive. Also undergoes full-body positron emission tomogram (PET)+ brain that showed the appearance of frontal lobe dementia. At the same time, analysis for real-time quaking-induced conversion (RT-QUIC) analysis in the process of continuing Creutzfeldt Jakob's diagnostics. The analysis fails in two trials, but it had still been seen signs of protein fragments in liquors. This gave strong suspicion that RT-QUIC was also positive and this in combination with the clinic and a positive 14-3-3 meant that the diagnosis of Creutzfeldt Jakob disease was made at the beginning of Sep2021. The woman gradually deteriorates during the care period motorically and cognitively. Could no longer stand up, had difficulty following instructions and closed her eyes most of the time. Speaks incoherently and was not oriented. During treatment, the woman's hallucinations have been treated with quetiapine 25 mg 2 tablets overnight, improved. When the diagnosis gave a gloomy prognosis, a decision was made about palliative care and the woman was discharged to a palliative care center. All oral drug treatment was discontinued. For event Creutzfeldt-Jakob disease, the seriousness criteria were life threatening, hospitalization, disability. The outcome of the event Creutzfeldt-Jakob disease was not recovered, for other events was unknown. No follow-up attempts are possible. No further information is expected.; Sender's Comments: Linked Report(s) : SE-PFIZER INC-202101229131 same patient/product, different dose/event

| Lab Data | Current Illness | Adverse Events After Prior Vaccinations |
|---|---|---|
| Test Date: 2021; Test Name: EEG; Result Unstructured Data: Test Result:no typical complexes; Comments: as in Creutzfeldt - Jakob disease; Test Date: 2021; Test Name: RT-QUIC; Test Result: Positive ; Test Date: 2021; Test Name: full-body PET + brain; Result Unstructured Data: Test Result:frontal lobe dementia; Test Date: 2021; Test Name: Protein 14-3-3; Test Result: Positive | Chronic obstructive lung disease; Glaucoma; Hyperlipidaemia; Hypertension; Osteoporosis; Polymyalgia rheumatica | |

| Medications At Time of Vaccination | History/Allergies |
| --- | --- |
| METOPROLOL SANDOZ [METOPROLOL TARTRATE]; TROMBYL; AMLODIPIN SANDOZ [AMLODIPINE BESILATE]; KALCIPOS-D; ENALAPRIL KRKA; SIMVASTATIN KRKA; OMEPRAZOL TEVA [OMEPRAZOLE] | |

# VAERS DETAIL

VAERS ID: 1754471

| Vaccine Type | Vaccine | Manufacturer | Lot | Dose | Route | Site |
|---|---|---|---|---|---|---|
| COVID19 | COVID19 (COVID19 (PFIZER-BIONTECH)) | PFIZER\BIONTECH | FE7011 | 2 | | |

| Event Information | | | |
|---|---|---|---|
| Patient Age | 73 | Sex | M |
| State/Territory | FR | Date Report Completed | |
| Date Vaccinated | 7/26/2021 | Date Report Received | 10/1/2021 |
| Date of Onset | 7/1/2021 | Date Died | 9/14/2021 |
| Days to Onset | | | |
| Vaccine Administered By | OTH | Vaccine Purchased By | |
| Mfr/Imm Project Number | | Split Type | DEPFIZER INC202101262381 |
| Recovered | N | Serious | |

| Event Categories | |
|---|---|
| Death | Yes |
| Life Threatening | Yes |
| 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 |
|---|
| Creutzfeldt-Jakob disease |

**Adverse Event Description**

Creutzfeld-Jacob disease; This is a spontaneous report from a non-contactable physician downloaded from the regulatory authority DE-PEI-202100194927. A 73-year-old male patient received the second dose of BNT162B2 (COMIRNATY, Lot Number: FE7011, strength: 0.3 ml), at the age of 73 years old, via an unspecified route of administration on 26Jul2021 at single dose for COVID-19 immunisation. Medical history included chronic obstructive pulmonary disease (COPD), arterial hypertension, alcohol use. The patient's concomitant medications were not reported. The patient previously received the first dose of BNT162B2 (Lot Number: FD9234), at the age of 73 years old, on 23Jun2021 at single dose for COVID-19 immunisation. The patient experienced Creutzfeld-Jacob disease in Jul2021. Duration was reported as 6 weeks. This report was serious - death, hospitalization, life threatening. Assessment of BNT162B2 to Creutzfeld-Jacob disease was assessed as C. Inconsistent causal association to immunization by the PEI. The outcome of event was fatal. The patient died on 14Sep2021. 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: Creutzfeld-Jacob disease

| Lab Data | Current Illness | Adverse Events After Prior Vaccinations |
|---|---|---|
| | | |

| Medications At Time of Vaccination | History/Allergies |
|---|---|
| | Medical History/Concurrent Conditions: Alcohol use; Arterial hypertension; COPD |

# VAERS DETAIL

VAERS ID: 1754973

| Vaccine Type | Vaccine | Manufacturer | Lot | Dose | Route | Site |
|---|---|---|---|---|---|---|
| COVID19 | COVID19 (COVID19 (MODERNA)) | MODERNA | | 2 | OT | |

| Event Information | | | |
|---|---|---|---|
| Patient Age | 60 | Sex | F |
| State/Territory | FR | Date Report Completed | |
| Date Vaccinated | 5/6/2021 | Date Report Received | 10/1/2021 |
| Date of Onset | 5/13/2021 | Date Died | |
| Days to Onset | 7 | | |
| Vaccine Administered By | UNK | Vaccine Purchased By | |
| Mfr/Imm Project Number | | Split Type | CHMODERNATX, INC.MOD20213 |
| Recovered | N | Serious | |

| Event Categories | |
|---|---|
| Death | No |
| Life Threatening | Yes |
| 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 folate |
| Blood thyroid stimulating hormone |
| Creutzfeldt-Jakob disease |
| CSF test |
| Ear, nose and throat examination |
| Electroencephalogram |
| Magnetic resonance imaging head |
| Magnetic resonance neurography |
| Neurological examination |
| Ultrasound Doppler |
| Ultrasound scan |
| Vitamin B12 |

| Adverse Event Description |
| --- |
| This regulatory authority case was reported by a pharmacist and describes the occurrence of CREUTZFELDT-JAKOB DISEASE (Creutzfeldt-Jakob) in a 60-year-old female patient who received mRNA-1273 (COVID-19 Vaccine Moderna) for COVID-19 vaccination. The patient's past medical history included Ex-alcohol user (Progress note 04-Jul-2021, no alcohol for the last 14 days, before that only a little on weekends.). Concomitant products included LORAZEPAM (TEMESTA EXPIDET) for an unknown indication. On 06-May-2021, the patient received first dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 1 dosage form. On 07-Jun-2021, received second dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) dosage was changed to 1 dosage form. On 13-May-2021, the patient experienced CREUTZFELDT-JAKOB DISEASE (Creutzfeldt-Jakob) (seriousness criteria hospitalization, medically significant and life threatening). At the time of the report, CREUTZFELDT-JAKOB DISEASE (Creutzfeldt-Jakob) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 09-Jun-2021, Blood folate: normal (normal) Normal. On 09-Jun-2021, Blood thyroid stimulating hormone: normal (normal) Normal. On 09-Jun-2021, Vitamin B12: normal (normal) Normal. On 11-Jun-2021, Magnetic resonance imaging head: abnormal (abnormal) A few individual non-specific glial scars. No evidence of ischemia, intracranial hemorrhage or mass. Signs of sinusitis of the right sphenoid sinus and the right posterior ethmoid cells.. In 2021, Magnetic resonance neurography: normal (normal) Normal. On 28-Jun-2021, Magnetic resonance neurography: abnormal (abnormal) Borderline CMAP decrease with irritation distal to the sulcus (by 13%), and proximal to the sulcus (by further 12%) otherwise ulnar neurography and dorsal interosseous artery angiography is normal.. On 30-Jun-2021, Ultrasound Doppler: normal (normal) Doppler/duplex sonography of the vessels supplying the brain is normal.. On 07-Jul-2021, Ear, nose and throat examination: no evidence of a peripheral vestibular dysfunction (normal) No evidence of a peripheral vestibular dysfunction. On 07-Jul-2021, Neurological examination: suspected phobic dizziness (abnormal) Suspected phobic dizziness. On 19-Jul-2021, CSF test: pathology (abnormal) CSF Puncture: 0 cells, glucose and lactate normal, no oligoclonal bands, no barrier disruption. CSF puncture 14-3-3 and RT-Quick: Pending. On 19-Jul-2021, Magnetic resonance imaging head: abnormal (abnormal) Highly pathological and progressive findings in the cortex of both hemispheres on the left and in the caudate nucleus on both sides. Encephalitis possible. On 20-Jul-2021, Electroencephalogram: pathology (abnormal) EEG with moderate general changes with GPDs without typical ictal evolution. Non convulsive status, however cannot be ruled out. EEG findings compatible with clinical suspicion of CJD.. On 20-Jul-2021, Ultrasound scan: abnormal (abnormal) Caudate head hyperechoic, basal ganglia plane diffusely hyper-echogenic. Finding compatible with CJD.. For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter considered CREUTZFELDT-JAKOB DISEASE (Creutzfeldt-Jakob) to be unlikely related. Treatment information was not provided On 07-Jun-2021, the patient done ENT presentation and no evidence of a peripheral vestibular dysfunction was found and on the same day Neurological presentation was done and suspected phobic dizziness. On 15-Jul-2021, Psychosomatic consultation was done and suspected conversion disorder in sever somatization disorder. On an unknown date Western blot for protein was done and the result was 14-3-3: Positive It was stated that on 20-July-2021, echography and on 04-Aug-2021, CSF Test was done and the result was unknown. Patient had began to manifest light headedness associated with complex psychiatric symptoms, including left hemi soma dysesthesia visual disturbances, unstable gait and difficulty concentrating about one week after the first dose. During the same period as the onset of these symptoms, the occurrence of negative events within the context of the family and friends of the patient were reported. The complaints had occurred for a few weeks after the vaccination. The dizziness started 1 week after the first dose of vaccination (06-May-2021) and lasted until the end of May. 3 days after the 2nd dose dizziness started again and persisted. Her husband reported symptoms of anxiety for several months/years, which had recently been exacerbated by panic attacks. The patient was hospitalized on 15-Jul-2021. The patient was transferred on 28-Jul-2021 to a hospital and the cause was unknown. Company Comment: This case concerns a 60-year-old, female patient with no relevant medical history, who experienced the unexpected events of Creutzfeld-Jacob disease. The events occurred approximately 8 days after the first dose of Spikevax. The rechallenge was unknown since no information about the second dose was disclosed. The reporter assessed the events as related to the product. The benefit-risk relationship of Spikevax is not affected by this report. Event seriousness assessed as per Regulatory Authority reporting, however there was no information in the source document supporting that the events resulted in a persistent or permanent incapacity Most recent FOLLOW-UP information incorporated above includes: On 23-Sep-2021: Translation document received on 28-Sep-2021, added the medical history and lab investigation and updated the I-narrative.; Sender's Comments: This case concerns a 60-year-old, female patient with no relevant medical history, who experienced the unexpected events of Creutzfeld-Jacob disease. The events occurred approximately 8 days after the first dose of Spikevax. The rechallenge was unknown since no information about the second dose was disclosed. The reporter assessed the events as related to the product. The benefit-risk relationship of Spikevax is not affected by this report. Event seriousness assessed as per Regulatory Authority reporting, however there was no information in the source document supporting that the events resulted in a persistent or permanent incapacity |

| Lab Data | Current Illness | Adverse Events After Prior Vaccinations |
|---|---|---|
| Test Date: 20210609; Test Name: Folic acid; Result Unstructured Data: Normal; Test Date: 20210609; Test Name: TSH; Result Unstructured Data: Normal; Test Date: 20210719; Test Name: CSF test abnormal; Result Unstructured Data: CSF Puncture: 0 cells, glucose and lactate normal, no oligoclonal bands, no barrier disruption. CSF puncture 14-3-3 and RT-Quick: Pending; Test Date: 20210707; Test Name: ENT presentation demo; Result Unstructured Data: No evidence of a peripheral vestibular dysfunction; Test Date: 20210720; Test Name: EEG; Result Unstructured Data: EEG with moderate general changes with GPDs without typical ictal evolution. Non convulsive status, however cannot be ruled out. EEG findings compatible with clinical suspicion of CJD.; Test Date: 20210611; Test Name: cMRI; Result Unstructured Data: A few individual non-specific glial scars. No evidence of ischemia, intracranial hemorrhage or mass. Signs of sinusitis of the right sphenoid sinus and the right posterior ethmoid cells.; Test Date: 20210719; Test Name: cMRI; Result Unstructured Data: Highly pathological and progressive findings in the cortex of both hemispheres on the left and in the caudate nucleus on both sides. Encephalitis possible; Test Date: 2021; Test Name: Median neurography; Result Unstructured Data: Normal; Test Date: 20210628; Test Name: Ulnar neurography; Result Unstructured Data: Borderline CMAP decrease with irritation distal to the sulcus (by 13%), and proximal to the sulcus (by further 12%) otherwise ulnar neurography and dorsal interosseous artery angiography is normal.; Test Date: 20210707; Test Name: Neurological presentation demo; Result Unstructured Data: Suspected phobic dizziness; Test Date: 20210630; Test Name: Doppler/duplex sonography; Result Unstructured Data: Doppler/duplex sonography of the vessels supplying the brain is normal.; Test Date: 20210720; Test Name: Transcranial ultrasound; Result Unstructured Data: Caudate head hyperechoic, basal ganglia plane diffusely hyper-echogenic. Finding compatible with CJD.; Test Date: 20210609; Test Name: Vitamin B12; Result Unstructured Data: Normal | | |

| Medications At Time of Vaccination | History/Allergies |
|---|---|
| TEMESTA EXPIDET | Medical History/Concurrent Conditions: Ex-alcohol user (Progress note 04-Jul-2021, no alcohol for the last 14 days, before that only a little on weekends.) |

# VAERS DETAIL

VAERS ID: 1760795

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

| Event Information | | | |
|---|---|---|---|
| Patient Age | 27 | Sex | M |
| State/Territory | FR | Date Report Completed | |
| Date Vaccinated | 7/28/2021 | Date Report Received | 10/5/2021 |
| Date of Onset | 7/28/2021 | Date Died | |
| Days to Onset | 0 | | |
| Vaccine Administered By | OTH | Vaccine Purchased By | |
| Mfr/Imm Project Number | | Split Type | GBPFIZER INC202101242772 |
| Recovered | N | Serious | |

| Event Categories | |
|---|---|
| Death | No |
| 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 |
|---|
| Creutzfeldt-Jakob disease |
| Headache |
| SARS-CoV-2 test |

## Adverse Event Description

very sporadic; Head pain; This is a spontaneous report from a contactable consumer received from the regulatory authority. The regulatory authority report number is GB-MHRA-WEBCOVID-202109201816451900-FYHBV. Sender's (Case) Safety Report Unique Identifier is GB-MHRA-ADR 25969849. A 27-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE, formulation: Solution for injection, Batch/Lot number was not reported), dose 2 via an unspecified route of administration on 28Jul2021 (age at the time of vaccination was 27-year-old) as dose 2, single for COVID-19 immunization. The patient medical history and concomitant medications were not reported. Historical vaccine included BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE, formulation: Solution for injection, Batch/Lot number was not reported), via an unspecified route of administration on an unspecified date as dose 1, single for COVID-19 immunization. Patient has not had symptoms associated with COVID-19. The patient has not tested positive for COVID-19 since having the vaccine. The patient was not enrolled in clinical trial. It was reported that the patient experienced short sharp pain in the left side of the forehead (Head pain) on 28Jul2021. Occurred every 5 minutes, very sporadic (creutzfeldt-jakob disease) on an unspecified date, does not happen every day. The patient underwent lab tests and procedures which included sars-cov-2 test: negative on 20Sep2021 (No - Negative COVID-19 test). Outcome of the event very sporadic was reported as Unknown and outcome of other event was reported as not recovered at this time of the report. No follow-up attempts are possible; information about lot/batch number cannot be obtained. No further information is expected.

| Lab Data | Current Illness | Adverse Events After Prior Vaccinations |
|---|---|---|
| Test Date: 20210920; Test Name: COVID-19 virus test; Test Result: Negative ; Comments: No - Negative COVID-19 test | | |

| Medications At Time of Vaccination | History/Allergies |
|---|---|
| | |

# VAERS DETAIL

VAERS ID: 1777781

| Vaccine Type | Vaccine | Manufacturer | Lot | Dose | Route | Site |
|---|---|---|---|---|---|---|
| COVID19 | COVID19 (COVID19 (MODERNA)) | MODERNA | 3000493 | 1 | OT | |

| Event Information | | | |
|---|---|---|---|
| Patient Age | 87 | Sex | M |
| State/Territory | FR | Date Report Completed | |
| Date Vaccinated | 3/27/2021 | Date Report Received | 10/11/2021 |
| Date of Onset | 6/21/2021 | Date Died | 9/7/2021 |
| Days to Onset | 86 | | |
| Vaccine Administered By | UNK | Vaccine Purchased By | |
| Mfr/Imm Project Number | | Split Type | FRMODERNATX, INC.MOD20213 |
| Recovered | N | Serious | |

| Event Categories | |
|---|---|
| Death | Yes |
| Life Threatening | Yes |
| 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 |
|---|
| Creutzfeldt-Jakob disease |

## Adverse Event Description

MALADIE DE CREUTZFELD-JAKOB; This case was received (Reference number: FR-AFSSAPS-TO20217545) on 04-Oct-2021 and was forwarded to Moderna on 04-Oct-2021. This regulatory authority case was reported by a physician and describes the occurrence of in an 87-year-old male patient who received mRNA-1273 (Spikevax) (batch nos. 3001653 and 3000493) for COVID-19 vaccination. Concurrent medical conditions included Hypertension arterial and Hypercholesterolaemia. On 27-Mar-2021, the patient received first dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 24-Apr-2021, received second dose of mRNA-1273 (Spikevax) (Intramuscular) dosage was changed to 1 dosage form. On 21-Jun-2021, after starting mRNA-1273 (Spikevax), the patient experienced (seriousness criteria death, hospitalization, medically significant and life threatening). The patient died on 07-Sep-2021. The reported cause of death was maladie de creutzfeld-jakob. An autopsy was not performed. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medications were mentioned. No treatment medication details were reported. Company comment: This case concerns a 87-year-old male patient, with reported medical history of hypertension arterial and hypercholesterolaemia, who experienced the unexpected fatal event of Creutzfeld-Jacob disease. The event occurred 27 days after the second dose of mRNA-1273 (Moderna COVID-19 Vaccine) and fatal outcome resulted 4 months 14 days post second dose. The rechallenge was not applicable as event developed after the second dose and had a fatal outcome. Causality for the reported event was not provided by the reporter. The benefit-risk relationship of mRNA-1273 (Moderna COVID-19 Vaccine) not affected by this report. Event seriousness assessed serious per Regulatory authority based on fatal outcome. Most recent FOLLOW-UP information incorporated above includes: On 04-Oct-2021: Translation received on 06-Oct-2021 as live follow up and updated with Dosage text.; Sender's Comments: This case concerns a 87-year-old male patient, with reported medical history of hypertension arterial and hypercholesterolaemia, who experienced the unexpected fatal event of Creutzfeld-Jacob disease. The event occurred 27 days after the second dose of mRNA-1273 (Moderna COVID-19 Vaccine) and fatal outcome resulted 4 months 14 days post second dose. The rechallenge was not applicable as event developed after the second dose and had a fatal outcome. Causality for the reported event was not provided by the reporter. The benefit-risk relationship of mRNA-1273 (Moderna COVID-19 Vaccine) not affected by this report. Event seriousness assessed serious per Regulatory authority based on fatal outcome.; Reported Cause(s) of Death:

| Lab Data | Current Illness | Adverse Events After Prior Vaccinations |
|---|---|---|
| | Hypercholesterolaemia; Hypertension arterial | |

| Medications At Time of Vaccination | History/Allergies |
|---|---|
| | |

# VAERS DETAIL

VAERS ID: 1786969

| Vaccine Type | Vaccine | Manufacturer | Lot | Dose | Route | Site |
|---|---|---|---|---|---|---|
| COVID19 | COVID19 (COVID19 (PFIZER-BIONTECH)) | PFIZER\BIONTECH | EX6564 | 2 | OT | |

| Event Information | | | |
|---|---|---|---|
| Patient Age | | Sex | F |
| State/Territory | FR | Date Report Completed | |
| Date Vaccinated | 5/5/2021 | Date Report Received | 10/15/2021 |
| Date of Onset | 5/5/2021 | Date Died | |
| Days to Onset | 0 | | |
| Vaccine Administered By | OTH | Vaccine Purchased By | |
| Mfr/Imm Project Number | | Split Type | NOPFIZER INC202101323204 |
| Recovered | N | Serious | |

| Event Categories | |
|---|---|
| Death | No |
| Life Threatening | Yes |
| 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 | Yes |

| Symptoms |
|---|
| Arrhythmia |
| Cognitive disorder |
| Creutzfeldt-Jakob disease |
| CSF protein |
| Electroencephalogram |
| General physical health deterioration |
| Inappropriate schedule of product administration |
| Investigation |
| Magnetic resonance imaging head |
| Nerve injury |

## Adverse Event Description

progressive cognitive failure; focal dysrhythmia; severe irreversible nerve damage; Her condition was deteriorating; CREUTZFELDT-JAKOB DISEASE; Vaccination with the first dose of Comirnaty was given 24Mar2021 and the second dose of Comirnaty 05May2021.; This is a spontaneous report from a contactable physician downloaded from the Regulatory Authority-WEB, regulatory authority number NO-NOMAADVRE-FHI-2021-Ue7z8m. A 75-year-old female patient received BNT162B2 (COMIRNATY), intramuscularly on 05May2021 (Batch/Lot Number: EX6564) as dose 2, single for COVID-19 immunisation. Medical history included well-regulated hypertension and type 2 diabetes mellitus. The patient's concomitant medications were not reported. The patient previously received first dose of COMIRNATY on 24Mar2021 for COVID-19 immunisation. In mid August the woman became rapidly ill. She was admitted to neurological ward in hospital 03Sep2021 with progressive cognitive failure. Gradually development of cerebellar and pyramidal signs. Head MRI suspect of Creutzfeldt-Jakob disease. Pathological EEG with focal dysrhythmia, but no generalized extension in Sep2021. Normal biochemistry. Cerebrospinal fluid with marked neurodegenerative changes. Total-tau 3000, corresponding to severe irreversible nerve damage in Sep2021. The patient had been transferred to a local health care facility. Her condition was deteriorating. Next of kin had been informed that the woman had been diagnosed with Creutzfeldt-Jacob disease based on a strong clinical suspicion, but that a final diagnosis could only be determined after autopsy. Fatal outcome was expected shortly. The woman was a wife and had previously been vital and with little illness. The woman had no family anamnesis of CJD, but she had been working on a farm with cows in the past. The outcome of the events was not recovered. Relatedness of COMIRNATY to reaction Creutzfeldt-Jakob disease was considered unlikely by Regulatory Authority. No follow-up attempts are possible. No further information is expected.; Sender's Comments: Based on the information in the case report event Creutzfeldt-Jakob disease may be not related to suspect drug BNT162B2, and more likely due to underlying medical condition and age related.

| Lab Data | Current Illness | Adverse Events After Prior Vaccinations |
|---|---|---|
| Test Date: 202109; Test Name: Cerebrospinal fluid protein; Result Unstructured Data: Test Result:3000; Comments: Marked neurodegenerative changes. Total-tau 3000, corresponding to severe irreversible nerve damage (reference area < 300).; Test Date: 202109; Test Name: EEG; Result Unstructured Data: Test Result:focal dysrhythmia; Comments: Pathological with focal dysrhythmia, but no generalized extension.; Test Name: biochemistry; Result Unstructured Data: Test Result:Normal; Test Date: 20210907; Test Name: Head MRI; Result Unstructured Data: Test Result:Suspect of Creutzfeldt-Jacob disease; Comments: Suspect of Creutzfeldt-Jacob disease | | |

| Medications At Time of Vaccination | History/Allergies |
|---|---|
| | Medical History/Concurrent Conditions: Hypertension (Well-regulated); Type 2 diabetes mellitus (Well-regulated) |

# VAERS DETAIL

VAERS ID: 1819557

| Vaccine Type | Vaccine | Manufacturer | Lot | Dose | Route | Site |
|---|---|---|---|---|---|---|
| COVID19 | COVID19 (COVID19 (PFIZER-BIONTECH)) | PFIZER\BIONTECH | FA5831 | UNK | OT | |

| Event Information | | | |
|---|---|---|---|
| Patient Age | | Sex | M |
| State/Territory | FR | Date Report Completed | |
| Date Vaccinated | | Date Report Received | 10/27/2021 |
| Date of Onset | 6/26/2021 | Date Died | |
| Days to Onset | | | |
| Vaccine Administered By | OTH | Vaccine Purchased By | |
| Mfr/Imm Project Number | | Split Type | ITPFIZER INC202101364322 |
| Recovered | U | Serious | |

| Event Categories | |
|---|---|
| Death | No |
| 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 | Yes |

| Symptoms |
|---|
| Ataxia |
| Balance disorder |
| Confusional state |
| Creutzfeldt-Jakob disease |
| CSF test |
| Cytogenetic analysis |
| Diabetes mellitus |
| Electroencephalogram |
| Magnetic resonance imaging |
| Specialist consultation |

## Adverse Event Description

early onset of Jakob-Creutzfeldt disease; diabetes mellitus; reactive confusion; the patient has balance disorders; reactive confusion; ataxia; This is a spontaneous report from a contactable consumer or other non hcp downloaded from the Regulatory Authority-WEB, regulatory authority number IT-MINISAL02-796425.  A 57-years-old male patient received BNT162B2 (COMIRNATY, solution for injection,lot Number was FA5831),via intramuscularly on an unspecified date as single dose for COVID-19 immunisation.The patient's medical history and concomitant medications were not reported.On 26Jun2021, the patient experienced early onset of jakob-creutzfeldt disease, diabetes mellitus, reactive confusion, the patient has balance disorders, reactive confusion, ataxia. The patient underwent lab tests and procedures which included csf test where the result was unknown, cytogenetic analysis  the result was unknown, electroencephalogram and result was unknown, magnetic resonance imaging and the result was unknown, specialist consultation and it was unknown result.The clinical outcome of the events was unknown.  Sender's comment: The reporter states the following: Among the actions taken, following the adverse reaction, there was the immediate hospitalization of the patient. In addition, he was subjected to magnetic resonance imaging with contrast, electroencephalogram, genetic analysis and Liquor, visited by numerous doctors who confirmed the early onset of Jakob-Creutzfeldt disease, following administration of the vaccine.  No follow-up attempts are possible No further information is expected.  follow up-14Oct2021 new information added dose administered date was obtained as 13May2021 and 17Jun2021.

| Lab Data | Current Illness | Adverse Events After Prior Vaccinations |
|---|---|---|
| Test Name: CSF TEST; Result Unstructured Data: Test Result:unknown results; Test Name: genetic analysis; Result Unstructured Data: Test Result:unknown results; Test Name: electroencephalogram; Result Unstructured Data: Test Result:unknown results; Test Name: magnetic resonance imaging with contrast; Result Unstructured Data: Test Result:unknown results; Test Name: specialist consultation; Result Unstructured Data: Test Result:unknown results | | |

| Medications At Time of Vaccination | History/Allergies |
|---|---|
| | |

# VAERS DETAIL

VAERS ID: 1828681

| Vaccine Type | Vaccine | Manufacturer | Lot | Dose | Route | Site |
|---|---|---|---|---|---|---|
| COVID19 | COVID19 (COVID19 (MODERNA)) | MODERNA | 004M20A. 012A | 2 | SYR | LA |

| Event Information | | | |
|---|---|---|---|
| Patient Age | 66 | Sex | M |
| State/Territory | TX | Date Report Completed | |
| Date Vaccinated | 1/27/2021 | Date Report Received | 10/29/2021 |
| Date of Onset | 6/1/2021 | Date Died | 8/27/2021 |
| Days to Onset | 125 | | |
| Vaccine Administered By | PUB | Vaccine Purchased By | |
| Mfr/Imm Project Number | | Split Type | |
| Recovered | N | Serious | |

| Event Categories | |
|---|---|
| Death | Yes |
| Life Threatening | Yes |
| Permanent Disability | No |
| Congenital Anomaly/Birth Defect | No |
| Hospitalized | Yes |
| Days in Hospital | 9 |
| Existing Hospitalization Prolonged | No |
| Emergency Room/Office Visit | Yes |
| Emergency Room | No |
| Office Visit | Yes |

| Symptoms |
|---|
| Autopsy |
| Creutzfeldt-Jakob disease |
| Death |
| Lumbar puncture |
| Magnetic resonance imaging head |
| Prostatectomy |

| Adverse Event Description |
|---|
| Died six months later from CJD. |

| Lab Data | Current Illness | Adverse Events After Prior Vaccinations |
|---|---|---|
| Spinal tap  Brain MRI and brain autopsy | None | |

| Medications At Time of Vaccination | History/Allergies |
|---|---|
| Blood pressure medicine, staten drug, Plavix,  Baby aspirin, Vitamin D, low dose of vitamin C | Had open heart surgery double bypass caught early that?s why he was on that medicine. Had his prostate removed in April 2021 |
| | None |

# VAERS DETAIL

VAERS ID: 1839151

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

| Event Information | | | |
|---|---|---|---|
| Patient Age | 67 | Sex | M |
| State/Territory | WA | Date Report Completed | |
| Date Vaccinated | 3/1/2021 | Date Report Received | 11/3/2021 |
| Date of Onset | 5/1/2021 | Date Died | |
| Days to Onset | 61 | | |
| Vaccine Administered By | UNK | Vaccine Purchased By | |
| Mfr/Imm Project Number | | Split Type | USPFIZER INC202101401363 |
| Recovered | N | Serious | |

| Event Categories | |
|---|---|
| Death | No |
| Life Threatening | No |
| Permanent Disability | Yes |
| 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 | Yes |

| Symptoms |
|---|
| Creutzfeldt-Jakob disease |

| Adverse Event Description |
|---|
| development of Cruetzfeldt-Jakobs Disease; This is a spontaneous report from a contactable consumer. A 67-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 2 via unspecified route in right arm on Mar2021 at 10:00 AM at patient age of 67-year-old as single dose for COVID-19 immunisation. The patient was not diagnosed with COVID-19 prior to vaccination. The patient had no known allergies. The patient medical history and concomitant medication was none. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient previously received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 1 via unspecified route in right arm on Mar2021 at 10:00 AM at patient age of 67-year-old as single dose for COVID-19 immunisation. The patient experienced development of Cruetzfeldt-Jakobs Disease in May2021. The event resulted in Doctor or other healthcare professional office/clinic visit, Disability or permanent damage. It was unknown if patient received treatment. The patient has not been tested for COVID-19 post vaccination. The outcome of the event was not recovered. The lot number for the vaccine, [BNT162B2], was not provided and will be requested during follow up. |

| 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 |

# VAERS DETAIL

VAERS ID: 1883259

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

| Event Information | | | |
|---|---|---|---|
| Patient Age | | Sex | F |
| State/Territory | FR | Date Report Completed | |
| Date Vaccinated | | Date Report Received | 11/19/2021 |
| Date of Onset | | Date Died | |
| Days to Onset | | | |
| Vaccine Administered By | OTH | Vaccine Purchased By | |
| Mfr/Imm Project Number | | Split Type | FRPFIZER INC202101524400 |
| Recovered | U | Serious | |

| Event Categories | |
|---|---|
| Death | No |
| 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 |
|---|
| Creutzfeldt-Jakob disease |

## Adverse Event Description

Creutzfeldt-Jakob disease; This is a spontaneous report from a contactable physician (patient was reporter's sister-in-law) via company representative and medical informaion team. A female patient of an unspecified age received bnt162b2 (COMIRNATY), via an unspecified route of administration on an unspecified date (Batch/Lot number was not reported) as single dose for covid-19 immunisation. The patient medical history and concomitant medications were not reported. The patient experienced creutzfeldt-jakob disease (medically significant) on an unspecified date 48h after injection of COMIRNATY with outcome of unknown.

| Lab Data | Current Illness | Adverse Events After Prior Vaccinations |
|---|---|---|
| | | |

| Medications At Time of Vaccination | History/Allergies |
|---|---|
| | |

# VAERS DETAIL

VAERS ID: 1885417

| Vaccine Type | Vaccine | Manufacturer | Lot | Dose | Route | Site |
|---|---|---|---|---|---|---|
| COVID19 | COVID19 (COVID19 (PFIZER-BIONTECH)) | PFIZER\BIONTECH | EN6198 | 1 | SYR | AR |
| COVID19 | COVID19 (COVID19 (PFIZER-BIONTECH)) | PFIZER\BIONTECH | EN6204 | 2 | SYR | AR |

| Event Information | | | |
|---|---|---|---|
| Patient Age | 67 | Sex | M |
| State/Territory | WA | Date Report Completed | |
| Date Vaccinated | 2/22/2021 | Date Report Received | 11/19/2021 |
| Date of Onset | 4/1/2021 | Date Died | 10/29/2021 |
| Days to Onset | 38 | | |
| Vaccine Administered By | OTH | Vaccine Purchased By | |
| Mfr/Imm Project Number | | Split Type | |
| 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 | Yes |

| Symptoms |
|---|
| Amnesia |
| Blood test |
| Computerised tomogram |
| Creutzfeldt-Jakob disease |
| Death |
| Irritability |
| Lumbar puncture |
| Magnetic resonance imaging |
| Motor dysfunction |

| Adverse Event Description |
|---|
| what began as memory loss and irritability was followed by loss of motor skills, later diagnosed as Cruetzfeldt-Jakobs disease. Death occurred early morning 10/29/2021. |

| Lab Data | Current Illness | Adverse Events After Prior Vaccinations |
|---|---|---|
| CT scan 9/10/2021 MRI 9/24/21 multiple blood tests and Lumbar Puncture late September 2021 | none | |

| Medications At Time of Vaccination | History/Allergies |
|---|---|
| Lisinopril 10mg | none |
| | none |

# VAERS DETAIL

VAERS ID: 1886651

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

| Event Information | | | |
|---|---|---|---|
| Patient Age | | Sex | M |
| State/Territory | FR | Date Report Completed | |
| Date Vaccinated | | Date Report Received | 11/19/2021 |
| Date of Onset | 11/1/2021 | Date Died | 11/1/2021 |
| Days to Onset | | | |
| Vaccine Administered By | OTH | Vaccine Purchased By | |
| Mfr/Imm Project Number | | Split Type | DEPFIZER INC202101591940 |
| 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 |
|---|
| Creutzfeldt-Jakob disease |

## Adverse Event Description

Creutzfeldt-Jakob disease; This is a spontaneous report from a contactable physician via a Pfizer sales representative. A 55-year-old male patient received bnt162b2 (COMIRNATY, Batch/Lot number was not reported), via an unspecified route of administration on an unspecified date as single dose for covid-19 immunisation. The patient's medical history and concomitant medications were not reported. It was reported that the patient with otherwise good state of health died due to Creutzfeldt-Jakob disease mid of the week (Nov2021) after vaccination with bnt162b2. The patient died on an unspecified date of Nov2021. It was not reported if an autopsy was performed. No follow-up attempts are possible; information about lot/batch number cannot be obtained. No further information is expected.; Sender's Comments: The limited information provided in this report does not allow a full assessment of the case. The event "Creutzfeldt-Jakob disease " with fatal outcome is assessed as related to the suspect drug per company guidance. This case will be reassessed when additional information, particularly the clinical course before death, complete medical history and concomitant medication and autopsy report, becomes available. The 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: Creutzfeldt-Jakob disease

| Lab Data | Current Illness | Adverse Events After Prior Vaccinations |
|---|---|---|
| | | |

| Medications At Time of Vaccination | History/Allergies |
|---|---|
| | |

# VAERS DETAIL

VAERS ID: 1902780

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

| Event Information | | | |
|---|---|---|---|
| Patient Age | 69 | Sex | M |
| State/Territory | FR | Date Report Completed | |
| Date Vaccinated | 4/7/2021 | Date Report Received | 11/26/2021 |
| Date of Onset | 4/1/2021 | Date Died | 7/23/2021 |
| Days to Onset | | | |
| Vaccine Administered By | OTH | Vaccine Purchased By | |
| Mfr/Imm Project Number | | Split Type | FRPFIZER INC202101635421 |
| 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 | Yes |

| Symptoms |
|---|
| Central nervous system lesion |
| Cerebellar ataxia |
| Cerebral infarction |
| Cognitive disorder |
| Creutzfeldt-Jakob disease |
| CSF protein |
| Disturbance in attention |
| Dysarthria |
| Electroencephalogram |
| Gait disturbance |
| Investigation |
| Magnetic resonance imaging head |
| Memory impairment |
| Psychomotor skills impaired |

## Adverse Event Description

Creutzfeldt-Jakob disease; Dysarthria; Cognitive disorder; psychomotor slowing down; memory and attention disorders; memory and attention disorders; lesions found on brain MRI; Disorder gait; moderate cerebellar ataxia; multi-territorial cerebral infarctions; This is a spontaneous report from a contactable physician downloaded from the Agency Regulatory Authority-WEB FR-AFSSAPS-PC20215138. A 69-year-old male patient received 1st dose of BNT162B2 (COMIRNATY, Batch/Lot Number unknown), intramuscular on 07Apr2021 (at the age of 69-year-old) as single dose for COVID-19 immunisation. Medical history included hernia inguinal, appendectomy, pampinocele, COVID-19 pneumonia in 2020, hypertension arterial, dyslipidaemia, tonsillectomy & adenoidectomy, prostate adenoma removal in 2018, urothelial carcinoma with resection and BCG in 2020 with a good response. No known allergy. Concomitant medications included pravastatin sodium (PRAVASTATINE ACCORD) and telmisartan. Way of life was Autonomous for activities of daily living. In Apr2021, a few days after the vaccination with COMIRNATY, the patient presented walking disorders (on 10Apr2021) of the type of moderate cerebellar ataxia, prompting a cerebral MRI in town. Brain MRI found bilateral cortical hypersignals interpreted as multi-territorial cerebral infarctions. Following a visit to the emergency room, the patient was put on acetylsalicylate lysine (KARDEGIC) 160mg with additional assessments to be carried out in town (additional assessments of aetiological normal income). In Jun2021, the patient presented for the neurology consultation in a wheelchair because of a great instability in rapidly progressive gait. He could no longer walk alone, he could move only with human help. He then presented a worsening of the cerebellar ataxia, without optical impairment, or associated sensory disorder or involvement of the cranial pairs. He presented dysarthria (and cognitive disorder), and psychomotor slowing down with memory and attention disorders reported by the family. Brain MRI was ordered again. The hypothesis of Creutzfeldt-Jakob disease was posed in front of lesions found on brain MRI. In Jul2021: diagnosis of a sporadic Creutzfeldt-Jakob disease posed in front of: a suggestive clinic (rapid progression of a cerebellar syndrome, aphasia, cognitive disorder, oculomotor disorder and myoclonus. a typical brain MRI. A compatible EEG: slowed down but reactive trace with many puffs of diffuse slow delta waves predominantly discreetly on the left frontal). In CSF: presence of protein 14-3-3 (without testing for other neurodegeneration markers). No argument for a genetic origin. A mandatory declaration was made to the Acute radiation syndrome. At the end of Jul2021: the patient's condition deteriorates with respiratory deterioration requiring sedation with HYPNOVEL and MORPHINIQUE leading to the death of the patient on 23Jul2021. In total: 70-year-old patient with a history of urothelial carcinoma in remission, Sars-Cov2 pneumonia, arterial hypertension and dyslipidemia, who presented with neurodegenerative disorders such as walking disorder, dysarthria and cognitive impairment of rapid evolution leading to the diagnosis of sporadic Creutzfeldt-Jakob disease a few months after Dose 1 by the vaccine by COMIRNATY. Evolution: death of the patient. The outcome of events cerebral infarction, cerebellar ataxia, psychomotor skills impaired, memory disturbance, attention impaired and brain lesion was unknown. The patient died on 23Jul2021 due to creutzfeldt-jakob disease, disorder gait, dysarthria and cognitive disorder. An autopsy was not performed. No follow-up attempts are possible; information about lot/batch number cannot be obtained. No further information is expected.; Reported Cause(s) of Death: Creutzfeldt-Jakob disease; Disorder gait; Dysarthria; Cognitive disorder

| Lab Data | Current Illness | Adverse Events After Prior Vaccinations |
|---|---|---|
| Test Date: 202107; Test Name: cerebrospinal fluid; Result Unstructured Data: Test Result:presence of protein 14-3-3; Comments: without testing for other neurodegeneration markers; Test Date: 202107; Test Name: EEG; Result Unstructured Data: Test Result:slowed down; Comments: but reactive trace with many puffs of diffuse slow delta waves predominantly discreetly on the left frontal); Test Date: 202107; Test Name: suggestive clinic; Result Unstructured Data: Test Result:rapid progression of a cerebellar syndrome; Comments: aphasia, cognitive disorder, oculomotor disorder and myoclonus; Test Date: 202104; Test Name: Brain MRI; Result Unstructured Data: Test Result:bilateral cortical hypersignals; Comments: interpreted as multi-territorial cerebral infarctions; Test Date: 202106; Test Name: Brain MRI; Result Unstructured Data: Test Result:lesions found; Test Date: 202107; Test Name: Brain MRI; Result Unstructured Data: Test Result:diagnosis of a sporadic Creutzfeldt-Jakob | | |

| Medications At Time of Vaccination | History/Allergies |
|---|---|
| PRAVASTATINE ACCORD; TELMISARTAN | Medical History/Concurrent Conditions: Appendectomy; Carcinoma excision; COVID-19 pneumonia; Dyslipidaemia; Hernia inguinal; Hypertension arterial; Pampinocele; Prostate adenoma removal; Tonsillectomy & Adenoidectomy; Urothelial carcinoma |

# VAERS DETAIL

VAERS ID: 1906868

| Vaccine Type | Vaccine | Manufacturer | Lot | Dose | Route | Site |
|---|---|---|---|---|---|---|
| COVID19 | COVID19 (COVID19 (PFIZER-BIONTECH)) | PFIZER\BIONTECH | EX6537 | 2 | OT | |

| Event Information | | | |
|---|---|---|---|
| Patient Age | | Sex | F |
| State/Territory | FR | Date Report Completed | |
| Date Vaccinated | 5/5/2021 | Date Report Received | 11/29/2021 |
| Date of Onset | 5/1/2021 | Date Died | |
| Days to Onset | | | |
| Vaccine Administered By | OTH | Vaccine Purchased By | |
| Mfr/Imm Project Number | | Split Type | FRPFIZER INC202101635433 |
| Recovered | N | Serious | |

| Event Categories | |
|---|---|
| Death | No |
| Life Threatening | Yes |
| 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 | No |

| Symptoms |
|---|
| Blood test |
| Cerebrovascular accident |
| Creutzfeldt-Jakob disease |
| CSF test |
| Dizziness |
| Dysarthria |
| Echocardiogram |
| Electrocardiogram |
| Electroencephalogram |
| Investigation |
| Limb discomfort |
| Magnetic resonance imaging |
| Magnetic resonance imaging head |
| Paraesthesia |
| Positron emission tomogram |
| SARS-CoV-2 test |
| Serology test |

| Adverse Event Description |
| --- |
| possible right semi-recent stroke; Creutzfeld-Jacob disease; dizziness; difficulty in articulating; paresthesias of G hemibody; cotton legs; This is a spontaneous report received from a contactable reporter(s) (Physician) from the Regulatory number: FR-AFSSAPS-PA20212070 (AFSSAPS). A 71 year-old female patient received bnt162b2 (COMIRNATY), intramuscular, administration date 05May2021 (Lot number: EX6537) as dose 2, 0.3 ml single for covid-19 immunisation. Relevant medical history included: "Unspecified essential hypertension" (unspecified if ongoing). No COVID infection. Concomitant medication(s) included: TAHOR; KARDEGIC; PERINDOPRIL ARROW; EUPANTOL. Vaccination history included: Covid-19 vaccine (dose 1, UNKNOWN MANUFACTURER), for covid-19 immunisation. The following information was reported: CREUTZFELDT-JAKOB DISEASE (hospitalization, life threatening) with onset 10Jun2021, outcome "not recovered", described as "Creutzfeld-Jacob disease"; CEREBROVASCULAR ACCIDENT (hospitalization) with onset 26Jul2021, outcome "unknown", described as "possible right semi-recent stroke"; DIZZINESS (non-serious) with onset May2021, outcome "unknown", described as "dizziness"; DYSARTHRIA (non-serious) with onset May2021, outcome "unknown", described as "difficulty in articulating"; PARAESTHESIA (non-serious) with onset May2021, outcome "unknown", described as "paresthesias of G hemibody"; LIMB DISCOMFORT (non-serious) with onset May2021, outcome "unknown", described as "cotton legs". The patient was hospitalized for creutzfeldt-jakob disease (start date: 28Aug2021, discharge date: 10Sep2021, hospitalization duration: 13 day(s)); for cerebrovascular accident (start date: 28Jul2021, discharge date: 31Jul2021, hospitalization duration: 3 day(s)). The patient underwent the following laboratory tests and procedures: blood test: (unspecified date) normal; csf test: (30Aug2021) positive, notes: cell-free, 0.4 g / l proteins, 4.22 mM glucose for a glycemia of 7 (N). Amyloid protein N. Phosphorylated tau protein 40. Very high Tau protein: 2000: p-tau / tau = 0.02 (cutoff <0.075); echocardiogram: (unspecified date) normal; electrocardiogram: (unspecified date) normal; electroencephalogram: (30Aug2021) creutzfeldt-jakob disease; (07Sep2021) slow tracing of the theta 6c / s band, notes: Slow tracing of the theta 6c / s band without focused or diffuse, critical or inter-critical epileptic activity. Demonstration of a 6-second burst of pseudoperiodic activity diffused at 1c / s as found in Creutzfeldt-Jakob disease; investigation: (unspecified date) normal; magnetic resonance imaging: (21Jul2021) normal; (16Aug2021) hyperintensity in cortical diffusion; (25Aug2021) hyperintensity in cortical diffusion; magnetic resonance imaging head: (26Jul2021) vascular type leukopathy, notes: vascular type leukopathy interpreted as possible right semi-recent stroke; (08Sep2021) no involvement of the central gray nuclei, notes: no involvement of the central gray nuclei and in particular of the detectable striatum; positron emission tomogram: (31Aug2021) creutzfeldt-jakob disease; (01Sep2021) no neoplastic focus; sars-cov-2 test: (unspecified date) negative; serology test: (unspecified date) <0; (unspecified date) <0. Therapeutic measures were taken as a result of creutzfeldt-jakob disease, cerebrovascular accident. clinical course: At end of May2021: dizziness, difficulty in articulating, cotton legs, paresthesias of G hemibody: treatment with Tanganil and Stresam. MRI 21Jul2021 is normal, put on Lodine. Aggravation with hospitalization from 28Jul2021 to 31Jul2021, Cerebral MRI 26Jul2021: vascular type leukopathy interpreted as possible right semi-recent stroke. Normal TSA, trans-thoracic echocardiography, ECG. Blood test N, Lyme / TPHA serology <0, PCR SARS cov 2 neg> Tahor, Eupantol, Kardegic, Perindopril, Furadantine. Beginning of Aug2021: Progressive worsening with MSG and MIG clonies then bilateralizing, coordination disorders, cerebellar syndrome evoking a picture of progressive myoclonic encephalopathy with images of hyperintensity in cortical diffusion on MRI of 16Aug2021. confirmed at the control of 25Aug2021. New hospitalization from 28Aug2021 to 10Sep2021 for exploration in the event of Creutzfeld Jacob's disease. Table of progressive myoclonic encephalopathy associated with images of hyperintensity in cortical diffusion but no central gray nuclei. Treatment with Valium for relaxing and anxiolytic purposes. EEG 30Aug2021: Slightly slowed background rhythm trace without focused or diffuse, critical or inter-critical epileptic activity and without sign of metabolic encephalopathy. Note a hint of pseudoperiodic activity localized in the left occipital region which in a context of myoclonus should suggest Creutzfeldt-Jakob disease even if the EEG trace is not typical. Neurological PET scan at 18 F-FDG 31Aug2021: Encephalic exploration witnessing a significant right hemispherical hypometabolism predominant in the frontal and right parietal areas, supporting the diagnosis of CJD or vascular involvement. PET scan 01Sep2021: no neoplastic focus. Analysis of the CSF of 30Aug2021: cell-free, 0.4 g / l proteins, 4.22 mM glucose for a glycemia of 7 (N). Detection of 14-3-3 protein in CSF: POSITIVE. Amyloid protein N. Phosphorylated tau protein 40. Very high Tau protein: 2000: p-tau / tau = 0.02 (cutoff <0.075). Test treatment with human Iglv immunoglobulin in the event of autoimmune encephalopathy: CLAIRYG 40 g per day for 3 days. EEG 07Sep2021: Slow tracing of the theta 6c / s band without focused or diffuse, critical or inter-critical epileptic activity. Demonstration of a 6-second burst of pseudoperiodic activity diffused at 1c / s as found in Creutzfeldt-Jakob disease. Brain MRI 08Sep2021: no involvement of the central gray nuclei and in particular of the detectable striatum. On 09Sep2021: Patient less asleep, right and left clonies rare but increased on stimuli, attitude in reducible spastic flexion of the 2 upper limbs, gaze ataxia, statokinetic cerebellar syndrome, left hemnegligence. transfer to another establishment. Conclusion of exit: very strong suspicion of Creutzfeld Jacob disease on clinical, biological, MRI, EEG, PET (very high tau protein in CSF). As of 09Oct2021: patient is bedridden, mutic, paralysis of 2 lower limbs, upper limbs in retraction, clonies of 4 limbs, semi-conscious for a few minutes / day, unable to swallow. Medicines on entry into hospital: Tahor 10mg, Kardegic 160mg, Perindopril arrow 2mg, Eupantol 20mg. Clinical summary: 71-year-old patient, with no significant history, presented with prion encephalopathy), 35 days after Dose 2 from Comirnaty on clinical and biological arguments (positive 14-3-3 protein in CSF, very high tau protein in CSF) and imaging. No follow-up attempts are possible. No further information is expected. |

| Lab Data | Current Illness | Adverse Events After Prior Vaccinations |
|---|---|---|
| Test Name: blood test; Result Unstructured Data: Test Result:normal; Test Date: 20210830; Test Name: detection of 14-3-3 protein in CSF; Test Result: Positive ; Comments: cell-free, 0.4 g / l proteins, 4.22 mM glucose for a glycemia of 7 (N). Amyloid protein N Phosphorylated tau protein 40 Very high Tau protein: 2000: p-tau / tau = 0.02 (cutoff <0.075); Test Name: trans-thoracic echocardiography; Result Unstructured Data: Test Result:normal; Test Name: ECG; Result Unstructured Data: Test Result:normal; Test Date: 20210830; Test Name: EEG; Result Unstructured Data: Test Result:Creutzfeldt-Jakob disease; Test Date: 20210907; Test Name: EEG; Result Unstructured Data: Test Result:Slow tracing of the theta 6c / s band; Comments: Slow tracing of the theta 6c / s band without focused or diffuse, critical or inter-critical epileptic activity. Demonstration of a 6-second burst of pseudoperiodic activity diffused at 1c / s as found in Creutzfeldt-Jakob disease.; Test Name: TSA; Result Unstructured Data: Test Result:normal; Test Date: 20210721; Test Name: MRI; Result Unstructured Data: Test Result:normal; Test Date: 20210816; Test Name: MRI; Result Unstructured Data: Test Result:hyperintensity in cortical diffusion; Test Date: 20210825; Test Name: MRI; Result Unstructured Data: Test Result:hyperintensity in cortical diffusion; Test Date: 20210726; Test Name: Cerebral MRI; Result Unstructured Data: Test Result:vascular type leukopathy; Comments: vascular type leukopathy interpreted as possible right semi-recent stroke; Test Date: 20210908; Test Name: Cerebral MRI; Result Unstructured Data: Test Result:no involvement of the central gray nuclei; Comments: no involvement of the central gray nuclei and in particular of the detectable striatum; Test Date: 20210831; Test Name: PET scan; Result Unstructured Data: Test Result:Creutzfeldt-Jakob disease; Test Date: 20210901; Test Name: PET scan; Result Unstructured Data: Test Result:no neoplastic focus; Test Name: Sars-Cov-2 PCR test; Test Result: Negative ; Test Name: Lyme; Result Unstructured Data: Test Result:<0; Test Name: TPHA; Result Unstructured Data: Test Result:<0 | | |

| Medications At Time of Vaccination | History/Allergies |
|---|---|
| TAHOR; KARDEGIC; PERINDOPRIL ARROW; EUPANTOL | Medical History/Concurrent Conditions: Unspecified essential hypertension |

# VAERS DETAIL

VAERS ID: 1952511

| Vaccine Type | Vaccine | Manufacturer | Lot | Dose | Route | Site |
|---|---|---|---|---|---|---|
| COVID19 | COVID19 (COVID19 (PFIZER-BIONTECH)) | PFIZER\BIONTECH | 1D016A | 2 | OT | |

| Event Information | | | |
|---|---|---|---|
| Patient Age | | Sex | M |
| State/Territory | FR | Date Report Completed | |
| Date Vaccinated | 6/16/2021 | Date Report Received | 12/15/2021 |
| Date of Onset | 6/16/2021 | Date Died | |
| Days to Onset | 0 | | |
| Vaccine Administered By | OTH | Vaccine Purchased By | |
| Mfr/Imm Project Number | | Split Type | DEPFIZER INC202101701743 |
| Recovered | U | Serious | |

| Event Categories | |
|---|---|
| Death | No |
| 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 |
|---|
| Creutzfeldt-Jakob disease |
| Dementia |
| Inappropriate schedule of product administration |

| Adverse Event Description |
|---|
| Creutzfeld-Jacob disease; Dementia; Inappropriate schedule of vaccine administered; This is a spontaneous report received from a non-contactable reporter(s) (Consumer or other non HCP) from the regulatory authority WEB. Regulatory number: DE-PEI-202100231789 (PEI). A 70 year-old male patient received bnt162b2 (COMIRNATY), intramuscular, administration date 16Jun2021 (Lot number: 1D016A) as dose 2, single for covid-19 immunisation. The patient's relevant medical history and concomitant medications were not reported. Vaccination history included: Comirnaty (1st dose, Intramuscular , LOT: EX 8679), administration date: 05May2021, for covid-19 immunisation. The following information was reported: CREUTZFELDT-JAKOB DISEASE (medically significant) with onset 01Jul2021, outcome "unknown", described as "Creutzfeld-Jacob disease"; DEMENTIA (medically significant) with onset 01Jul2021, outcome "unknown", described as "Dementia"; INAPPROPRIATE SCHEDULE OF PRODUCT ADMINISTRATION (medically significant) with onset 16Jun2021, outcome "unknown", described as "Inappropriate schedule of vaccine administered". Result of assessment for all events /PEI / D. Unclassifiable. No follow-up attempts are possible. No further information is expected. |

| Lab Data | Current Illness | Adverse Events After Prior Vaccinations |
|---|---|---|
| | | |

| Medications At Time of Vaccination | History/Allergies |
|---|---|
| | |

# VAERS DETAIL

VAERS ID: 1991174

| Vaccine Type | Vaccine | Manufacturer | Lot | Dose | Route | Site |
|---|---|---|---|---|---|---|
| COVID19 | COVID19 (COVID19 (PFIZER-BIONTECH)) | PFIZER\BIONTECH | FF2752 | 2 | | |

| Event Information | | | |
|---|---|---|---|
| Patient Age | | Sex | F |
| State/Territory | FR | Date Report Completed | |
| Date Vaccinated | 8/2/2021 | Date Report Received | 12/30/2021 |
| Date of Onset | | Date Died | 12/13/2021 |
| Days to Onset | | | |
| Vaccine Administered By | OTH | Vaccine Purchased By | |
| Mfr/Imm Project Number | | Split Type | NLPFIZER INC202101799184 |
| Recovered | N | Serious | |

| Event Categories | |
|---|---|
| Death | Yes |
| Life Threatening | Yes |
| 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 | Yes |

| Symptoms |
|---|
| Blood test |
| Creutzfeldt-Jakob disease |
| Electroencephalogram |
| Electromyogram |
| Magnetic resonance imaging |
| SARS-CoV-2 test |
| Specialist consultation |

## Adverse Event Description

This is a spontaneous report received from a contactable reporter(s) (Consumer or other non HCP) from the Regulatory Authority-WEB. Regulatory number: NL-LRB-00722968 (RA). Other Case identifier(s): NL-LRB-00728291 (RA). A 73 year-old female patient received bnt162b2 (COMIRNATY), administration date 02Aug2021 (Lot number: FF2752) as dose 2, single for covid-19 immunisation. Relevant medical history included: "Hypertension" (unspecified if ongoing). Concomitant medication(s) included: PROPRANOLOL taken for hypertension. Vaccination history included: Comirnaty (dose 1), administration date: 28Jun2021, for covid-19 immunisation, reaction(s): "No adverse reaction". The following information was reported: CREUTZFELDT-JAKOB DISEASE (death, life threatening), outcome "fatal", described as "Jakob-Creutzfeld disease". The event "Jakob-Creutzfeld disease" was evaluated at the physician office visit. The patient underwent the following laboratory tests and procedures: blood test: (unspecified date) no abnormalities; electroencephalogram: (21Nov2021) diagnosis: Creutzfeldt Jakob; electromyogram: (16Nov2021) no explanation for complaints seen; magnetic resonance imaging: (04Nov2021) no abnormalities seen; sars-cov-2 test: (13Aug2021) negative; specialist consultation: (01Nov2021) no clear diagnosis. The patient date of death was 13Dec2021. The reported cause of death was Creutzfeldt Jakob disease. It was not reported if an autopsy was performed. A week after vaccination patient developed hyperhidrosis without exertion. After 14 days patient got influenza-like symptoms with fever, coughing and nasopharyngitis. COVID test was done and was negative. A few days later patient notices that cycling is more difficult than before, but at that time they blamed that on the influenza like illness she has had. After this, her strength to cycle decreases. 1.5 months after vaccination patient does not feel like doing anything anymore, she does not go rowing, hiking or cycling anymore and becomes insecure while crossing the street in town. She has her blood tested: no abnormalities. She also feels that the problems might be caused by her glasses that she has had for 6 years. She makes an appointment with the optician: she needs new glasses due to worsening of her eye sight. She also experiences problems with her balance. About two months after vaccination patient has more balance complaints and she contacts her GP. Her GP examines her, but does not find anything to make a diagnosis. She returned to her GP in a week, who concluded that her balance complaints sound more likely to be an emotional problem (but also thinks of a small TIA) and referred her to a psycho-somatic therapist and neurologist. In the mean time she developed memory impairment, fatigue, loss of strength, visual impairment, loss of taste and appetite, crying and unable to sleep well. She also developes difficulty with breathing and painful legs. Three months after vaccination patient finally can visit the neurologist. MRI scan was made and showed no abnormalities. Later EMG was made: no abnormalities were seen. After that EEG was made and she was diagnosed with Creutzfeld Jacob disease. Follow-up: patient deceased about 4 months after vaccination due to Jacob Creutzfeld disease. Sender Comment: Latency time of 'Jakob Creutzfeld disease' changed from 1 day to 1 week, due to the information in attachment that states that the first complaints she had (hyperhidrosis) was a week after vaccination. No follow-up attempts are possible. No further information is expected.; Reported Cause(s) of Death: Jakob-Creutzfeld disease

| Lab Data | Current Illness | Adverse Events After Prior Vaccinations |
|---|---|---|
| Test Name: blood test; Result Unstructured Data: Test Result: no abnormalities; Test Date: 20211121; Test Name: EEG; Result Unstructured Data: Test Result: Diagnosis: Creutzfeldt Jacob; Test Date: 20211116; Test Name: EMG; Result Unstructured Data: Test Result: no explanation for complaints seen; Test Date: 20211104; Test Name: MRI scan; Result Unstructured Data: Test Result: no abnormalities seen; Test Date: 20210813; Test Name: corona test; Test Result: Negative; Test Date: 20211101; Test Name: neurologist; Result Unstructured Data: Test Result: no clear diagnosis. | | |

| Medications At Time of Vaccination | History/Allergies |
|---|---|
| Propranolol | Medical History/Concurrent Conditions: Hypertension |

# VAERS DETAIL

VAERS ID: 2007544

| Vaccine Type | Vaccine | Manufacturer | Lot | Dose | Route | Site |
|---|---|---|---|---|---|---|
| COVID19 | COVID19 (COVID19 (PFIZER-BIONTECH)) | PFIZER\BIONTECH | et6956 | 2 | OT | |

| Event Information | | | |
|---|---|---|---|
| Patient Age | | Sex | F |
| State/Territory | FR | Date Report Completed | |
| Date Vaccinated | 4/24/2021 | Date Report Received | 1/6/2022 |
| Date of Onset | 5/1/2021 | Date Died | |
| Days to Onset | 7 | | |
| Vaccine Administered By | OTH | Vaccine Purchased By | |
| Mfr/Imm Project Number | | Split Type | FRPFIZER INC202101874248 |
| Recovered | N | Serious | |

| Event Categories | |
|---|---|
| Death | No |
| Life Threatening | Yes |
| Permanent Disability | Yes |
| 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 | Yes |

| Symptoms |
|---|
| Blood creatinine |
| Blood folate |
| Blood glucose |
| Blood pressure measurement |
| Blood thyroid stimulating hormone |
| Body height |
| Body mass index |
| Body temperature |
| Chest X-ray |
| Computerised tomogram |
| C-reactive protein |
| Creutzfeldt-Jakob disease |
| CSF glucose |
| CSF protein |
| Electroencephalogram |
| Glomerular filtration rate |
| Haemoglobin |
| Heart rate |
| Hepatitis B virus test |
| Hepatitis C virus test |
| HIV test |
| Lumbar puncture |
| Magnetic resonance imaging head |
| Platelet count |
| Treponema test |
| Vitamin B12 |
| Vitamin D |
| Weight |
| White blood cell count |

| Adverse Event Description |
| --- |
| Creutzfeld-Jacob disease; This is a spontaneous report received from a contactable reporter(s) (Pharmacist) from the Regulatory Authority-WEB. Regulatory number: FR-AFSSAPS-MP20219436. A 53 year-old female patient received bnt162b2 (COMIRNATY), intramuscular, administration date 24Apr2021 (Lot number: et6956) as dose 2, single for covid-19 immunisation. Relevant medical history included: "Open angle glaucoma" (unspecified if ongoing); "Horseshoe kidney" (unspecified if ongoing). Concomitant medication(s) included: ESCITALOPRAM, start date: Sep2021; ALPRAZOLAM, start date: Sep2021; TANGANIL; METOPIMAZINE; ZOPHREN [ONDANSETRON]. Vaccination history included: Comirnaty (1st dose, lot er9470), administration date: 25Mar2021, for covid-19 immunisation. The following information was reported: CREUTZFELDT-JAKOB DISEASE (hospitalization, disability, medically significant, life threatening) with onset May2021, outcome "not recovered", described as "Creutzfeld-Jacob disease". The event "creutzfeld-jacob disease" was evaluated at the physician office visit and emergency room visit. The patient underwent the following laboratory tests and procedures: blood creatinine: (Oct2021) 69 umol/l; blood folate: (Oct2021) 16.2 nmol/L; blood glucose: (Oct2021) 0.93 g/l; blood pressure measurement: (Oct2021) 129/109 mmHg; blood thyroid stimulating hormone: (Oct2021) 0.98 MiU/L; body height: (Oct2021) 156 cm; body mass index: (Oct2021) 18.49, notes: kg/m2; body temperature: (Oct2021) 36.5 Centigrade; chest x-ray: (08Nov2021) no focus. no cul-de-sac filling.; computerised tomogram: (18Oct2021) horseshoe kidneys, notes: Nephrographic and excretory delay on the lower polar face of the right kidney, suggesting a focus of nephritis, to be compared with the rest of the assessment. No other lesion of progressive appearance elsewhere; c-reactive protein: (Oct2021) 1 mg/l; csf glucose: (08Oct2021) normal glycorrhachia; csf protein: (08Oct2021) normal proteinorrhachia; electroencephalogram: (14Oct2021) in description, notes: Trace finding a deteriorated background electrogenesis, overall slowed down especially on the right with a loss of spatial organization and the presence of ample two-phase elements which tend to organize themselves in a repetitive, rhythmic, monomorphic and unsupported manner, predominant in the right hemispherical regions; glomerular filtration rate: (Oct2021) 86.4 ml/min; haemoglobin: (Oct2021) 14.8 g/dl; heart rate: (Oct2021) 77 bpm; hepatitis b virus test: (Oct2021) negative, notes: vaccinal immunity; hepatitis c virus test: (Oct2021) negative; hiv test: (Oct2021) negative; lumbar puncture: (08Oct2021) no cells, no oligoclonal band, notes: Anti neuronal antibodies negative, neuropil antibodies negative, biomarkers: isolated and very high increase in tau protein; magnetic resonance imaging head: (04Oct2021) a hypersignal in diffusion and flair, notes: and restriction in apparent diffusion coefficient of the 2 caudate nuclei and of the bilateral cortex, asymmetric, predominant on the right; platelet count: (Oct2021) 346 x10 9/l; treponema test: (Oct2021) negative; vitamin b12: (Oct2021) 460 pmol/L; vitamin d: (Oct2021) 92 nmol/L; weight: (Oct2021) 45 kg; white blood cell count: (Oct2021) 9.24 x10 9/l. Therapeutic measures were taken as a result of creutzfeldt-jakob disease. Detail clinical course was reported as At the end of May2021, appearance of cognitive disorders with attention difficulties and memory disorders. At the beginning of August, anxiodepressive syndrome with overwork. Insomnia. Anorexia with loss of 10kg in a context of nausea (with increased sensitivity to odors) with vomiting. Aug2021: Vertiginous sensations with instability when walking and gradual increase till making walking difficult (requiring support against walls / objects) which led to being put on sick leave by the treating doctor in mid-September. 06Oct2021, the patient is referred to the SAU (emergency reception service) by her general practitioner due to the major general state alteration. Neurological opinion in favor of probable prion disease or less probable dysimmune encephalitis. Patient hospitalized for the rest of the treatment. Vigilant, oriented, consistent. No sensory motor deficit, no facial paralysis, no language disorders. Bilateral abduction deficit, multidirectional nystagmus, jerky pursuit of the eye. Visual ataxia. Cerebellar ataxia of the left upper limb and both lower limbs predominantly on the right. Quick stretch reflex in all four limbs with exhaustible left ankle trepidation. Plantar reflex in non-specific extension. No extrapyramidal syndrome. No frontal syndrome. No abnormal movements. Hollow feet. No pallesthesia disorders. Enlargement of the support polygon at the upright position with frank ataxia. Walking impossible. Cognitive ability tests on 14Oct2021: MoCA (Montreal Cognitive Assessment) 25/30 (5/5 in visual-spatial / executive, 3/3 in denomination, 6/6 in the attention, 2/3 in the language, 2/2 in the abstraction, 2/5 in the recall (no found with indexing, 2/3 found among a list of multiple choices, 6/6 with orientation). Clock test passed. Dubois 5 words test: 9/10 (5/5 + 4/5, failure despite indexing). Antineuron antibodies, neuropil antibodies, IgLON5 antibodies, anti-CASPR2 antibodies negative. Biomarkers in CSF: Tau> 2000, ptau 17 (normal), ratio 117 (> 20). Evolution: Deterioration during hospitalization with worsening of cognitive disorders with significant psychomotor slowing down, increase in ataxia and appearance of dystonia of the upper left limb as well as myoclonus of the 4 limbs. Incontinence, toilet performed in bed. Introduction DEPAKINE 250 mg morning and evening for symptomatic treatment of myoclonus, started on 08Nov2021. Verticalization and walking possible with the C4R in physiotherapy but remains very unstable. Putting in a wheelchair possible. Air mattress in static mode from 05Nov2021. On the etiological level: all the clinical and biological elements and the data from the cerebral MRI and the EEG made it possible to retain the diagnosis of Creutzfeldt-Jakob disease and to eliminate the differential diagnoses. Given the young age and in the absence of contaminating factors found, a PRNP genetic research was carried out, the results are pending. Mandatory declaration made. Initially setting up a home hospitalization. In view of the rapid pejorative clinical development, it was decided to transfer the patient on 08Nov2021 for the continuation of the palliative care. On the nutritional level, installation of Percutaneous Endoscopic Gastrotomy in interventional radiology. No follow-up attempts are possible. No further information is expected. |

| Lab Data | Current Illness | Adverse Events After Prior Vaccinations |
|---|---|---|
| Test Date: 202110; Test Name: creatinine; Result Unstructured Data: Test Result:69 umol/l; Test Date: 202110; Test Name: vitamin B9; Result Unstructured Data: Test Result:16.2 nmol/L; Test Date: 202110; Test Name: blood glucose; Result Unstructured Data: Test Result:0.93 g/l; Test Date: 202110; Test Name: blood pressure; Result Unstructured Data: Test Result:129/109 mmHg; Test Date: 202110; Test Name: TSH; Result Unstructured Data: Test Result:0.98 MiU/L; Test Date: 202110; Test Name: height; Result Unstructured Data: Test Result:156 cm; Test Date: 202110; Test Name: BMI; Result Unstructured Data: Test Result:18.49; Comments: kg/m2; Test Date: 202110; Test Name: body temperature; Result Unstructured Data: Test Result:36.5 Centigrade; Test Date: 20211108; Test Name: chest X-ray; Result Unstructured Data: Test Result:No focus. No cul-de-sac filling.; Test Date: 20211018; Test Name: thorax-abdomen-pelvis CT scan; Result Unstructured Data: Test Result:horseshoe kidneys; Comments: Nephrographic and excretory delay on the lower polar face of the right kidney, suggesting a focus of nephritis, to be compared with the rest of the assessment. No other lesion of progressive appearance elsewhere.; Test Date: 202110; Test Name: CRP; Result Unstructured Data: Test Result:1 mg/l; Test Date: 20211008; Test Name: CSF glucose; Result Unstructured Data: Test Result:normal glycorrhachia; Test Date: 20211008; Test Name: CSF protein; Result Unstructured Data: Test Result:normal proteinorrhachia; Test Date: 20211014; Test Name: EEG; Result Unstructured Data: Test Result:in description; Comments: Trace finding a deteriorated background electrogenesis, overall slowed down especially on the right with a loss of spatial organization and the presence of ample two-phase elements which tend to organize themselves in a repetitive, rhythmic, monomorphic and unsupported manner, predominant in the right hemispherical regions.; Test Date: 202110; Test Name: GFR; Result Unstructured Data: Test Result:86.4 ml/min; Test Date: 202110; Test Name: hemoglobin; Result Unstructured Data: Test Result:14.8 g/dl; Test Date: 202110; Test Name: heart rate; Result Unstructured Data: Test Result:77 bpm; Test Date: 202110; Test Name: HBV serology; Result Unstructured Data: Test Result:negative; Comments: vaccinal immunity; Test Date: 202110; Test Name: HCV serology; Result Unstructured Data: Test Result:negative; Test Date: 202110; Test Name: HIV serology; Result Unstructured Data: Test Result:negative; Test Date: 20211008; Test Name: lumbar puncture; Result Unstructured Data: Test Result:no cells, no oligoclonal band; Comments: Anti neuronal antibodies negative, neuropil antibodies negative, biomarkers: isolated and very high increase in tau protein.; Test Date: 20211004; Test Name: brain MRI; Result Unstructured Data: Test Result:a hypersignal in Diffusion and Flair; Comments: and restriction in apparent diffusion coefficient of the 2 caudate nuclei and of the bilateral cortex, asymmetric, predominant on the right; Test Date: 202110; Test Name: platelets; Result Unstructured Data: Test Result:346 x10 9/l; Test Date: 202110; Test Name: syphilis serology; Result Unstructured Data: Test Result:negative; Test Date: 202110; Test Name: vitamin B12; Result Unstructured Data: Test Result:460 pmol/L; Test Date: 202110; Test Name: vitamin D; Result Unstructured Data: Test Result:92 nmol/L; Test Date: 202110; Test Name: body weight; Test Result:  45 kg; Test Date: 202110; Test Name: leukocytes; Result Unstructured Data: Test Result:9.24 x10 9/l | | |

| Medications At Time of Vaccination | History/Allergies |
|---|---|
| ESCITALOPRAM; ALPRAZOLAM; TANGANIL; METOPIMAZINE; ZOPHREN [ONDANSETRON] | Medical History/Concurrent Conditions: Horseshoe kidney; Open angle glaucoma |

# VAERS DETAIL

VAERS ID: 2040844

| Vaccine Type | Vaccine | Manufacturer | Lot | Dose | Route | Site |
|---|---|---|---|---|---|---|
| COVID19 | COVID19 (COVID19 (PFIZER-BIONTECH)) | PFIZER\BIONTECH | FC1526 | 2 | OT | |

| Event Information | | | |
|---|---|---|---|
| Patient Age | | Sex | M |
| State/Territory | FR | Date Report Completed | |
| Date Vaccinated | 6/4/2021 | Date Report Received | 1/17/2022 |
| Date of Onset | 6/4/2021 | Date Died | 12/5/2021 |
| Days to Onset | 0 | | |
| Vaccine Administered By | OTH | Vaccine Purchased By | |
| Mfr/Imm Project Number | | Split Type | FRPFIZER INC202200045615 |
| 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 |
|---|
| Antibody test |
| Anti-neuronal antibody |
| Anti-NMDA antibody |
| Creutzfeldt-Jakob disease |
| Electroencephalogram |
| Inappropriate schedule of product administration |
| Investigation |
| Lumbar puncture |
| Magnetic resonance imaging head |
| Neurological examination |
| Polymerase chain reaction |
| Scan brain |

## Adverse Event Description

Creutzfeld-Jacob disease; Inappropriate schedule of vaccine administered; This is a spontaneous report received from a contactable Physician from the Agency Agency-WEB. Regulatory number: FR-AFSSAPS-GR20215216. A 78 year-old male patient received BNT162b2 (COMIRNATY), intramuscular, administration date 04Jun2021 (Lot number: FC1526) as dose 2, 0.3 ml single for COVID-19 immunisation. Relevant medical history included: "Hypercholesterolemia" (unspecified if ongoing); "Chronic renal insufficiency" (unspecified if ongoing); "Carotid artery atheroma" (unspecified if ongoing); "Dilated cardiomyopathy" (unspecified if ongoing); "Arterial hypertension" (unspecified if ongoing); "AFib" (unspecified if ongoing); "Adenocarcinoma of prostate" (unspecified if ongoing); "Peripheral arterial occlusive disease" (unspecified if ongoing); "Degenerative joint disease" (unspecified if ongoing); "Coronaropathy" (unspecified if ongoing); "Type II diabetes mellitus" (unspecified if ongoing); "pain" (unspecified if ongoing). Concomitant medications included: ZYLORIC; TAHOR; CARDENSIEL; ATACAND; LASILIX SPECIAL [FUROSEMIDE]; LASILIX [FUROSEMIDE]; GALVUS; NOVONORM; KARDEGIC; COUMADINE; COUMADINE; TRINIPATCH; DAFALGAN taken for pain. Vaccination history included: Comirnaty (Dose 1, 0.3 mL; batch/lot number: EW4815, Route of Administration: intramuscular), administration date: 23Apr2021, for COVID-19 immunization. The following information was reported: CREUTZFELDT-JAKOB DISEASE (death, hospitalization, medically significant) with onset Oct2021, outcome "fatal", described as "Creutzfeld-Jacob disease"; INAPPROPRIATE SCHEDULE OF PRODUCT ADMINISTRATION (non-serious) with onset 04Jun2021, outcome "unknown", described as "Inappropriate schedule of vaccine administered". Clinical course was reported as follows: On mid October 2021, appearance of neurological disorders, such as dysgraphia, tremor, psychomotor slowing down and slow walking. On 04Nov2021, hospitalization for assessment due to the worsening of these disorders. On 16Nov2021, worsening of the phasic disorder with lack of word. On 23Nov2021, increasingly severe tremors, major speech disorders. On 26Nov2021, worsening of the phasic disorder (impossibility to communicate verbally). Degradation of walking on the locomotor level. On 02Dec2021, implementation of midazolam (i.v.) by electric syringe pump in view of the patient's agitation. MRI + EEG. During the night of 4 to 5 December 21, the patient died. Autopsy planned, but no CR (conventional radiograph) available. Approximate time of occurrence of the adverse event: Mid October 2021. The patient underwent the following laboratory tests and procedures: On 10Nov2021, a lumbar puncture was performed: no suspicious cells on pathology; hyperproteinorachy on biochemistry; sterile cultures. TAP scan normal. On 30Nov2021, results of the LP (lumbar puncture) of 10Nov: PCR of neurotropic viruses negative, antibodies against neurons, VGKC, NMDA, AMPAr negative, doubt on 14.3.3. Additional lab tests and procedures included electroencephalogram: (08Nov2021) Diffuse, sometimes pseudo periodic, asymmetrical slow and sharp wave bursts in the left hemisphere, possibly compatible with encephalitis (including CJD, although the pattern is not characteristic); (01Dec2021) pseudoperiodic activity, therefore in favour of Creutzfeld Jacob disease; magnetic resonance imaging head: (05Nov2021) cortical diffusion abnormalities including some in hypoADC (apparent diffusion coefficient), HS FLAIR, bilateral, predominantly on the left parieto-temporo-occipital junction. No basal ganglia signal abnormality. The hypothesis of Creutzfeld Jacob's disease is to be preferred; (03Dec2021) in favour of Creutzfeld Jacob disease. Diagnosis retained in front of the 2 MRI + EEG; scan brain: (04Nov2021) no recent ischemic lesion. Calcified atheromatous stenosis of both carotid arteries. Neurological opinion: dysexecutive DS (disease steps) with praxis disorders (right hand in particular), agraphia, impaired verbal fluency, atypical tremors. No obvious reflex pyramidal DS. The patient date of death was 05Dec2021. The reported cause of death was creutzfeldt-jakob disease. Reporter Comment: Creutzfeld-Jacob disease or related No follow-up attempts are possible. No further information is expected.; Reported Cause(s) of Death: Creutzfeld-Jacob disease

| Lab Data | Current Illness | Adverse Events After Prior Vaccinations |
|---|---|---|
| Test Date: 20211110; Test Name: 14.3.3.; Result Unstructured Data: Test Result:doubt; Comments: 14-3-3 protein; Test Date: 20211110; Test Name: AMPAr; Test Result: Negative ; Comments: amino-3-hydroxy-5-methyl-4-isoxazolepropionic acid (AMPA)-type glutamate receptor; Test Date: 20211110; Test Name: VGKC; Test Result: Negative ; Comments: Voltage-gated potassium channel; Test Date: 20211110; Test Name: antibodies against neurons; Test Result: Negative ; Test Date: 20211110; Test Name: NMDA; Test Result: Negative ; Test Date: 20211108; Test Name: EEG; Result Unstructured Data: Test Result:possibly compatible with encephalitis; Comments: EEG: Diffuse, sometimes pseudo periodic, asymmetrical slow and sharp wave bursts in the left hemisphere, possibly compatible with encephalitis (including CJD, although the pattern is not characteristic); Test Date: 20211201; Test Name: EEG; Result Unstructured Data: Test Result:pseudoperiodic activity; Comments: therefore in favour of Creutzfeld Jacob disease.; Test Date: 20211110; Test Name: biochemistry; Result Unstructured Data: Test Result:sterile cultures; Test Date: 20211110; Test Name: TAP scan; Result Unstructured Data: Test Result:normal; Comments: Thoracoabdomino-pelvic; Test Date: 20211110; Test Name: lumbar puncture; Result Unstructured Data: Test Result:no suspicious cells on pathology; Comments: On 10Nov2021, a lumbar puncture was performed: no suspicious cells on pathology; hyperproteinorachy on biochemistry; sterile cultures. TAP scan normal. On 30Nov2021, results of the LP (lumbar puncture) of 10Nov: PCR of neurotropic viruses negative, antibodies against neurons, VGKC, NMDA, AMPAr negative, doubt on 14.3.3.; Test Date: 20211105; Test Name: brain MRI; Result Unstructured Data: Test Result:hypothesis of Creutzfeld Jacob's disease; Comments: cortical diffusion abnormalities including some in hypoADC (apparent diffusion coefficient), HS FLAIR, bilateral, predominantly on the left parieto-temporo-occipital junction. No basal ganglia signal abnormality. The hypothesis of Creutzfeld Jacob's disease is to be preferred.; Test Date: 20211203; Test Name: brain MRI; Result Unstructured Data: Test Result:in favour of Creutzfeld Jacob disease; Comments: On 03Dec2021, brain MRI in favour of Creutzfeld Jacob disease. Diagnosis retained in front of the 2 MRI + EEG.; Test Date: 20211104; Test Name: neurological examination; Result Unstructured Data: Test Result:dysexecutive disease steps with praxis disorder; Comments: dysexecutive DS (disease steps) with praxis disorders (right hand in particular), agraphia, impaired verbal fluency, atypical tremors. No obvious reflex pyramidal DS; Test Date: 20211110; Test Name: PCR of neurotropic viruse; Test Result: Negative ; Test Date: 20211104; Test Name: Brain scan; Result Unstructured Data: Test Result:no recent ischemic lesion.; Comments: Brain scan: no recent ischemic lesion. Calcified atheromatous stenosis of both carotid arteries. Neurological opinion: dysexecutive DS (disease steps) with praxis disorders (right hand in particular), agraphia, impaired verbal fluency, atypical tremors. No obvious reflex pyramidal DS. | | |

| Medications At Time of Vaccination | History/Allergies |
|---|---|
| ZYLORIC; TAHOR; CARDENSIEL; ATACAND; LASILIX SPECIAL [FUROSEMIDE]; LASILIX [FUROSEMIDE]; GALVUS; NOVONORM; KARDEGIC; COUMADINE; COUMADINE; TRINIPATCH; DAFALGAN | Medical History/Concurrent Conditions: Adenocarcinoma of prostate; AFib; Arterial hypertension; Carotid artery atheroma; Chronic renal insufficiency; Coronaropathy; Degenerative joint disease; Dilated cardiomyopathy; Hypercholesterolemia; Pain; Peripheral arterial occlusive disease; Type II diabetes mellitus |

# VAERS DETAIL

VAERS ID: 2055169

| Vaccine Type | Vaccine | Manufacturer | Lot | Dose | Route | Site |
|---|---|---|---|---|---|---|
| COVID19 | COVID19 (COVID19 (PFIZER-BIONTECH)) | PFIZER\BIONTECH | EX3599 | 2 | | |

| Event Information | | | |
|---|---|---|---|
| Patient Age | | Sex | F |
| State/Territory | FR | Date Report Completed | |
| Date Vaccinated | 5/7/2021 | Date Report Received | 1/21/2022 |
| Date of Onset | 5/7/2021 | Date Died | |
| Days to Onset | 0 | | |
| Vaccine Administered By | OTH | Vaccine Purchased By | |
| Mfr/Imm Project Number | | Split Type | DEPFIZER INC202200045004 |
| 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 |
|---|
| Creutzfeldt-Jakob disease |
| Inappropriate schedule of product administration |

## Adverse Event Description

Creutzfeld-Jacob disease; Second dose more than 42 days after the first one; This is a spontaneous report received from a non-contactable reporter(s) (Consumer or other non HCP) from a regulatory authority. Regulatory number: DE-PEI-CADR2022241559. Other Case identifier(s): DE-CADRPEI-2022241559, DE-PEI-202200009226.  A 70 year-old female patient received bnt162b2 (COMIRNATY), administration date 07May2021 (Lot number: EX3599) as dose 2, 0.3 ml single for covid-19 immunisation. Relevant medical history included: "Hashimoto's thyroiditis" (ongoing). The patient's concomitant medications were not reported. Vaccination history included: Comirnaty (Dose 1, BATCH/LOT UNKNOWN), administration date: 26Mar2021, for COVID-19 immunisation. The following information was reported: CREUTZFELDT-JAKOB DISEASE (death), outcome "fatal", described as "Creutzfeld-Jacob disease"; INAPPROPRIATE SCHEDULE OF PRODUCT ADMINISTRATION (non-serious) with onset 07May2021, outcome "unknown", described as "Second dose more than 42 days after the first one". The patient date of death was unknown. The reported cause of death was Creutzfeldt-Jakob disease. 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: Creutzfeld-Jacob disease

| Lab Data | Current Illness | Adverse Events After Prior Vaccinations |
|---|---|---|
| | Hashimoto's thyroiditis | |

| Medications At Time of Vaccination | History/Allergies |
|---|---|
| | |

# VAERS DETAIL

VAERS ID: 2083747

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

| Event Information | | | |
|---|---|---|---|
| Patient Age | | Sex | F |
| State/Territory | FR | Date Report Completed | |
| Date Vaccinated | | Date Report Received | 2/3/2022 |
| Date of Onset | | Date Died | |
| Days to Onset | | | |
| Vaccine Administered By | OTH | Vaccine Purchased By | |
| Mfr/Imm Project Number | | Split Type | FRPFIZER INC202101783123 |
| Recovered | U | Serious | |

| Event Categories | |
|---|---|
| Death | No |
| 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 |
|---|
| Creutzfeldt-Jakob disease |

## Adverse Event Description

This is a spontaneous report received from non-contactable consumer or other non-HCP, for a Pfizer sponsored program (004654). A female patient received unknown dose number of BNT162B2 (Comirnaty, batch/lot# unknown), via unspecified route of administration, on unspecified date, single dose, for COVID-19 immunisation. The patient's medical history and concomitant medications not reported. The patient developed Creutzfeldt-Jakob disease (medically significant), with outcome of unknown. Clinical course: The patient's husband reported "Today I continue to take care of my wife 24 hours a day. It is very heavy. There are no words to describe this disease. My wife is in a steady state, which is rather surprising, but logical given the new form of the post immunization CJ. In terms of testimonies, I always receive many, and I am at 21 cases of "mad cow" disease. This is a concern knowing it is a rare disease and all cases have the same profile." No follow-up attempts possible. Information about batch/lot number cannot be obtained. No further information expected.

| Lab Data | Current Illness | Adverse Events After Prior Vaccinations |
|---|---|---|
| | | |

| Medications At Time of Vaccination | History/Allergies |
|---|---|
| | |

# VAERS DETAIL

VAERS ID: 2094046

| Vaccine Type | Vaccine | Manufacturer | Lot | Dose | Route | Site |
|---|---|---|---|---|---|---|
| COVID19 | COVID19 (COVID19 (PFIZER-BIONTECH)) | PFIZER\BIONTECH | FF2834 | 3 | OT | RA |

| Event Information | | | |
|---|---|---|---|
| Patient Age | | Sex | F |
| State/Territory | FR | Date Report Completed | |
| Date Vaccinated | 11/18/2021 | Date Report Received | 2/8/2022 |
| Date of Onset | 12/1/2021 | Date Died | |
| Days to Onset | 13 | | |
| Vaccine Administered By | OTH | Vaccine Purchased By | |
| Mfr/Imm Project Number | | Split Type | FRPFIZER INC202200198825 |
| Recovered | N | Serious | |

| Event Categories | |
|---|---|
| Death | No |
| Life Threatening | Yes |
| 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 | Yes |

| Symptoms |
|---|
| Abulia |
| Anxiety |
| Asthenia |
| Borrelia test |
| Computerised tomogram |
| Creutzfeldt-Jakob disease |
| CSF protein |
| Decreased appetite |
| Depression |
| Electroencephalogram |
| Hallucination, visual |
| Hepatitis B virus test |
| Hepatitis C virus test |
| HIV test |
| Lumbar puncture |
| Magnetic resonance imaging head |
| Mini mental status examination |
| Myoclonus |
| Neurological examination |
| Polymerase chain reaction |
| SARS-CoV-2 test |
| Sleep disorder |
| Specialist consultation |
| Treponema test |

## Adverse Event Description

Notion of visual hallucinations.; appearance of myoclonus; anxiety-depressive syndrome; anxiety-depressive syndrome; Abulia; REM sleep disorders; loss of appetite; Appearance of asthenia; Creutzfeld-Jacob disease; This is a spontaneous report received from a contactable reporter (s) (Physician) from the Medicines Agency () -WEB. Regulatory number: FR-AFSSAPS-AM20220219 (AFSSAPS). A 70 year-old female patient received bnt162b2 (COMIRNATY), intramuscular, administered in deltoid right, administration date 18Nov2021 (Lot number: FF2834) as dose 3 (booster), single for covid-19 immunisation. Relevant medical history included: "Cataract" (unspecified if ongoing); "Neoplasm breast" (unspecified if ongoing), notes: Treated with AROMASINE (from 2019 to 14jan2022), Orally; "Hypertension arterial" (unspecified if ongoing), notes: Treated with Cosmiprel, 1 DF, 1x/Day, Orally.; "breast resection", start date: 2019 (unspecified if ongoing). The patient's concomitant medications were not reported. Past drug history included: Hexatrione, start date: 03Dec2021, stop date: 03Dec2021, for Osteoarthritis knee, notes: Administered via Intra-articular; Paroxetine, start date: 2021, for Mood Disorder, notes: 20mg, 1x/day, Orally, Lot number unknown.; Flector, stop date: 11Jan2022, for Osteoarthritis knee, notes: Orally, Lot Number: Unknown; Rosuvastatin, stop date: 11Jan2022, for Dyslipidemia, notes: 5mg, 1x/day, orally. Vaccination history included: Comirnaty (1st dose of Comirnaty, Lot: EW2246), administration date: 12Apr2021, for COVID-19 immunization; Comirnaty (2nd dose of Comirnaty, Lot: FA5831), administration date: 10May2021, for COVID-19 immunization. The following information was reported: CREUTZFELDT-JAKOB DISEASE (medically significant, life threatening) with onset Dec2021, outcome "not recovered", described as "Creutzfeld-Jacob disease"; HALLUCINATION, VISUAL (medically significant), outcome "unknown", described as "Notion of visual hallucinations."; MYOCLONUS (medically significant), outcome "unknown", described as "appearance of myoclonus"; ANXIETY (medically significant), DEPRESSION (medically significant), outcome "unknown" and all described as "anxiety-depressive syndrome"; ABULIA (non-serious), outcome "unknown", described as "Abulia"; SLEEP DISORDER (non-serious), outcome "unknown", described as "REM sleep disorders"; DECREASED APPETITE (non-serious), outcome "unknown", described as "loss of appetite"; ASTHENIA (non-serious), outcome "unknown", described as "Appearance of asthenia". The event "creutzfeld-jacob disease" was evaluated at the physician office visit and emergency room visit.Clinical course: Beginning of December 2021 appearance of visual troubles motivating an ophthalmological consultation on the sixth, finding a normal sight examination. Then appearance of asthenia, anxiety-depressive syndrome, loss of appetite, abulia. REM sleep disorders, appearance of myoclonus, praxis disorders of the upper limbs. Notion of visual hallucinations. Referred to emergency by her GP on 11Jan for suspected Parkinson's syndrome. On admission, neurological examination found akinetorigid syndrome with tremors predominantly on the left, cogwheel, bilateral grasping, praxic disorders, walking with small steps, amimia, disorientation and anosognosia. Presence of MS myoclonus. As of 20 January, persistent myoclonus, presence of swallowing difficulties (nasogastric tube planned), responds to simple questions and orders. The patient underwent the following laboratory tests and procedures: borrelia test: (unspecified date) negative; computerised tomogram: (unspecified date) without anomaly; csf protein: (13Jan2022) positive; electroencephalogram: (unspecified date) showing triphasic waves in favour of encephalopath; hepatitis b virus test: (unspecified date) negative; hepatitis c virus test: (unspecified date) negative; hiv test: (unspecified date) negative; lumbar puncture: (13Jan2022) haemorrhagic fluid, no atypical cells, tau protein, notes: haemorrhagic fluid, no atypical cells, tau protein search in progress; magnetic resonance imaging head: (14Jan2022) without argument for ischemic or hemorrhagic accid, notes: without argument for ischemic or hemorrhagic accident, signs of vascular leukopathy but no other abnormality; mini mental status examination: (unspecified date) 7 out of 30. diagnostic hypothesis of creutzfeldt-, notes: 7 out of 30. Diagnostic hypothesis of Creutzfeldt-Jakob disease; neurological examination: (unspecified date) found akinetorigid syndrome with tremors predomina, notes: found akinetorigid syndrome with tremors predominantly on the left, cogwheel, bilateral grasping, praxic disorders, walking with small steps, amimia, disorientation and anosognosia. Presence of MS myoclonus; polymerase chain reaction: (unspecified date) negative; sars-cov-2 test: (unspecified date) negative; specialist consultation: (06Dec2021) finding a normal sight examination; treponema test: (unspecified date) negative. No follow-up attempts are possible. No further information is expected.

| Lab Data | Current Illness | Adverse Events After Prior Vaccinations |
|---|---|---|
| Test Name: borrelia test; Test Result: Negative ; Test Name: CT scan; Result Unstructured Data: Test Result:without anomaly; Test Date: 20220113; Test Name: 14-3-3 protein; Test Result: Positive ; Test Name: EEG; Result Unstructured Data: Test Result:showing triphasic waves in favour of encephalopath; Test Name: Hepatitis B virus test; Test Result: Negative ; Test Name: HCV viral serology; Test Result: Negative ; Test Name: HIV viral serology; Test Result: Negative ; Test Date: 20220113; Test Name: Lumbar puncture; Result Unstructured Data: Test Result:haemorrhagic fluid, no atypical cells, tau protein; Comments: haemorrhagic fluid, no atypical cells, tau protein search in progress.; Test Date: 20220114; Test Name: cerebral MRI; Result Unstructured Data: Test Result:without argument for ischemic or hemorrhagic accid; Comments: without argument for ischemic or hemorrhagic accident, signs of vascular leukopathy but no other abnormality; Test Name: mini mental state examination; Result Unstructured Data: Test Result:7 out of 30. Diagnostic hypothesis of Creutzfeldt-; Comments: 7 out of 30. Diagnostic hypothesis of Creutzfeldt-Jakob disease; Test Name: neurological examination; Result Unstructured Data: Test Result:found akinetorigid syndrome with tremors predomina; Comments: found akinetorigid syndrome with tremors predominantly on the left, cogwheel, bilateral grasping, praxic disorders, walking with small steps, amimia, disorientation and anosognosia. Presence of MS myoclonus.; Test Name: multiplex PCR; Test Result: Negative ; Test Name: SARS-CoV 2 PCR; Test Result: Negative ; Test Date: 20211206; Test Name: ophthalmological consultation; Result Unstructured Data: Test Result:finding a normal sight examination; Test Name: syphilis test; Test Result: Negative | | |

| Medications At Time of Vaccination | History/Allergies |
|---|---|
| | Medical History/Concurrent Conditions: Cataract; Hypertension arterial (Treated with Cosmiprel, 1 DF, 1x/Day, Orally.); Mastectomy; Neoplasm breast (Treated with AROMASINE (from 2019 to 14jan2022), Orally) |

# VAERS DETAIL

VAERS ID: 2109446

| Vaccine Type | Vaccine | Manufacturer | Lot | Dose | Route | Site |
|---|---|---|---|---|---|---|
| COVID19 | COVID19 (COVID19 (MODERNA)) | MODERNA | 017F21A | 3 | IM | UN |

| Event Information | | | |
|---|---|---|---|
| Patient Age | 58 | Sex | M |
| State/Territory | KS | Date Report Completed | |
| Date Vaccinated | 10/28/2021 | Date Report Received | 2/12/2022 |
| Date of Onset | 11/22/2021 | Date Died | |
| Days to Onset | 25 | | |
| Vaccine Administered By | PVT | Vaccine Purchased By | |
| Mfr/Imm Project Number | | Split Type | |
| Recovered | N | Serious | |

| Event Categories | |
|---|---|
| Death | No |
| Life Threatening | Yes |
| Permanent Disability | No |
| Congenital Anomaly/Birth Defect | No |
| Hospitalized | Yes |
| Days in Hospital | 5 |
| Existing Hospitalization Prolonged | No |
| Emergency Room/Office Visit | Yes |
| Emergency Room | No |
| Office Visit | Yes |

| Symptoms |
|---|
| Amnesia |
| Coordination abnormal |
| Creutzfeldt-Jakob disease |
| Lumbar puncture |
| Magnetic resonance imaging head abnormal |
| Myoclonus |
| Tremor |

## Adverse Event Description

Patient's wife states his symptoms of tremors, loss of coordination, startle myoclonus, and memory loss began after receiving the COVID-19 vaccination (symptom onset late 11/2021). COVID-19 booster was given in conjunction with a flu shot but it is currently unknown which type of influenza vaccine and the lot number of said vaccine. He himself is unable to provide reliable history and wife refuses to entertain possibility of symptom onset prior to vaccination, only repeatedly saying there are no symptoms prior to this event. Patient's symptoms have progressed until hospital admission was necessary. He met all criteria for Probable Creutzfeld-Jakob Disease. He denies ingestion of any wild game, receiving blood transfusions, and being out of the country in the past 10 years. Given the pathophysiology of the disease and the mechanism of the vaccine, it is difficult to draw a correlation between two events outside of coincidence. CJD occurs sporadically in over 90% of cases. Wife is requesting a report be filed given the onset of symptoms after Moderna booster dose.

| Lab Data | Current Illness | Adverse Events After Prior Vaccinations |
|---|---|---|
| Lumbar puncture (02/08/22), RTQuiC (pending, sent 02/08/22), MRI Head with findings consistent with CJD (02/08/22) | | |

| Medications At Time of Vaccination | History/Allergies |
|---|---|
| Lisinopril 10mg, aspirin 81mg, balance of nature fruit supplement, balance of nature veggie supplement | |

# VAERS DETAIL

VAERS ID: 2112364

| Vaccine Type | Vaccine | Manufacturer | Lot | Dose | Route | Site |
|---|---|---|---|---|---|---|
| COVID19 | COVID19 (COVID19 (PFIZER-BIONTECH)) | PFIZER\BIONTECH | 31134TB | 3 | | |

| Event Information | | | |
|---|---|---|---|
| Patient Age | | Sex | F |
| State/Territory | FR | Date Report Completed | |
| Date Vaccinated | 11/1/2021 | Date Report Received | 2/15/2022 |
| Date of Onset | 11/1/2021 | Date Died | |
| Days to Onset | 0 | | |
| Vaccine Administered By | OTH | Vaccine Purchased By | |
| Mfr/Imm Project Number | | Split Type | SEPFIZER INC202200222705 |
| 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 | Yes |

| Symptoms |
|---|
| Confusional state |
| Coordination abnormal |
| Creutzfeldt-Jakob disease |
| CSF test |
| Electroencephalogram |
| Investigation |
| Lumbar puncture |
| Magnetic resonance imaging head |
| Memory impairment |
| Speech disorder |
| Urinary tract infection |

## Adverse Event Description

Creutzfeldt-Jakob disease; Confusion; Coordination impaired; Forgetfulness; Speech disorder; infection in the urine tract; This is a spontaneous report received from a contactable reporter(s) (Consumer or other non HCP) from the Regulatory Authority-WEB. Regulatory number: SE-MPA-2022-004182. Other Case identifier(s): SE-VISMA-1642717159291.  A 86 year-old female patient received bnt162b2 (COMIRNATY), administration date Nov2021 (Lot number: 31134TB) as dose 3 (booster), single for covid-19 immunisation. Relevant medical history included: "Hypertension" (unknown if ongoing); "Myocardial infarct" (not ongoing), notes: Took Trombyl after a couple of heart attacks a few years ago. Fully recovered.; "Hyperlipidaemia" (unknown if ongoing); "Hearing decreased" (unknown if ongoing); "Subdural haematoma" (unspecified if ongoing); "Hypothyroidism" (unspecified if ongoing). Concomitant medication(s) included: LEVAXIN taken for hypothyroidism; ATORVASTATIN, stop date: 20Dec2021; TROMBYL taken for myocardial infarction, stop date: 20Dec2021. Vaccination history included: Comirnaty (1st dose), administration date: 09Mar2021, for Covid-19 immunization; Comirnaty (2nd dose), administration date: 20Apr2021, for Covid-19 immunization, reaction(s): "Inappropriate schedule of product administration". The following information was reported: CREUTZFELDT-JAKOB DISEASE (death, hospitalization) with onset Dec2021, outcome "fatal", described as "Creutzfeldt-Jakob disease"; CONFUSIONAL STATE (death, hospitalization) with onset Nov2021, outcome "fatal", described as "Confusion"; COORDINATION ABNORMAL (death, hospitalization) with onset Nov2021, outcome "fatal", described as "Coordination impaired"; MEMORY IMPAIRMENT (death, hospitalization) with onset Nov2021, outcome "fatal", described as "Forgetfulness"; SPEECH DISORDER (death, hospitalization) with onset Nov2021, outcome "fatal", described as "Speech disorder"; URINARY TRACT INFECTION (non-serious), outcome "unknown", described as "infection in the urine tract". The events "creutzfeldt-jakob disease", "confusion", "coordination impaired", "forgetfulness", "speech disorder" and "infection in the urine tract" were evaluated at the physician office visit. The patient underwent the following laboratory tests and procedures: csf test: the analyzes were all negative, notes: regarding Autoimmune encephalitis in serum, Paraneoplastic syndromes in serum, Autoimmune encephalitis in CSF, Paraneoplastic syndromes in CSF. Result regarding CJD proteine in CSF were at the time not yet completed. The clinical course and cerebrospinal fluid analysis that showed parenchymal damage strongly suggest sporadic CJD. Analysis of CSF regarding Proteine 14-3-3 in and RT-QuIC later confirmed CJD; electroencephalogram: patological. generalized slowing., notes: Lateral asymmetry and occasionally slower on the left side. No typical changes indicating CJD; investigation: confirmed creutzfeldt-jakob disease; infection, notes: prescribed antibiotics; lumbar puncture: confirmed creutzfeldt-jakob disease; magnetic resonance imaging head: widespread vascular-due white matter changes, notes: with decreased brain tissue supratentorially, and status after previous minor infarctions. Therapeutic measures were taken as a result of urinary tract infection. Clinical Course: A week after the vaccination she said that she probably should give up car-driving due to the discomfort. The next-coming days she started to develop a slower pace, started to forget things, and started to have problems expressing herself. Four weeks after the vaccination they had had another contact with the doctor who planned to perform examinations due to her symptoms and the rapid progress. At this point she wasn't able to identify her relatives, she did not know their names, ate very slow and was very confused. The woman's general health condition continued to deteriorate rapidly. After a week at the hospital, she had lost her ability to walk and eat. Ten days later after further deterioration she was moved to a nursing home. The patient date of death was unknown. The reported cause of death was creutzfeldt-jakob disease.  No follow-up attempts are possible. No further information is expected.; Sender's Comments: Linked Report(s) : SE-PFIZER INC-202200232304 same patient/ different events/ different doses; Reported Cause(s) of Death: Creutzfeld-Jakob disease

| Lab Data | Current Illness | Adverse Events After Prior Vaccinations |
|---|---|---|
| Test Name: Analysis of serum and cerebrospinal fluid (CSF); Result Unstructured Data: Test Result:The analyzes were all negative; Comments: regarding Autoimmune encephalitis in serum, Paraneoplastic syndromes in serum, Autoimmune encephalitis in CSF, Paraneoplastic syndromes in CSF. Result regarding CJD proteine in CSF were at the time not yet completed. The clinical course and cerebrospinal fluid analysis that showed parenchymal damage strongly suggest sporadic CJD. Analysis of CSF regarding Proteine 14-3-3 in and RT-QuIC later confirmed CJD.; Test Name: EEG; Result Unstructured Data: Test Result:Patological. Generalized slowing.; Comments: Lateral asymmetry and occasionally slower on the left side. No typical changes indicating CJD.; Test Name: protein 14-3-3; Result Unstructured Data: Test Result:confirmed Creutzfeldt-Jakob disease; Test Name: urine tract test; Result Unstructured Data: Test Result:infection; Comments: prescribed antibiotics; Test Name: lumbar punction; Result Unstructured Data: Test Result:confirmed Creutzfeldt-Jakob disease; Test Name: MRI of the brain; Result Unstructured Data: Test Result:Widespread vascular-due white matter changes; Comments: with decreased brain tissue supratentorially, and status after previous minor infarctions. | | |

| Medications At Time of Vaccination | History/Allergies |
|---|---|
| LEVAXIN; ATORVASTATIN; TROMBYL | Medical History/Concurrent Conditions: Hearing decreased; Hyperlipidaemia; Hypertension; Hypothyroidism; Myocardial infarct (Took Trombyl after a couple of heart attacks a few years ago. Fully recovered.); Subdural haematoma |

# VAERS DETAIL

VAERS ID: 2121388

| Vaccine Type | Vaccine | Manufacturer | Lot | Dose | Route | Site |
|---|---|---|---|---|---|---|
| COVID19 | COVID19 (COVID19 (PFIZER-BIONTECH)) | PFIZER\BIONTECH | EP9598 | 2 | | |

| Event Information | | | |
|---|---|---|---|
| Patient Age | 59 | Sex | F |
| State/Territory | FR | Date Report Completed | |
| Date Vaccinated | 3/5/2021 | Date Report Received | 2/18/2022 |
| Date of Onset | 3/5/2021 | Date Died | 1/30/2022 |
| Days to Onset | 0 | | |
| Vaccine Administered By | OTH | Vaccine Purchased By | |
| Mfr/Imm Project Number | | Split Type | DEPFIZER INC202200216910 |
| 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 |
| Creutzfeldt-Jakob disease |
| CSF test |
| Death |
| Dementia |
| Feeling abnormal |
| General physical health deterioration |
| Personality change |
| Restlessness |
| Sleep disorder |
| Walking disability |

## Adverse Event Description

rapid development of dementia; severe deterioration; sleep disorders; foggy feeling in the head; weakness; inability to walk; restlessness; Cause of death unknown; CSF PUNCTURE.: Suspicion of Creutzfeld Jakob disease. Diagnosis early 22Jan DEATH on 30Jan22; initially personality change, weakness, restlessness, sleep disorders, foggy feeling in the head,; This is a spontaneous report received from a non-contactable reporter(s) (Consumer or other non HCP) from the RA. Regulatory number: DE-PEI-CADR2022269165. Other Case identifier(s): DE-CADRPEI-2022269165 (RA Webportal), DE-PEI-202200068060.  A 59 year-old female patient received bnt162b2 (COMIRNATY), administration date 05Mar2021 (Lot number: EP9598) at the age of 59 years as dose 2, single for covid-19 immunisation. Relevant medical history included: "Knee prosthesis user", start date: 15Sep2021 (ongoing). The patient's concomitant medications were not reported. Vaccination history included: Comirnaty (Dose 1, strength: 0.3 mL), administration date: 12Feb2021, for covid-19 immunisation, reaction(s): "exhaustion", "general physical health deterioration". The following information was reported: DEATH (death) with onset 30Jan2022, outcome "fatal", described as "Cause of death unknown"; CREUTZFELDT-JAKOB DISEASE (medically significant) with onset Jan2022, outcome "not recovered", described as "CSF PUNCTURE.: Suspicion of Creutzfeld Jakob disease. Diagnosis early 22Jan DEATH on 30Jan22"; PERSONALITY CHANGE (medically significant) with onset 05Mar2021, outcome "not recovered", described as "initially personality change, weakness, restlessness, sleep disorders, foggy feeling in the head,"; DEMENTIA (non-serious), outcome "unknown", described as "rapid development of dementia"; GENERAL PHYSICAL HEALTH DETERIORATION (non-serious), outcome "unknown", described as "severe deterioration"; SLEEP DISORDER (non-serious), outcome "unknown", described as "sleep disorders"; FEELING ABNORMAL (non-serious), outcome "unknown", described as "foggy feeling in the head"; ASTHENIA (non-serious), outcome "unknown", described as "weakness"; WALKING DISABILITY (non-serious), outcome "unknown", described as "inability to walk"; RESTLESSNESS (non-serious), outcome "unknown", described as "restlessness". The patient underwent the following laboratory tests and procedures: csf test: (22Jan2022) suspicion of creutzfeld jakob disease. The patient date of death was 30Jan2022. The reported cause of death was "Unknown cause of death". It was not reported if an autopsy was performed.  Relatedness of Comirnaty to events: Creutzfeld-Jacob disease, Character change, Unknown cause of death / Source of assessment: RA.  Result of Assessment: D.  Unclassifiable.  No follow-up attempts are possible. No further information is expected.; Sender's Comments: Linked Report(s) : DE-PFIZER INC-202200232430 The same patient, different events/doses; Reported Cause(s) of Death: Unknown cause of death

| Lab Data | Current Illness | Adverse Events After Prior Vaccinations |
|---|---|---|
| Test Date: 20220122; Test Name: csf puncture; Result Unstructured Data: Test Result:suspicion of Creutzfeld Jakob disease | Knee prosthesis user | |

| Medications At Time of Vaccination | History/Allergies |
|---|---|
| | |

# VAERS DETAIL

VAERS ID: 2133845

| Vaccine Type | Vaccine | Manufacturer | Lot | Dose | Route | Site |
|---|---|---|---|---|---|---|
| COVID19 | COVID19 (COVID19 (PFIZER-BIONTECH)) | PFIZER\BIONTECH | FE2625 | 2 | OT | LA |

| Event Information | | | |
|---|---|---|---|
| Patient Age | | Sex | M |
| State/Territory | FR | Date Report Completed | |
| Date Vaccinated | 6/28/2021 | Date Report Received | 2/23/2022 |
| Date of Onset | 6/28/2021 | Date Died | |
| Days to Onset | 0 | | |
| Vaccine Administered By | OTH | Vaccine Purchased By | |
| Mfr/Imm Project Number | | Split Type | ITPFIZER INC202200278901 |
| Recovered | U | Serious | |

| Event Categories | |
|---|---|
| Death | No |
| Life Threatening | Yes |
| 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 |
|---|
| Balance disorder |
| Creutzfeldt-Jakob disease |
| Inappropriate schedule of product administration |
| Inflammation |
| Magnetic resonance imaging |
| Visual impairment |

## Adverse Event Description

Initially in August Loss of balance and then visions until MRI discovered prion inflammation (Creutzfeldt-Jacob disease); Initially in August Loss of balance and then visions until MRI discovered prion inflammation (Creutzfeldt-Jacob disease); Initially in August Loss of balance and then visions until MRI discovered prion inflammation (Creutzfeldt-Jacob disease); Initially in August Loss of balance and then visions until MRI discovered prion inflammation (Creutzfeldt-Jacob disease); Inappropriate schedule of vaccine administered; This is a spontaneous report received from a contactable reporter(s) (Consumer or other non HCP) from the Agency WEB. Regulatory number: IT-MINISAL02-842209 (RA). A 64 year-old male patient received bnt162b2 (COMIRNATY), intramuscular, administered in arm left, administration date 28Jun2021 (Lot number: FE2625) as dose 2, single for covid-19 immunisation. The patient's relevant medical history and concomitant medications were not reported. Vaccination history included: Comirnaty (DOSE 1, SINGLE, LOT: FA4597), administration date: 17May2021, for covid-19 immunization. The following information was reported: BALANCE DISORDER (hospitalization, life threatening), VISUAL IMPAIRMENT (hospitalization, life threatening), CREUTZFELDT-JAKOB DISEASE (hospitalization, medically significant, life threatening), INFLAMMATION (hospitalization, life threatening) all with onset 20Aug2021, outcome "unknown" and all described as "Initially in August Loss of balance and then visions until MRI discovered prion inflammation (Creutzfeldt-Jacob disease)"; INAPPROPRIATE SCHEDULE OF PRODUCT ADMINISTRATION (non-serious) with onset 28Jun2021, outcome "unknown", described as "Inappropriate schedule of vaccine administered". The patient underwent the following laboratory tests and procedures: magnetic resonance imaging: (Aug2021) prion inflammation (creutzfeldt-jacob disease), notes: MRI discovered prion inflammation (Creutzfeldt-Jacob disease). It was reported that hospitalization with worsening day by day. Unfortunately there was no cure for this disease. Impact on quality of life (10/10). Sender's comment: Follow-up required: clinical documentation (reports and diagnosis) Awaiting response. No follow-up attempts are possible. No further information is expected.

| Lab Data | Current Illness | Adverse Events After Prior Vaccinations |
|---|---|---|
| Test Date: 202108; Test Name: MRI; Result Unstructured Data: Test Result:prion inflammation (Creutzfeldt-Jacob disease); Comments: MRI discovered prion inflammation (Creutzfeldt-Jacob disease) | | |

| Medications At Time of Vaccination | History/Allergies |
|---|---|
| | |

# VAERS DETAIL

VAERS ID: 2165031

| Vaccine Type | Vaccine | Manufacturer | Lot | Dose | Route | Site |
|---|---|---|---|---|---|---|
| COVID19 | COVID19 (COVID19 (MODERNA)) | MODERNA | 3001656 | 1 | OT | |

| Event Information | | | |
|---|---|---|---|
| Patient Age | 67 | Sex | F |
| State/Territory | FR | Date Report Completed | |
| Date Vaccinated | 4/24/2021 | Date Report Received | 3/8/2022 |
| Date of Onset | 10/1/2021 | Date Died | |
| Days to Onset | 160 | | |
| Vaccine Administered By | UNK | Vaccine Purchased By | |
| Mfr/Imm Project Number | | Split Type | CHMODERNATX, INC.MOD20225 |
| Recovered | N | Serious | |

| Event Categories | |
|---|---|
| Death | No |
| Life Threatening | Yes |
| 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 |
|---|
| Creutzfeldt-Jakob disease |
| Electroencephalogram |
| Magnetic resonance imaging head |

| Adverse Event Description |
| --- |
| Creutzfeld-Jakob disease; This regulatory authority case was reported by a physician and describes the occurrence of CREUTZFELDT-JAKOB DISEASE (Creutzfeld-Jakob disease) in a 67-year-old female patient who received mRNA-1273 (COVID-19 Vaccine Moderna) (batch nos. 3002541 and 3001656) for COVID-19 vaccination. The patient's past medical history included Suicide attempt in June 2021. Concurrent medical conditions included Schizoaffective disorder depressive type and Meningioma. Concomitant products included ATORVASTATIN CALCIUM (ATORVASTATIN AXAPHARM), PANTOPRAZOLE SODIUM SESQUIHYDRATE (PANTOPRAZOL AXAPHARM) and LORAZEPAM (TEMESTA [LORAZEPAM]) for an unknown indication. On 24-Apr-2021, the patient received first dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 1 dosage form once a day. On 22-May-2021, received second dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) dosage was changed to 1 dosage form. In October 2021, the patient experienced CREUTZFELDT-JAKOB DISEASE (Creutzfeld-Jakob disease) (seriousness criteria hospitalization, medically significant and life threatening). At the time of the report, CREUTZFELDT-JAKOB DISEASE (Creutzfeld-Jakob disease) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 09-Dec-2021, Magnetic resonance imaging head: test_result = test_result = On 15-Dec-2021, Electroencephalogram: test_result = For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter considered CREUTZFELDT-JAKOB DISEASE (Creutzfeld-Jakob disease) to be unlikely related. No treatment medication was provided. Company comment: This regulatory authority case concerns a 67-year-old female patient with a relevant medical history of schizo-affective depressive disorder for 16 years, who experienced the life-threatening (and serious due to hospitalization and medically significant) unexpected event of Creutzfeldt-Jakob disease (sporadic), approximately 4 to 6 months after receiving the second dose of mRNA- 1273 vaccine. Additionally, the patient experienced drug overdose (aripiprazole), approximately 1 month after the second dose, and was admitted to the Psychiatric Clinic for approximately 4 months. Onset latency is approximate, since precise start date of the events was not disclosed. Clinical manifestations of Creutzfeldt-Jakob disease included rapid cognitive decline, aphasia, echolalia, apraxia and abulia, that led to readmission. Brain MRI revealed extensive signal alteration of the cortex with symmetrical involvement of the temporal, frontal and parietal lobes (without involvement of the peri Rolandic cortex). Electroencephalogram showed a slight slowdown in the basic activity, slow sub continuous activity of a rhythmic in the front-central location, without frank epileptiform abnormalities. Routine cerebrospinal fluid analysis and biofire analysis were normal. However, cerebrospinal Tau protein was elevated (>1559 ng/L) and RT-Quic tests and 14&#65533;3&#65533;3 protein showed positive results. Infectious, autoimmune and paraneoplastic encephalitis were rule out. At the time of the report, the patient was clinically unchanged and had been transferred to a residential institution. Previous history of psychiatric disorder could be a confounder. The event was considered unrelated to the vaccine per the reporter's assessment. The benefit-risk relationship of mRNA- 1273 vaccine is not affected by this report. Sporadic Creutzfeld-Jacob Disease The patient was known for schizo-affective depressive disorder that began about 16 years ago, small meningioma at the mid-anterior third of the brain scythe, with no effect mass, not known for allergies. He chronically takes Atorvastatin Axapharm 10 mg/day, Pantoprazol Axapharm 20 mg/day, and Temesta 1 mg/day. The patient was also known for previous temptation with intoxication from Abilify in June 2021 for which she was admitted to the Psychiatric Clinic until 13 september and then transferred to a protected home. In the course there was an initial management problem with regard to drug therapy (she took all the drugs together at once) and her daughter reports that between October - November 2021 she started a rapid cognitive decay, then noticed also by the attending physician, with aphasia, echolalia, apraxia and abulia. It was therefore decided for a new admission to the Psychiatric Clinic for drug wash-out, without nevertheless noticing changes in the neurological picture. In the Clinic, a brain MRI was therefore performed from which doubtful findings emerge with evidence of extensive signal alteration of the cortex with symmetrical involvement of the temporal, frontal and parietal lobes, with Saving perirolandic cortex, and involvement of the crawler ride. She was therefore admitted to the hospital on 14 Dec 2021 for the examinations of the case. The in-patient diagnostic balance provided for an EEG that showed a slight slowdown in the basic activity with the presence of slow sub continuous activity of a rhythmic and sharp character in the front-central location bilateral, without frank epileptiform abnormalities. A lumbar puncture was then performed, resulting in normal (chemical/physical examination and Biofire). The neuro-antibody balance (for autoimmune and/or paraneoplastic encephalitis) was also negative. While research by Dementia Markers on liquor shows a high increase in Tau protein (>1559 ng/L). Upon diagnostic completion, RT-Quic tests and protein research was performed 14.3.3, positive results. An extensive infectious and autoimmune laboratory balance was devoid of particularities. In this context, against the clinic presented (rapidly progressive neurocognitive syndrome and psychiatric symptoms), a positive brain MRI, the value of RT-Quic and protein 14.3.3 on LCR Positive, there was a diagnosis of probable Creutzfeld-Jacob disease, sporadic. Given the poor prognosis, the patient was discharged on 21-Dec-2021 and transferred to the Senior House. At the end of the stay, the patient was clinically unchanged. More information was not known.; Reporter's Comments: Sporadic Creutzfeld-Jacob disease arose approximately 5 months after the vaccine cycle (two doses) with Spikevax vaccine in a 68 year old patient. Given the unsuccessful prognosis of the disease (100% lethal) the case is considered to be severe. In the Swiss monograph of mRNA vaccines against COVID-19, as well as in international monographs (FDA/EMA) and in the main medical-scientific databases (Uptodate, Micromedex Drugdex, AHFS, Martindale) is not reported a possible sporadic Creutzfeld-Jakob disease (ScjD) among the adverse events observed in relation to COVID-19 vaccination with mRNA vaccines. Also in the literature (Pumed) there are no cases of ScJD related to the administration of these vaccines. The latency time between the two doses of vaccine (late April and late May 2021) and the onset of symptoms (October november 2021) could be suggestive for a causal role. However, considering the slow pathogenesis of the disease, which can become clinically manifested even many months/years after the onset of organic changes, and considering the age in the patient under consideration (68) years) that is close to the average age of onset of the disease according to UptoDate (i.e. 62 years), it is difficult to temporally correlate the administration of the two doses of Spikevax with the natural history biological pathology itself. According to what has been said, therefore, at the current state of knowledge there is no scientific evidence to support a possible causal role of the Spikevax vaccine in the ScjD disease, so we believe the unlikely link.; Sender's Comments: This regulatory authority case concerns a 67-year-old female patient with a relevant medical history of schizo-affective depressive disorder for 16 years, who experienced the life-threatening (and serious due to hospitalization and medically significant) unexpected event of Creutzfeldt-Jakob disease (sporadic), approximately 4 to 6 months after receiving the second dose of mRNA- 1273 vaccine. Additionally, the patient experienced drug overdose (aripiprazole), approximately 1 month after the second dose, and was admitted to the Psychiatric Clinic for approximately 4 months. Onset latency is approximate, since precise start date of the events was not disclosed. Clinical manifestations of Creutzfeldt-Jakob disease included rapid cognitive decline, aphasia, echolalia, apraxia and abulia, that led to readmission. Brain MRI revealed extensive signal alteration of the cortex with symmetrical involvement of the temporal, frontal and parietal lobes (without involvement of the peri Rolandic cortex). Electroencephalogram showed a slight slowdown in the basic activity, slow sub continuous activity of a rhythmic in the front-central location, without frank epileptiform abnormalities. Routine cerebrospinal fluid analysis and biofire analysis were normal. However, cerebrospinal Tau protein was elevated (>1559 ng/L) and RT-Quic tests and 14&#65533;3&#65533;3 protein showed positive results. Infectious, autoimmune and paraneoplastic encephalitis were rule out. At the time of the report, the patient was clinically unchanged and had been transferred to a residential institution. Previous history of psychiatric disorder could be a confounder. The event was considered unrelated to the vaccine per the reporter's assessment. The benefit-risk relationship of mRNA- 1273 vaccine is not affected by this report. |

| Lab Data | Current Illness | Adverse Events After Prior Vaccinations |
|---|---|---|
| Test Date: 20211215; Test Name: Electroencephalogram; Result Unstructured Data: test_result = ; Test Date: 20211209; Test Name: Magnetic resonance imaging brain; Result Unstructured Data: test_result = | Meningioma; Schizoaffective disorder depressive type | |

| Medications At Time of Vaccination | History/Allergies |
|---|---|
| ATORVASTATIN AXAPHARM; PANTOPRAZOL AXAPHARM; TEMESTA [LORAZEPAM] | Medical History/Concurrent Conditions: Suicide attempt |

# VAERS DETAIL

VAERS ID: 2174145

| Vaccine Type | Vaccine | Manufacturer | Lot | Dose | Route | Site |
|---|---|---|---|---|---|---|
| COVID19 | COVID19 (COVID19 (MODERNA)) | MODERNA | 3001532 | 1 | OT | |

| Event Information | | | |
|---|---|---|---|
| Patient Age | 71 | Sex | M |
| State/Territory | FR | Date Report Completed | |
| Date Vaccinated | 4/28/2021 | Date Report Received | 3/11/2022 |
| Date of Onset | | Date Died | |
| Days to Onset | | | |
| Vaccine Administered By | UNK | Vaccine Purchased By | |
| Mfr/Imm Project Number | | Split Type | ESMODERNATX, INC.MOD20225 |
| 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 |
|---|
| Creutzfeldt-Jakob disease |

## Adverse Event Description

This case was received via Regulatory Agency (Reference number: ES-AEMPS-1107809) on 07-Mar-2022 and was forwarded to Moderna on 07-Mar-2022. This regulatory authority case was reported by a consumer and describes the occurrence of CREUTZFELDT-JAKOB DISEASE (Deadly and untreated degenerative neurological disease. Prion) in a 71-year-old male patient who received mRNA-1273 (Spikevax) (batch nos. 3002183 and 3001532) for COVID-19 vaccination. No Medical History information was reported. On 28-Apr-2021, the patient received first dose of mRNA-1273 (Spikevax) (Intramuscular) .5 milliliter. On 26-May-2021, received second dose of mRNA-1273 (Spikevax) (Intramuscular) dosage was changed to .5 milliliter. On an unknown date, the patient experienced CREUTZFELDT-JAKOB DISEASE (Deadly and untreated degenerative neurological disease. Prion) (seriousness criterion death). It is unknown if an autopsy was performed. Concomitant product use was not provided by the reporter. Treatment information was not provided. Company comment- This is a fatal regulatory authority case concerning a 71-year-old male patient with no medical history reported who experienced the unexpected and serious (death) event of Creutzfeldt-Jakob disease 10 days after a second dose of mRNA-1273 vaccine was administered. It is not known if an autopsy was performed. The date of death is unknown. No further details were provided for medical reviewing. Patient's age remains as a possible contributory risk factor for the event. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 07-Mar-2022: Follow up contains no new information. Sender's Comments: This is a fatal regulatory authority case concerning a 71-year-old male patient with no medical history reported who experienced the unexpected and serious (death) event of Creutzfeldt-Jakob disease 10 days after a second dose of mRNA-1273 vaccine was administered. It is not known if an autopsy was performed. The date of death is unknown. No further details were provided for medical reviewing. Patient's age remains as a possible contributory risk factor for the event. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.

| Lab Data | Current Illness | Adverse Events After Prior Vaccinations |
|---|---|---|
| | | |

| Medications At Time of Vaccination | History/Allergies |
|---|---|
| | |

# VAERS DETAIL

VAERS ID: 2174273

| Vaccine Type | Vaccine | Manufacturer | Lot | Dose | Route | Site |
|---|---|---|---|---|---|---|
| COVID19 | COVID19 (COVID19 (PFIZER-BIONTECH)) | PFIZER\BIONTECH | FG7911 | 3 | OT | |

| Event Information | | | |
|---|---|---|---|
| Patient Age | | Sex | M |
| State/Territory | FR | Date Report Completed | |
| Date Vaccinated | 9/22/2021 | Date Report Received | 3/12/2022 |
| Date of Onset | 11/15/2021 | Date Died | 1/15/2022 |
| Days to Onset | 54 | | |
| Vaccine Administered By | OTH | Vaccine Purchased By | |
| Mfr/Imm Project Number | | Split Type | FRPFIZER INC202200376407 |
| 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 | Yes |

| Symptoms |
|---|
| Aphasia |
| Creutzfeldt-Jakob disease |
| Dysphagia |
| Echocardiogram |
| Ejection fraction |
| Electroencephalogram |
| General physical health deterioration |
| Lumbar puncture |
| Magnetic resonance imaging |
| Magnetic resonance imaging head |
| Scan brain |
| Specialist consultation |
| Ultrasound Doppler |
| Visual impairment |

## Adverse Event Description

deterioration of general condition; visual disturbances; Creutzfeld-Jacob disease; progressively loses speech; swallowing function deraded; This is a spontaneous report received from contactable reporter(s) (Consumer or other non HCP and Other HCP) from a regulatory authority. Regulatory number: FR-AFSSAPS-DJ20220535. A 81 year-old male patient received bnt162b2 (COMIRNATY), intramuscular, administration date 22Sep2021 (Lot number: FG7911) as dose 3 (booster), single for covid-19 immunisation. Relevant medical history included: "Sigmoid diverticulosis" (unspecified if ongoing); "Hypertension arterial" (unspecified if ongoing); "AFib" (unspecified if ongoing), notes: atrial fibrillation complete arrhythmia; "Cataract extraction", start date: 2019 (unspecified if ongoing). Concomitant medication(s) included: CANDESARTAN ARROW; PRADAXA; FLECAINE. Vaccination history included: Comirnaty (Dose 2, single, intramuscular injection, lot number: EP2166), administration date: 05Mar2021, for Covid-19 immunisation; Comirnaty (Dose 1, single, intramuscular injection, lot number: EJ6788), administration date: 05Feb2021, for Covid-19 immunisation. The following information was reported: CREUTZFELDT-JAKOB DISEASE (death, hospitalization) with onset 15Nov2021, outcome "fatal", described as "Creutzfeld-Jacob disease"; VISUAL IMPAIRMENT (hospitalization), outcome "unknown", described as "visual disturbances"; GENERAL PHYSICAL HEALTH DETERIORATION (hospitalization), outcome "unknown", described as "deterioration of general condition"; APHASIA (non-serious), outcome "unknown", described as "progressively loses speech"; DYSPHAGIA (non-serious), outcome "unknown", described as "swallowing function deraded". The patient was hospitalized for creutzfeldt-jakob disease, visual impairment (start date: 02Dec2021, discharge date: 09Dec2021, hospitalization duration: 7 day(s)); for general physical health deterioration (start date: 27Dec2021). The events "creutzfeld-jacob disease", "visual disturbances" and "deterioration of general condition" were evaluated at the physician office visit. Therapeutic measures were taken as a result of creutzfeldt-jakob disease. The patient date of death was 15Jan2022. The reported cause of death was creutzfeldt-jakob disease. It was not reported if an autopsy was performed. This serious case, of type Spontaneous Notification, - Access to healthcare services was notified by a patient (medically confirmed). Clinical summary: Patient hospitalised from 02Dec2021 to 09Dec2021, in the context of visual disturbances for 15 days initially suspecting a stroke. The patient consulted 2 ophthalmologists who did not find any anomalies of the ophthalmological sphere. It should be noted that on 11Nov2021, the patient had no visual problems. The brain scan was normal. The transthoracic echocardiography showed a slightly dilated left atrium, left vetricule ejection fraction 60%, no visible thrombus. Doppler of the supra aortic trunks was normal. Brain MRI showed signal abnormalities in the cortical and posterior occipital areas bilaterally, especially on the left. The 3D Time-of-Flight sequence showed total thrombosis of the left M3 and M4. No bleeding signal. Diffusion and flair hypersignal, discrete hyposignal on Apparent diffusion coefficient which may correspond to cortical hypoxia. The Electroencephalogram trace consists of a quasi-continuous periodic degraded slow spike activity increased in the pathological left occipital region. In view of this pattern, the doctors suggested a prion disease. Treatment with valproic acid prolonged release 500 mg morning and evening is started. Confirmation of Creutzfeldt-Jacob disease, which had also been suspected on MRI and Electroencephalogram. The lumbar puncture found l4-3-3 protein suggestive of this diagnosis. Rediscussion with the neurologists: confirmation of the diagnosis of this pathology. The patient was referred to hospital on 27Dec2021 by his general practitioner for a deterioration in his general condition with difficulty in remaining at home, deterioration in autonomy, with progressive grabatisation. Treatment with valproic acid had initially been introduced for a suspected epileptic pathology; this treatment was stopped on recommendation. There was no clear epileptic episode, rather myoclonus characteristic of this pathology. There is no other point of call for the deterioration of the general state which seems to be really linked to the evolution of the disease. The patient progressively loses speech. The swallowing function is initially quite degraded and then evolves towards a total absence of swallowing making the administration of oral treatments impossible. In view of the progressive and irreversible deterioration of this general state: progressive evolution towards exclusive palliative care in agreement with the family, which is informed as the treatment progresses. The patient died on 15Jan2022. No follow-up attempts are possible. No further information is expected.; Reported Cause(s) of Death: Creutzfeld-Jacob disease

| Lab Data | Current Illness | Adverse Events After Prior Vaccinations |
|---|---|---|
| Test Name: transthoracic echocardiography; Result Unstructured Data: Test Result:showed a slightly dilated left atrium,; Comments: left vetricule ejection fraction 60%, no visible thrombus.; Test Name: left vetricule ejection fraction; Test Result:  60 %; Test Name: Electroencephalogram; Result Unstructured Data: Test Result:consists of a quasi-continuous periodic degraded; Comments: slow spike activity increased in the pathological left occipital region; Test Name: Electroencephalogram; Result Unstructured Data: Test Result:Confirmation of Creutzfeldt-Jacob disease; Test Name: lumbar puncture; Result Unstructured Data: Test Result:l4-3-3 protein; Test Name: MRI; Result Unstructured Data: Test Result:Confirmation of Creutzfeldt-Jacob disease; Test Name: MRI brain; Result Unstructured Data: Test Result:signal abnormalities in the cortical; Comments: and posterior occipital areas bilaterally, especially on the left. The 3D Time-of-Flight sequence showed total thrombosis of the left M3 and M4. No bleeding signal. Diffusion and flair hypersignal, discrete hyposignal on Apparent diffusion coefficient  which may correspond to cortical hypoxia.; Test Name: brain scan; Result Unstructured Data: Test Result:normal; Test Name: neurologist consultation; Result Unstructured Data: Test Result:confirmation of the diagnosis of this pathology; Test Name: ophthalmologists consultation; Result Unstructured Data: Test Result:did not find any anomalies; Comments: of the ophthalmological sphere; Test Name: Doppler of the supra aortic trunks; Result Unstructured Data: Test Result:normal | | |

| Medications At Time of Vaccination | History/Allergies |
|---|---|
| CANDESARTAN ARROW; PRADAXA; FLECAINE | Medical History/Concurrent Conditions: AFib (atrial fibrillation complete arrhythmia); Cataract extraction; Hypertension arterial; Sigmoid diverticulosis |

# VAERS DETAIL

VAERS ID: 2179519

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

| Event Information | | | |
|---|---|---|---|
| Patient Age | 49 | Sex | F |
| State/Territory | FR | Date Report Completed | |
| Date Vaccinated | 9/29/2021 | Date Report Received | 3/15/2022 |
| Date of Onset | 11/1/2021 | Date Died | |
| Days to Onset | 33 | | |
| Vaccine Administered By | UNK | Vaccine Purchased By | |
| Mfr/Imm Project Number | | Split Type | ARMODERNATX, INC.MOD20225 |
| Recovered | N | Serious | |

| Event Categories | |
|---|---|
| Death | No |
| Life Threatening | No |
| Permanent Disability | Yes |
| 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 |
|---|
| Arthropathy |
| Balance disorder |
| Cognitive disorder |
| Condition aggravated |
| Creutzfeldt-Jakob disease |
| CSF test |
| Dementia |
| Diplopia |
| Electroencephalogram |
| Electromyogram |
| Extensor plantar response |
| Eye movement disorder |
| Gait disturbance |
| General physical health deterioration |
| Hyperreflexia |
| Hypoaesthesia |
| Limb discomfort |
| Magnetic resonance imaging |
| Magnetic resonance imaging head |
| Magnetic resonance imaging spinal |
| Myoclonus |
| Speech disorder |
| Vision blurred |

## Adverse Event Description

rapidly progressive dementia; rapid loss of all cognitive functions; C-J disease; Does not speak; She has her eyes to the right but can move them -with strong stimulation- to the right; double and blurred vision; double and blurred vision; diffuse myoclonus; Diffuse hyperreflexia; right spontaneous Babinski; general status deteriorated; numbness from her left knee to her foot; Pins and needles developed in her left arm; left knee started to give way; continued to worsen; loss of stability; difficulty walking; This spontaneous case was reported by a health care professional and describes the occurrence of DEMENTIA (rapidly progressive dementia), COGNITIVE DISORDER (rapid loss of all cognitive functions), GAIT DISTURBANCE (difficulty walking), GENERAL PHYSICAL HEALTH DETERIORATION (general status deteriorated), CREUTZFELDT-JAKOB DISEASE (C-J disease), BALANCE DISORDER (loss of stability), SPEECH DISORDER (Does not speak) and EYE MOVEMENT DISORDER (She has her eyes to the right but can move them -with strong stimulation- to the right) in a 49-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 29-Sep-2021, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. In November 2021, received second dose of mRNA-1273 (Spikevax) (unknown route) dosage was changed to 1 dosage form. In 2021, the patient experienced GAIT DISTURBANCE (difficulty walking) (seriousness criterion disability), BALANCE DISORDER (loss of stability) (seriousness criterion disability), LIMB DISCOMFORT (Pins and needles developed in her left arm), ARTHROPATHY (left knee started to give way) and CONDITION AGGRAVATED (continued to worsen). In November 2021, the patient experienced HYPOAESTHESIA (numbness from her left knee to her foot). In February 2022, the patient experienced GENERAL PHYSICAL HEALTH DETERIORATION (general status deteriorated) (seriousness criterion disability). On an unknown date, the patient experienced DEMENTIA (rapidly progressive dementia) (seriousness criterion disability), COGNITIVE DISORDER (rapid loss of all cognitive functions) (seriousness criterion disability), CREUTZFELDT-JAKOB DISEASE (C-J disease) (seriousness criterion disability), SPEECH DISORDER (Does not speak) (seriousness criterion disability), EYE MOVEMENT DISORDER (She has her eyes to the right but can move them -with strong stimulation- to the right) (seriousness criterion disability), VISION BLURRED (double and blurred vision), DIPLOPIA (double and blurred vision), MYOCLONUS (diffuse myoclonus), HYPERREFLEXIA (Diffuse hyperreflexia) and EXTENSOR PLANTAR RESPONSE (right spontaneous Babinski). The patient was treated with METHYLPREDNISOLONE SODIUM SUCCINATE (SOLUMEDROL) at a dose of 4 gram; IMMUNOGLOBULINS NOS (IMMUNOGLOBULIN I.V) (intravenous) at an unspecified dose and frequency and PREDNISONE (DELTISONE) at a dose of 80 milligram. At the time of the report, DEMENTIA (rapidly progressive dementia), COGNITIVE DISORDER (rapid loss of all cognitive functions), GENERAL PHYSICAL HEALTH DETERIORATION (general status deteriorated), CREUTZFELDT-JAKOB DISEASE (C-J disease), BALANCE DISORDER (loss of stability), SPEECH DISORDER (Does not speak), EYE MOVEMENT DISORDER (She has her eyes to the right but can move them -with strong stimulation- to the right), LIMB DISCOMFORT (Pins and needles developed in her left arm), ARTHROPATHY (left knee started to give way), CONDITION AGGRAVATED (continued to worsen), VISION BLURRED (double and blurred vision), DIPLOPIA (double and blurred vision), MYOCLONUS (diffuse myoclonus), HYPERREFLEXIA (Diffuse hyperreflexia), EXTENSOR PLANTAR RESPONSE (right spontaneous Babinski) and HYPOAESTHESIA (numbness from her left knee to her foot) outcome was unknown and GAIT DISTURBANCE (difficulty walking) was resolving. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In December 2021, Magnetic resonance imaging: no pathological findings (normal) with Gadolinium but with no pathological findings. In February 2022, CSF test: result pending (Inconclusive) sent for 14-3-3 protein considering C-J disease (results pending for another 20 days).. In February 2022, Magnetic resonance imaging: normal (normal) normal. On an unknown date, CSF test: normal (normal) normal. On an unknown date, Electroencephalogram: normal (normal) normal. On an unknown date, Electromyogram: normal (normal) normal. On an unknown date, Magnetic resonance imaging head: normal (normal) normal. On an unknown date, Magnetic resonance imaging spinal: normal (normal) normal. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. Patient had received full vaccination with Moderna and has developed a rapidly progressive dementia. The was a complaint of rapid loss of all cognitive functions. Patient was in her usual, perfect, state of health until November 2021. Four days after receiving her second dose of the Moderna vaccine she complained of numbness from her left knee to her foot. She had received the first Moderna dose on September 29. Her left knee started to give way. Pins and needles developed in her left arm. One week later she had difficulty walking described as loss of stability. Was evaluated by ENT and a neurologist. MRI of the brain and spine were normal. She received 4 grams of solumedrol and IV immunoglobulin and was discharged. According to her husband, before treatment she required walking assistance and one week after discharge, she could drive -with some difficulty- although he noted improvement. She then continued to worsen and was evaluated at a neurological institute. MRI was repeated (December) with Gadolinium but with no pathological findings. CSF, an EMG and an EEG were normal. She developed double and blurred vision. Her general status deteriorated and again was admitted for evaluation (February). MRI (again normal) and the LP were repeated, and CSF sent for 14-3-3 protein considering C-J disease (results pending for another 20 days). No seizures

have occurred. She was previously healthy and does not have history of psychiatric disease. No history of neurosurgeries. No previous medications. Did not smoke or drink and slept well. Has 3 healthy children. On exam she was brought in a wheelchair with a spastic posture arm flexed and legs straight. An NG tube has been placed. She had her eyes to the right but can move them -with strong stimulation- to the right. Does not speak or follow any commands. She has diffuse myoclonus. Diffuse hyperreflexia and a right spontaneous Babinski. All tests were normal Company comment - This is a spontaneous case concerning a 49 year old female patient with no reported medical history, who experienced the unexpected, serious (disability) events of Dementia, Cognitive disorder, Gait disturbance, General physical health deterioration, Creutzfeldt-Jakob disease, Balance disorder, Speech disorder and Eye movement disorder after receiving the second dose of mRNA-1273 vaccine. Four days after receiving her second dose of the vaccine she complained of numbness from her left knee to her foot. Pins and needles developed in her left arm. One week later she had difficulty walking described as loss of stability. She was evaluated by an ENT specialist and a neurologist. MRI of the brain and spine were normal. She received 4 grams of solumedrol and IV immunoglobulin and was discharged. Before treatment she required walking assistance and one week after discharge, she could drive with some difficulty. She then continued to worsen and was evaluated at a neurological institute. MRI was repeated with Gadolinium but with no pathological findings. CSF analysis, EMG and an EEG were normal. She developed double and blurred vision. Her general status deteriorated and again was admitted for evaluation. MRI (again normal) and the Lumbar puncture were repeated, and CSF sent for 14-3-3 protein considering Creutzfeldt-Jakob disease (results pending). No seizures occurred. She was previously healthy and does not have history of psychiatric disease or neurosurgeries. No previous medications. Did not smoke or drink and slept well. She is wheelchair bound with a spastic posture, arm flexed and legs straight. A nasogastric tube has been placed. She had her eyes to the right but can move them with strong stimulation to the right. She does not speak or follow any commands. She has diffuse myoclonus. Diffuse hyperreflexia and a right spontaneous Babinski. All other tests were normal. The benefit-risk relationship of mRNA-1273 in not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 08-Mar-2022: Added events and lab tests On 09-Mar-2022: Added treatment drugs, patient details.; Sender's Comments: This is a spontaneous case concerning a 49 year old female patient with no reported medical history, who experienced the unexpected, serious (disability) events of Dementia, Cognitive disorder, Gait disturbance, General physical health deterioration, Creutzfeldt-Jakob disease, Balance disorder, Speech disorder and Eye movement disorder after receiving the second dose of mRNA-1273 vaccine. Four days after receiving her second dose of the vaccine she complained of numbness from her left knee to her foot. Pins and needles developed in her left arm. One week later she had difficulty walking described as loss of stability. She was evaluated by an ENT specialist and a neurologist. MRI of the brain and spine were normal. She received 4 grams of solumedrol and IV immunoglobulin and was discharged. Before treatment she required walking assistance and one week after discharge, she could drive with some difficulty. She then continued to worsen and was evaluated at a neurological institute. MRI was repeated with Gadolinium but with no pathological findings. CSF analysis, EMG and an EEG were normal. She developed double and blurred vision. Her general status deteriorated and again was admitted for evaluation. MRI (again normal) and the Lumbar puncture were repeated, and CSF sent for 14-3-3 protein considering Creutzfeldt-Jakob disease (results pending). No seizures occurred. She was previously healthy and does not have history of psychiatric disease or neurosurgeries. No previous medications. Did not smoke or drink and slept well. She is wheelchair bound with a spastic posture, arm flexed and legs straight. A nasogastric tube has been placed. She had her eyes to the right but can move them with strong stimulation to the right. She does not speak or follow any commands. She has diffuse myoclonus. Diffuse hyperreflexia and a right spontaneous Babinski. All other tests were normal. The benefit-risk relationship of mRNA-1273 in not affected by this report.

| Lab Data | Current Illness | Adverse Events After Prior Vaccinations |
|---|---|---|
| Test Name: CSF; Result Unstructured Data: normal; Test Date: 202202; Test Name: CSF; Test Result: Inconclusive ; Result Unstructured Data: sent for 14-3-3 protein considering C-J disease (results pending for another 20 days).; Test Name: EEG; Result Unstructured Data: normal; Test Name: EMG; Result Unstructured Data: normal; Test Date: 202112; Test Name: MRI; Result Unstructured Data: with Gadolinium but with no pathological findings; Test Date: 202202; Test Name: MRI; Result Unstructured Data: normal; Test Name: MRI of brain; Result Unstructured Data: normal; Test Name: MRI of spine; Result Unstructured Data: normal | | |

| Medications At Time of Vaccination | History/Allergies |
|---|---|
| | |

# VAERS DETAIL

VAERS ID: 2207800

| Vaccine Type | Vaccine | Manufacturer | Lot | Dose | Route | Site |
|---|---|---|---|---|---|---|
| COVID19 | COVID19 (COVID19 (PFIZER-BIONTECH)) | PFIZER\BIONTECH | FE6975 | 2 | | |

| Event Information | | | |
|---|---|---|---|
| Patient Age | 62 | Sex | M |
| State/Territory | FR | Date Report Completed | |
| Date Vaccinated | 7/7/2021 | Date Report Received | 3/31/2022 |
| Date of Onset | 7/7/2021 | Date Died | 8/2/2021 |
| Days to Onset | 0 | | |
| Vaccine Administered By | OTH | Vaccine Purchased By | |
| Mfr/Imm Project Number | | Split Type | DEPFIZER INC202200413590 |
| Recovered | N | Serious | |

| Event Categories | |
|---|---|
| Death | Yes |
| Life Threatening | Yes |
| 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 |
|---|
| Apraxia |
| Ataxia |
| Creutzfeldt-Jakob disease |
| Interchange of vaccine products |
| Off label use |

## Adverse Event Description

Ataxia; Apraxia; Creutzfeld-Jacob disease; off label use; interchange of vaccine products; This is a spontaneous report received from a non-contactable reporter(s) (Physician) from the Agency Agency-WEB. Regulatory number: DE-PEI-202200089336. A 62 year-old male patient received bnt162b2 (COMIRNATY), administration date 07Jul2021 (Lot number: FE6975) at the age of 62 years as dose 2 (initial pfizer dose), single for covid-19 immunisation. Relevant medical history included: "Arterial hypertension" (unspecified if ongoing); "Arteriosclerosis" (unspecified if ongoing); "Hypercholesteraemia" (unspecified if ongoing). The patient's concomitant medications were not reported. Vaccination history included: VAXZEVRIA (dose 1), administration date: 06May2021, when the patient was 62 years old, for covid-19 immunisation, reaction (s): "Visual disturbance", "Light headedness", "Head tightness", "Drowsiness". The following information was reported: OFF LABEL USE (death, hospitalization, life threatening) with onset 07Jul2021, outcome "fatal", described as "off label use"; INTERCHANGE OF VACCINE PRODUCTS (death, hospitalization, life threatening) with onset 07Jul2021, outcome "fatal", described as "interchange of vaccine products"; ATAXIA (death, hospitalization, life threatening) with onset 16Jul2021, outcome "fatal", described as "Ataxia"; APRAXIA (death, hospitalization, life threatening) with onset 16Jul2021, outcome "fatal", described as "Apraxia"; CREUTZFELDT-JAKOB DISEASE (death, hospitalization, life threatening) with onset 16Jul2021, outcome "fatal", described as "Creutzfeld-Jacob disease". The patient date of death was 02Aug2021. The reported cause of death was creutzfeldt-jakob disease. It was not reported if an autopsy was performed. Relatedness of Comirnaty to events: Apraxia, Ataxia, Creutzfeld-Jacob disease as provided by Agency: C. Inconsistent causal association to immunization No follow-up attempts are possible. No further information is expected. Follow-up (25Mar2022): This is a spontaneous follow-up report received from a physician from the Agency Agency-WEB. Regulatory number: DE-PEI-202200089336. Updated information included: case has been overwritten based on information provided-reporter, patients gender and age, medical history, suspect products, events, cause and date of death overwritten.; Reported Cause(s) of Death: Creutzfeld-Jacob disease

| Lab Data | Current Illness | Adverse Events After Prior Vaccinations |
|---|---|---|
| | | |

| Medications At Time of Vaccination | History/Allergies |
|---|---|
| | Medical History/Concurrent Conditions: Arterial hypertension; Arteriosclerosis; Hypercholesteraemia |

# VAERS DETAIL

VAERS ID: 2212737

| Vaccine Type | Vaccine | Manufacturer | Lot | Dose | Route | Site |
|---|---|---|---|---|---|---|
| COVID19 | COVID19 (COVID19 (PFIZER-BIONTECH)) | PFIZER\BIONTECH | 9974818 | 2 | | |

| Event Information | | | |
|---|---|---|---|
| Patient Age | | Sex | M |
| State/Territory | FR | Date Report Completed | |
| Date Vaccinated | 5/3/2021 | Date Report Received | 4/2/2022 |
| Date of Onset | 5/3/2021 | Date Died | 3/9/2022 |
| Days to Onset | 0 | | |
| Vaccine Administered By | OTH | Vaccine Purchased By | |
| Mfr/Imm Project Number | | Split Type | NLPFIZER INC202200477927 |
| 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 |
|---|
| Creutzfeldt-Jakob disease |
| Inappropriate schedule of product administration |
| Scan |

## Adverse Event Description

Proteins have been changed into a different shape, causing cells in the brain to die; Dose 1 in May2021, dose 2 on 03May2021; This is a spontaneous report received from a contactable reporter (Consumer or other non HCP) from the Regulatory Authority. Regulatory number: NL-LRB-00799492.  A 61 year-old male patient received bnt162b2 (COMIRNATY), administration date 03May2021 (Lot number: 9974818) as dose 2, single for covid-19 immunisation. The patient's relevant medical history was not reported. No previous COVID-19 infection. There were no concomitant medications. Vaccination history included: Biontech/pfizer vaccine (comirnaty) (Dose 1), administration date: May2021, for Covid-19 immunisation. The following information was reported: CREUTZFELDT-JAKOB DISEASE (death) with onset 17Dec2021, outcome "fatal", described as "Proteins have been changed into a different shape, causing cells in the brain to die"; INAPPROPRIATE SCHEDULE OF PRODUCT ADMINISTRATION (non-serious) with onset 03May2021, outcome "unknown", described as "Dose 1 in May2021, dose 2 on 03May2021". The patient underwent the following laboratory tests and procedures: scan: unknown results. The patient date of death was 09Mar2022. The reported cause of death was creutzfeldt-jakob disease. It was not reported if an autopsy was performed. Clinical course: His complaints started with blurred vision, difficulty walking and patient could not do stuff anymore, and later patient became bedridden and eventually passed away. Patient passed away about 4 months after his complaints started.  Reporter comments: Blurred vision, staggering walking, and being able to do less and less in a short time which ended in being bedridden, and eventually death.  No follow-up attempts are possible. No further information is expected.; Reported Cause(s) of Death: Proteins have been changed into a different shape, causing cells in the brain to die

| Lab Data | Current Illness | Adverse Events After Prior Vaccinations |
|---|---|---|
| Test Name: scans; Result Unstructured Data: Test Result:unknown results | | |

| Medications At Time of Vaccination | History/Allergies |
|---|---|
| | |

# VAERS DETAIL

VAERS ID: 2223072

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

| Event Information | | | |
|---|---|---|---|
| Patient Age | 60 | Sex | F |
| State/Territory | MO | Date Report Completed | |
| Date Vaccinated | 9/21/2021 | Date Report Received | 4/8/2022 |
| Date of Onset | 9/25/2021 | Date Died | 2/1/2022 |
| Days to Onset | 4 | | |
| Vaccine Administered By | PVT | Vaccine Purchased By | |
| Mfr/Imm Project Number | | Split Type | |
| Recovered | N | Serious | |

| Event Categories | |
|---|---|
| Death | Yes |
| Life Threatening | No |
| Permanent Disability | No |
| Congenital Anomaly/Birth Defect | No |
| Hospitalized | Yes |
| Days in Hospital | 14 |
| Existing Hospitalization Prolonged | No |
| Emergency Room/Office Visit | Yes |
| Emergency Room | No |
| Office Visit | No |

| Symptoms |
|---|
| Creutzfeldt-Jakob disease |
| Death |
| Dysstasia |
| Gait inability |
| Hemiparesis |
| Tremor |

| Adverse Event Description |
|---|
| Shakiness and weakness on left side, inability to stand or walk. Diagnosed as Creutzfeldt - Jacob Disease resulting in death on 02/21/2022 |

| Lab Data | Current Illness | Adverse Events After Prior Vaccinations |
|---|---|---|
| See Healthcare records from 01/30/2022 through 02/19/2022 | | |

| Medications At Time of Vaccination | History/Allergies |
|---|---|
| SSRI, Lisinopril, Multi Vitamins | None |
| | NoneNone |

# VAERS DETAIL

VAERS ID: 2240043

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

| Event Information | | | |
|---|---|---|---|
| Patient Age | | Sex | F |
| State/Territory | FR | Date Report Completed | |
| Date Vaccinated | | Date Report Received | 4/19/2022 |
| Date of Onset | | Date Died | |
| Days to Onset | | | |
| Vaccine Administered By | OTH | Vaccine Purchased By | |
| Mfr/Imm Project Number | | Split Type | FRPFIZER INC202200552477 |
| Recovered | U | Serious | |

| Event Categories | |
|---|---|
| Death | No |
| 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 |
|---|
| Creutzfeldt-Jakob disease |
| Epilepsy |
| Headache |
| Pyrexia |
| Scan |

## Adverse Event Description

epilepsy; Creutzfeldt-Jakob disease; high fever; headache; This is a spontaneous report received from a contactable reporter(s) (Physician). A 26-year-old female patient received BNT162b2 (COMIRNATY), as dose 2, single (Batch/Lot number: unknown) for covid-19 immunisation. The patient's relevant medical history and concomitant medications were not reported. Vaccination history included: Covid-19 vaccine (DOSE 1) (UNSPECIFIED MANUFACTURER)), for covid-19 immunization. The following information was reported: EPILEPSY (hospitalization, medically significant), outcome "unknown"; CREUTZFELDT-JAKOB DISEASE (hospitalization, medically significant), outcome "unknown"; PYREXIA (hospitalization), outcome "unknown", described as "high fever"; HEADACHE (hospitalization), outcome "unknown". The patient underwent the following laboratory tests and procedures: Scan: lesions and oedemas. Clinical information: Reporter stated that patient was admitted to intensive care with high fever, headaches, epilepsy, scanner: lesions and oedemas after two and half months to three months of second comiranty vaccination. Reporter also stated that it was Creutzfeldt-Jacob disease although the hospital center does not confirm it. Reporter also says that reporter found in all her patients that the vaccine was not effective and had many side effects. The information on the batch/lot number for BNT162b2 has been requested and will be submitted if and when received.; Sender's Comments: Based on the information in the case report and a plausible temporal relationship, 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.

| Lab Data | Current Illness | Adverse Events After Prior Vaccinations |
|---|---|---|
| Test Name: scanner; Result Unstructured Data: Test Result:lesions and oedemas | | |

| Medications At Time of Vaccination | History/Allergies |
|---|---|
| | |

# VAERS DETAIL

VAERS ID: 2251071

| Vaccine Type | Vaccine | Manufacturer | Lot | Dose | Route | Site |
|---|---|---|---|---|---|---|
| COVID19 | COVID19 (COVID19 (PFIZER-BIONTECH)) | PFIZER\BIONTECH | unknown | 3 | OT | |

| Event Information | | | |
|---|---|---|---|
| Patient Age | | Sex | M |
| State/Territory | FR | Date Report Completed | |
| Date Vaccinated | 12/1/2021 | Date Report Received | 4/26/2022 |
| Date of Onset | 3/8/2022 | Date Died | 4/9/2022 |
| Days to Onset | 97 | | |
| Vaccine Administered By | OTH | Vaccine Purchased By | |
| Mfr/Imm Project Number | | Split Type | FRPFIZER INC202200612221 |
| 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 |
|---|
| Activated partial thromboplastin time |
| Antibody test |
| Blood creatinine |
| Blood test |
| Borrelia test |
| Cardiolipin antibody |
| Coma scale |
| Computerised tomogram abdomen |
| C-reactive protein |
| Creutzfeldt-Jakob disease |
| Cytomegalovirus test |
| Electroencephalogram |
| Eosinophil count |
| Epstein-Barr virus test |
| Full blood count |
| Glomerular filtration rate |
| Haemoglobin |
| Hepatitis B antibody |
| Hepatitis C virus test |
| HIV antibody |
| Investigation |
| Lymphocyte count |
| Magnetic resonance imaging head |
| Neutrophil count |
| Platelet count |
| Protein total |
| Prothrombin time |
| Rheumatoid factor |
| Syphilis |
| White blood cell count |

## Adverse Event Description

Creutzfeld-Jacob disease; This is a spontaneous report received from a contactable reporter(s) (Physician) from the Regulatory Authority. Regulatory number: FR-AFSSAPS-TS20221092. A 69-year-old male patient received BNT162b2 (COMIRNATY), in Dec2021 as dose 3 (booster), single (Lot number: unknown) intramuscular for covid-19 immunisation. The patient's relevant medical history included: "Anxiodepressive syndrome" (ongoing), notes: for approximately 30 years; "Diabetes" (ongoing), notes: Non-insulin-dependent type 2; "Hypertension arterial" (ongoing); "dyslipidemia" (unspecified if ongoing); "benign prostatic hypertrophy" (unspecified if ongoing). Concomitant medication(s) included: VILDAGLIPTIN/METFORMIN TEVA; ESCITALOPRAM; OXAZEPAM; ATORVASTATIN; PERINDOPRIL. Vaccination history included: comirnaty (1st dose, batch EX0893), administration date: 26Apr2021, for covid-19 immunisation; comirnaty (2nd dose, batch FD0785), administration date: 04Jun2021, for covid-19 immunisation. The following information was reported: CREUTZFELDT-JAKOB DISEASE (death, hospitalization) with onset 08Mar2022, outcome "fatal", described as "Creutzfeld-Jacob disease". The patient underwent the following laboratory tests and procedures: Activated partial thromboplastin time: (unspecified date) normal; Antibody test: (unspecified date) negative; (unspecified date) negative; (unspecified date) negative; (unspecified date) negative; Blood creatinine: (unspecified date) 58 umol/l; (22Mar2022) 142 umol/l; Blood test: (unspecified date) normal; Borrelia test: (unspecified date) negative; Cardiolipin antibody: (unspecified date) negative; Coma scale: (unspecified date) 15; Computerised tomogram abdomen: (31Mar2022) no abnormality, notes: Assuming paraneoplastic encephalitis: no abnormality; C-reactive protein: (unspecified date) 1.2 mg/l; Cytomegalovirus test: (unspecified date) serology in favor of an old infection (IgG+, IgM-); Electroencephalogram: (unspecified date) triphasic waves next to the right temporal leads,, notes: with periodic activity; (25Mar2022) increase and bilateralization of abnormalities; Eosinophil count: (unspecified date) 0.14 x10 9/l; Epstein-Barr virus test: (unspecified date) serology in favor of an old infection (IgG+, IgM-); Full blood count: (18Mar2022) clear liquid, 0 leukocytes, 1 red blood cell, norm, notes: clear liquid, 0 leukocytes, 1 red blood cell, normal proteinorachia 0.22 g/l, normal lactatorachia 2.3 mmol/l, high glycorachia at 7.3 mmol/l. Negative cultures. Negative multiplex PCR (Escherichia coli, Haemophilus influenzae, Listeria monocytogenes, Neisseria meningitidis, Streptococcus agalactiae, Streptococcus pneumoniae, herpes virus 1 and 2, varicella zoster virus, cytomegalovirus, HHV6, enterovirus, Parechovirus, Cryptococcus neoformans and gattii); (21Mar2022) proteinorachia (0.31 g/l), lactatorachia (2.3 mmol, notes: proteinorachia (0.31 g/l), lactatorachia (2.3 mmol/l) normal, glycorachia high at 6.52 mmol/l; Glomerular filtration rate: (unspecified date) 99 ml/min, notes: GFR CKD-EPI 99 ml/min; (22Mar2022) 43 ml/min; Haemoglobin: (unspecified date) 12 g/dl; Hepatitis B antibody: (unspecified date) HBS antigen and anti-HBC antibodies negative, anti, notes: HBS antigen and anti-HBC antibodies negative, anti-HBS antibodies positive; Hepatitis C virus test: (unspecified date) negative; HIV antibody: (unspecified date) negative; hepatic balance sheet: (unspecified date) normal; TAU/p - TAU ratio (normal high range 31.8): (unspecified date) 238.2; Lymphocyte count: (unspecified date) 2.7 x10 9/l; Magnetic resonance imaging head: (20Mar2022) symmetric hypersignals in diffusion of the caudate, notes: symmetric hypersignals in diffusion of the caudate nuclei, putamen, cortex, asymmetrically predominant on the right and mainly affecting the fronto-parietal territories. Minimal left frontal basi contralateral attack. No sequela of intracranial bleeding in peri-cerebral. No suspicious leptomeningeal or intraparenchymal enhancement. No pathological perfusion. The spectroscopic study shows an increase in choline and a relative decrease in NAA; Neutrophil count: (unspecified date) 4.8 x10 9/l; Platelet count: (unspecified date) 251 x10 9/l; Protein total (normal low range 725): (unspecified date) 720 ng/L, notes: beta amyloid proteins 1 42 weak at 720 ng/l; Protein total: (unspecified date) 26 ng/L; Protein total (normal high range 410): (unspecified date) 6265 ng/L; Prothrombin time: (unspecified date) 93 %; Rheumatoid factor: (unspecified date) negative; Syphilis: (unspecified date) negative; White blood cell count: (unspecified date) 8.4 x10 9/l. Therapeutic measures were taken as a result of creutzfeldt-jakob disease. The patient date of death was 09Apr2022. Reported cause of death: "Creutzfeld-Jacob disease". No autopsy was performed. Additional information: Protein 14.3.3 pending. Anti neuropil antibodies pending. No circulating anticoagulant. The whole clinical picture, EEG, MRI, TAU protein, even if the results of protein 14.3.3 are still pending, are very characteristic according to Creutzfeldt-Jakob disease clinicians. Familial genetic analysis started. Evolution marked rapidly by an ideomotor slowing down, persistence of agitation, delirium, onset of agnosia for objects and colors, apraxia of walking, dressing. Loss of autonomy in care and food. Death on 09Apr2022 from the consequences of this pathology No follow-up attempts are possible; information about lot/batch number cannot be obtained. No further information is expected.; Reported Cause(s) of Death: Creutzfeld-Jacob disease

| Lab Data | Current Illness | Adverse Events After Prior Vaccinations |
|---|---|---|
| Test Name: activated partial thromboplastin time; Result | Anxiodepressive syndrome | |

| | | | |
|---|---|---|---|
| Unstructured Data: Test Result:normal; Test Name: anti-ccp; Result Unstructured Data: Test Result:negative; Test Name: Antinuclear antibodies; Result Unstructured Data: Test Result:negative; Test Name: beta-2GP1 serum; Result Unstructured Data: Test Result:negative; Test Name: onco-neuronal antibodies; Result Unstructured Data: Test Result:negative; Test Name: serum creatinine; Result Unstructured Data: Test Result:58 umol/l; Test Date: 20220322; Test Name: serum creatinine; Result Unstructured Data: Test Result:142 umol/l; Test Name: ionogram; Result Unstructured Data: Test Result:normal; Test Name: borreliosis; Result Unstructured Data: Test Result:negative; Test Name: cardiolipin; Result Unstructured Data: Test Result:negative; Test Name: Glasgow; Result Unstructured Data: Test Result:15; Test Date: 20220331; Test Name: Thoraco-abdominal CT; Result Unstructured Data: Test Result:no abnormality; Comments: Assuming paraneoplastic encephalitis: no abnormality; Test Name: c-reactive protein; Result Unstructured Data: Test Result:1.2 mg/l; Test Name: cmv; Result Unstructured Data: Test Result:serology in favor of an old infection (IgG+, IgM-); Test Name: eeg; Result Unstructured Data: Test Result:triphasic waves next to the right temporal leads,; Comments: with periodic activity; Test Date: 20220325; Test Name: eeg; Result Unstructured Data: Test Result:increase and bilateralization of abnormalities; Test Name: eosinophil count; Result Unstructured Data: Test Result:0.14 x10 9/l; Test Name: ebv; Result Unstructured Data: Test Result:serology in favor of an old infection (IgG+, IgM-); Test Date: 20220318; Test Name: complete blood count; Result Unstructured Data: Test Result:clear liquid, 0 leukocytes, 1 red blood cell, norm; Comments: clear liquid, 0 leukocytes, 1 red blood cell, normal proteinorachia 0.22 g/l, normal lactatorachia 2.3 mmol/l, high glycorachia at 7.3 mmol/l. Negative cultures. Negative multiplex PCR (Escherichia coli, Haemophilus influenzae, Listeria monocytogenes, Neisseria meningitidis, Streptococcus agalactiae, Streptococcus pneumoniae, herpes virus 1 and 2, varicella zoster virus, cytomegalovirus, HHV6, enterovirus, Parechovirus, Cryptococcus neoformans and gattii).; Test Date: 20220321; Test Name: complete blood count; Result Unstructured Data: Test Result:proteinorachia (0.31 g/l), lactatorachia (2.3 mmol; Comments: proteinorachia (0.31 g/l), lactatorachia (2.3 mmol/l) normal, glycorachia high at 6.52 mmol/l.; Test Name: gfr; Result Unstructured Data: Test Result:99 ml/min; Comments: GFR CKD-EPI 99 ml/min; Test Date: 20220322; Test Name: gfr; Result Unstructured Data: Test Result:43 ml/min; Test Name: hemoglobin; Result Unstructured Data: Test Result:12 g/dl; Test Name: hbv; Result Unstructured Data: Test Result:HBS antigen and anti-HBC antibodies negative, anti; Comments: HBS antigen and anti-HBC antibodies negative, anti-HBS antibodies positive; Test Name: hcv; Result Unstructured Data: Test Result:negative; Test Name: hiv; Result Unstructured Data: Test Result:negative; Test Name: hepatic balance sheet; Result Unstructured Data: Test Result:normal; Test Name: tau/p - tau ratio; Result Unstructured Data: Test Result:238.2; Test Name: lymphocyte count; Result Unstructured Data: Test Result:2.7 x10 9/l; Test Date: 20220320; Test Name: cerebral mri; Result Unstructured Data: Test Result:symmetric hypersignals in diffusion of the caudate; Comments: symmetric hypersignals in diffusion of the caudate nuclei, putamen, cortex, asymmetrically predominant on the right and mainly affecting the fronto-parietal territories. Minimal left frontal basi contralateral attack. No sequela of intracranial bleeding in peri-cerebral. No suspicious leptomeningeal or intraparenchymal enhancement. No pathological perfusion. The spectroscopic study shows an increase in choline and a relative decrease in NAA.; Test Name: neutrophil count; Result Unstructured Data: Test Result:4.8 x10 9/l; Test Name: platelet count; Result Unstructured Data: Test Result:251 x10 9/l; Test Name: beta amyloid protein; Result Unstructured Data: Test Result:720 | (for approximately 30 years); Diabetes (Non-insulin-dependent type 2); Hypertension arterial | | |

| | | |
|---|---|---|
| ng/L; Comments: beta amyloid proteins 1 42 weak at 720 ng/l; Test Name: phospho tau protein; Result Unstructured Data: Test Result:26 ng/L; Test Name: tau protein; Result Unstructured Data: Test Result:6265 ng/L; Test Name: pt; Test Result:  93 %; Test Name: rheumatoid factor; Result Unstructured Data: Test Result:negative; Test Name: syphilis; Result Unstructured Data: Test Result:negative; Test Name: leukocyte; Result Unstructured Data: Test Result:8.4 x10 9/l | | |

| Medications At Time of Vaccination | History/Allergies |
|---|---|
| VILDAGLIPTIN/METFORMIN TEVA; ESCITALOPRAM; OXAZEPAM; ATORVASTATIN; PERINDOPRIL | Medical History/Concurrent Conditions: Benign prostatic hypertrophy; Dyslipidemia |

# VAERS DETAIL

VAERS ID: 2251224

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

| Event Information | | | |
|---|---|---|---|
| Patient Age | 68 | Sex | F |
| State/Territory | FR | Date Report Completed | |
| Date Vaccinated | 7/23/2021 | Date Report Received | 4/26/2022 |
| Date of Onset | 8/1/2021 | Date Died | |
| Days to Onset | 9 | | |
| Vaccine Administered By | OTH | Vaccine Purchased By | |
| Mfr/Imm Project Number | | Split Type | JPPFIZER INC202200592190 |
| Recovered | N | Serious | |

| Event Categories | |
|---|---|
| Death | No |
| Life Threatening | No |
| Permanent Disability | No |
| Congenital Anomaly/Birth Defect | No |
| Hospitalized | Yes |
| Days in Hospital | 133 |
| Existing Hospitalization Prolonged | No |
| Emergency Room/Office Visit | No |
| Emergency Room | No |
| Office Visit | No |

| Symptoms |
|---|
| Altered state of consciousness |
| Bedridden |
| Creutzfeldt-Jakob disease |
| Dizziness |
| Head discomfort |
| Magnetic resonance imaging |

## Adverse Event Description

Creutzfeldt-Jakob disease; Consciousness disturbed; Heaviness of head; Dizziness; Bedridden; This is a spontaneous report received from a contactable reporter(s) (Physician) from Regulatory Authority. Regulatory number: v2210000551. A 68-year and 6-month female patient received BNT162b2 (COMIRNATY), on 23Jul2021 as dose 1, single (Batch/Lot number: unknown) at the age of 68 years for covid-19 immunisation. The patient's relevant medical history and concomitant medications were not reported. 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). The following information was reported: BEDRIDDEN (non-serious) with onset Aug2021, outcome "recovered with sequelae" (18Feb2022); ALTERED STATE OF CONSCIOUSNESS (medically significant) with onset Aug2021, outcome "recovered with sequelae" (18Feb2022), described as "Consciousness disturbed"; CREUTZFELDT-JAKOB DISEASE (hospitalization, medically significant) with onset Aug2021, outcome "recovered with sequelae" (18Feb2022); DIZZINESS (non-serious) with onset Aug2021, outcome "recovered with sequelae" (18Feb2022); ENTERAL NUTRITION (non-serious) with onset Aug2021, outcome "recovered with sequelae" (18Feb2022), described as "Gavage"; HEAD DISCOMFORT (non-serious) with onset Aug2021, outcome "recovered with sequelae" (18Feb2022), described as "Heaviness of head". The patient was hospitalized for creutzfeldt-jakob disease (start date: 08Oct2021, discharge date: 18Feb2022, hospitalization duration: 133 day(s)). The patient underwent the following laboratory tests and procedures: Magnetic resonance imaging: (05Oct2021) High-signal changes in the cerebral cortex. Clinical course: On 23Jul2021 (the day of vaccination), the patient received the first single dose of BNT162B2 (COMIRNATY) via an unspecified route of administration for COVID-19 immunization. On 08Oct2021 (77 days after the vaccination), the patient was admitted to the hospital. On 18Feb2022 (210 days after the vaccination), the patient discharged from hospital. On 18Feb2022 (210 days after the vaccination), the outcome of the event was recovered with sequel. (Consciousness disturbed (JCS 200-300 degree), Gavage). From Aug2021, the patient began to feel heaviness of head and dizziness and difficulty in seeing, and gradually his family became aware of his forgetfulness and dizziness. On 24Sep2021 of the same year, she was treated in the cerebral neurology department of another hospital. She was treated at this hospital on 05Oct2021 after a computerized MRI diffusion-emphasized image showed High-signal changes in the cerebral cortex. She was hospitalized from the 8th of the same month, temporarily transferred to the privacy Epidemiology Center for examination, and readmitted to our hospital in November. The patient was diagnosed with Creutzfeldt-Jakob disease and her consciousness disturbed progressed to the point where he became bedridden and had to be gavage. On 18Feb2022, she was transferred to a (privacy) hospital to continue her inpatient care. The reporting physician the event as serious (Hospitalized) and the causality between the event and BNT162B2 as unassessable. Other possible cause of the event such as any other diseases was/were usually solitary Creutzfeldt-Jakob disease. The reporting physician commented as follows: The patient's family strongly wished to be notified. The results of the examination and the observation period are consistent with a solitary case of Creutzfeldt-Jakob disease. No follow-up attempts are possible; information about lot/batch number cannot be obtained. No further information is expected.

| Lab Data | Current Illness | Adverse Events After Prior Vaccinations |
|---|---|---|
| Test Date: 20211005; Test Name: MRI; Result Unstructured Data: Test Result:High-signal changes in the cerebral cortex | | |

| Medications At Time of Vaccination | History/Allergies |
|---|---|
| | |

# VAERS DETAIL

VAERS ID: 2255278

| Vaccine Type | Vaccine | Manufacturer | Lot | Dose | Route | Site |
|---|---|---|---|---|---|---|
| COVID19 | COVID19 (COVID19 (MODERNA)) | MODERNA | | 3 | OT | |

| Event Information | | | |
|---|---|---|---|
| Patient Age | 48 | Sex | F |
| State/Territory | FR | Date Report Completed | |
| Date Vaccinated | 1/25/2022 | Date Report Received | 4/28/2022 |
| Date of Onset | 1/27/2022 | Date Died | |
| Days to Onset | 2 | | |
| Vaccine Administered By | UNK | Vaccine Purchased By | |
| Mfr/Imm Project Number | | Split Type | ATMODERNATX, INC.MOD20225 |
| Recovered | N | Serious | |

| Event Categories | |
|---|---|
| Death | No |
| 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 |
|---|
| Creutzfeldt-Jakob disease |
| Visual impairment |

## Adverse Event Description

Creutzfeld-Jakob; blurred vision; This case was received via regulatory authority (Reference number: AT-BASGAGES-2022-049643) on 26-Apr-2022 and was forwarded to Moderna on 26-Apr-2022. This regulatory authority case was reported by a consumer and describes the occurrence of VISUAL IMPAIRMENT (blurred vision) and CREUTZFELDT-JAKOB DISEASE (Creutzfeld-Jakob) in a 48-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. No Medical History information was reported. On 25-Jan-2022, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 27-Jan-2022, the patient experienced VISUAL IMPAIRMENT (blurred vision) (seriousness criterion medically significant) and CREUTZFELDT-JAKOB DISEASE (Creutzfeld-Jakob) (seriousness criterion hospitalization). At the time of the report, VISUAL IMPAIRMENT (blurred vision) and CREUTZFELDT-JAKOB DISEASE (Creutzfeld-Jakob) had not resolved. No concomitant products were reported. No treatment drugs were reported It was reported that patient was very healthy until 25.Jan.2022. Company comment This regulatory authority case concerns a 48-year-old female patient, with no reported medical history, who experienced the unexpected serious events of VISUAL IMPAIRMENT (medically significant) and CREUTZFELDT-JAKOB DISEASE (hospitalization), which occurred 3 days after receiving the third dose of mRNA-1273 vaccine. It was reported that patient was very healthy until she received the third dose. No further clinical or diagnostic information was disclosed. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.; Sender's Comments: This regulatory authority case concerns a 48-year-old female patient, with no reported medical history, who experienced the unexpected serious events of VISUAL IMPAIRMENT (medically significant) and CREUTZFELDT-JAKOB DISEASE (hospitalization), which occurred 3 days after receiving the third dose of mRNA-1273 vaccine. It was reported that patient was very healthy until she received the booster dose. No further clinical or diagnostic information was disclosed. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.

| Lab Data | Current Illness | Adverse Events After Prior Vaccinations |
|---|---|---|
| | | |

| Medications At Time of Vaccination | History/Allergies |
|---|---|
| | |

# VAERS DETAIL

VAERS ID: 2256142

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

| Event Information | | | |
|---|---|---|---|
| Patient Age | 70 | Sex | F |
| State/Territory | | Date Report Completed | |
| Date Vaccinated | 2/16/2021 | Date Report Received | 4/28/2022 |
| Date of Onset | | Date Died | 8/2/2021 |
| Days to Onset | | | |
| Vaccine Administered By | UNK | Vaccine Purchased By | |
| Mfr/Imm Project Number | | Split Type | USMODERNATX, INC.MOD20225 |
| Recovered | N | Serious | |

| Event Categories | |
|---|---|
| Death | Yes |
| Life Threatening | No |
| Permanent Disability | Yes |
| 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 |
|---|
| Creutzfeldt-Jakob disease |

## Adverse Event Description

Creutzfeldt-Jakob Disease ,fatal degenerative brain disorder , and her brain degenerated until she passed away on Aug. 2, 2021; This spontaneous case was reported by a consumer and describes the occurrence of CREUTZFELDT-JAKOB DISEASE (Creutzfeldt-Jakob Disease ,fatal degenerative brain disorder , and her brain degenerated until she passed away on Aug. 2, 2021) in a 70-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. No Medical History information was reported. On 16-Feb-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 17-Mar-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On an unknown date, the patient experienced CREUTZFELDT-JAKOB DISEASE (Creutzfeldt-Jakob Disease ,fatal degenerative brain disorder , and her brain degenerated until she passed away on Aug. 2, 2021) (seriousness criteria death, disability and medically significant). The patient died on 02-Aug-2021. The reported cause of death was creutzfeldt-jakob disease ,fatal degenerative brain disorder , and her brain degenerated until she passed away on aug. 2, 2021. It is unknown if an autopsy was performed. No concomitant medications reported by reporter. After Moderna vaccination patient felt different and patient developed the symptoms of sporadic Creutzfeldt-Jakob Disease (CJD) included that the Patient developed numbness that spread throughout the entire left side of her body, blindness and hearing loss. Patient lost the ability to walk and communicate, and her brain degenerated until she passed away on 02-Aug-2021. Patient was died just five months after receiving her second dose of Moderna. No treatment medications provided by the reporter. Company Comment: This spontaneous case concerns a 70-year-old female patient with no medical history reported, who experienced the unexpected serious event of Creutzfeldt-Jakob Disease, that occurred on an unknown date after receiving the second dose of mRNA-1273 vaccine (latency between vaccine and event cannot be established), that led to the eventual demise of the patient and assessed as disabling and medically significant. Patient developed numbness that spread throughout the left side of the body and a clinical course of blindness, deafness, loss of ability to walk and communicate, and brain degeneration. Patient reportedly died from the rapid and fatal degenerative brain disorder Creutzfeldt-Jakob Disease 4 months and 16 days post vaccination. However, an autopsy report was not provided. Previously received first dose of COVID-19 vaccine was also mRNA-1273 vaccine (interval between two doses is 29 days). The benefit-risk relationship of mRNA-1273 Vaccine is not affected by this report.; Sender's Comments: This spontaneous case concerns a 70-year-old female patient with no medical history reported, who experienced the unexpected serious event of Creutzfeldt-Jakob Disease, that occurred on an unknown date after receiving the second dose of mRNA-1273 vaccine (latency between vaccine and event cannot be established), that led to the eventual demise of the patient and assessed as disabling and medically significant. Patient developed numbness that spread throughout the left side of the body and a clinical course of blindness, deafness, loss of ability to walk and communicate, and brain degeneration. Patient reportedly died from the rapid and fatal degenerative brain disorder Creutzfeldt-Jakob Disease 4 months and 16 days post vaccination. However, an autopsy report was not provided. Previously received first dose of COVID-19 vaccine was also mRNA-1273 vaccine (interval between two doses is 29 days). The benefit-risk relationship of mRNA-1273 Vaccine is not affected by this report.; Reported Cause(s) of Death: Creutzfeldt-Jakob Disease ,fatal degenerative brain disorder , and her brain degenerated until she passed away on Aug. 2, 2021

| Lab Data | Current Illness | Adverse Events After Prior Vaccinations |
|---|---|---|
| | | |

| Medications At Time of Vaccination | History/Allergies |
|---|---|
| | |

# VAERS DETAIL

VAERS ID: 2260958

| Vaccine Type | Vaccine | Manufacturer | Lot | Dose | Route | Site |
|---|---|---|---|---|---|---|
| COVID19 | COVID19 (COVID19 (PFIZER-BIONTECH)) | PFIZER\BIONTECH | Unknown | 3 | OT | |

| Event Information | | | |
|---|---|---|---|
| Patient Age | 82 | Sex | M |
| State/Territory | FR | Date Report Completed | |
| Date Vaccinated | 9/28/2021 | Date Report Received | 5/3/2022 |
| Date of Onset | 12/1/2021 | Date Died | 1/23/2022 |
| Days to Onset | 64 | | |
| Vaccine Administered By | OTH | Vaccine Purchased By | |
| Mfr/Imm Project Number | | Split Type | FRPFIZER INC202200635691 |
| 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 |
|---|
| Cardiovascular examination |
| Computerised tomogram head |
| Creutzfeldt-Jakob disease |
| Lumbar puncture |
| Magnetic resonance imaging |
| Mini mental status examination |
| Neurological examination |
| Physical examination |
| SARS-CoV-2 test |
| Specialist consultation |

## Adverse Event Description

Creutzfeld-Jacob disease; This is a spontaneous report received from a contactable reporter(s) (Consumer or other non HCP) from the Agency Agency-WEB. Regulatory number: FR-AFSSAPS-MA20221653. An 82-year-old male patient received BNT162b2 (COMIRNATY), on 28Sep2021 as dose 3 (booster), single (Lot number: Unknown) at the age of 82 years intramuscular for covid-19 immunisation. The patient's relevant medical history included: "Embolism pulmonary" (unspecified if ongoing), notes: pulmonary embolism on deep vein thrombosis treated with Previscan; "deep vein thrombosis" (unspecified if ongoing); "Occasional alcohol" (unspecified if ongoing). The patient's concomitant medications were not reported. Vaccination history included: comirnaty (dose 1), administration date: 04Mar2021, for covid-19 immunisation; comirnaty (dose 2), administration date: 12Apr2021, for covid-19 immunisation. The following information was reported: CREUTZFELDT-JAKOB DISEASE (death) with onset Dec2021, outcome "fatal", described as "Creutzfeld-Jacob disease". The event "creutzfeld-jacob disease" required emergency room visit. The patient underwent the following laboratory tests and procedures: Cardiovascular examination: (unspecified date) normal, no edema of the lower limbs, notes: no sign of deep vein thrombosis, regular restoration of continuity, peripheral pulses well perceived; Computerised tomogram head: (unspecified date) no hemorrhage, no mass syndrome, notes: no sign in favor of intracranial hypertension; Lumbar puncture: (unspecified date) Positive 14-3-3 protein, notes: tau protein in the CSF; Magnetic resonance imaging: (16Dec2021) diffusion restriction anomaly of, notes: of the right fronto-parieto-temporal cortex and at least the left; Mini mental status examination: (Nov2021) 23/30, notes: cognitive impairment was labeled mild hippocampal; Neurological examination: (unspecified date) no motor deficit, notes: plantar reflex in flexion, no tone disorder, no vestibular or cerebellar syndrome (exam at the entrance); Physical examination: (unspecified date) conscious patient, not oriented in time and space, notes: stupefaction, psychomotor retardation, apraxic; SARS-CoV-2 test: (10Jan2022) positive; Specialist consultation: (unspecified date) normal; (unspecified date) normal; (unspecified date) normal. The patient date of death was 23Jan2022. The reported cause of death was unknown. Clinical course: local number 22-2407, MA20221653. The patient's son declares that his father was in very good health before the vaccination, independent in movement on daily basis. No stay in a foreign country in the last 12 months. At the beginning of Dec2021, appearance of neurological disorders. On the night of 12Dec2021/13Dec2021: hallucinations: the patient sees people in his home. Stay in the emergency room then in geriatrics for management of cognitive disorders such as hallucinations and desire for hetero-aggressive acts. Dementia assessment in progress, neuropsychological assessment not practical due to the patient's condition. Positive 14-3-3 protein suggesting a diagnosis of Creutzfeld Jacob's disease, confirmation by the neurologist, result of pending genetic research, uncertain prognosis. The declarant specifies that, according to the medical profession, it is an acquired form, and not genetic, without further information. Evolution: Gradual deterioration of the patient, implementation of end-of-life support, death of the patient on 23Jan2022. No brain sample for confirmation of the diagnosis (refusal of the family). No follow-up attempts are possible; information about lot/batch number cannot be obtained. No further information is expected.; Sender's Comments: Linked Report(s) : FR-PFIZER INC-202200641565 same patient, LOE/booster dose report; Reported Cause(s) of Death: Unknown cause of death

| Lab Data | Current Illness | Adverse Events After Prior Vaccinations |
|---|---|---|
| Test Name: Cardiovascular examination; Result Unstructured Data: Test Result:normal, no edema of the lower limbs; Comments: no sign of deep vein thrombosis, regular restoration of continuity, peripheral pulses well perceived; Test Name: Computerised tomogram head; Result Unstructured Data: Test Result:no hemorrhage, no mass syndrome; Comments: no sign in favor of intracranial hypertension; Test Name: Lumbar puncture; Result Unstructured Data: Test Result:Positive 14-3-3 protein; Comments: tau protein in the CSF; Test Date: 20211216; Test Name: Magnetic resonance imaging; Result Unstructured Data: Test Result:diffusion restriction anomaly of; Comments: of the right fronto-parieto-temporal cortex and at least the left; Test Date: 202111; Test Name: Mini mental status examination; Result Unstructured Data: Test Result:23/30; Comments: cognitive impairment was labeled mild hippocampal; Test Name: Neurological examination; Result Unstructured Data: Test Result:no motor deficit; Comments: plantar reflex in flexion, no tone disorder, no vestibular or cerebellar syndrome (exam at the entrance); Test Name: Physical examination; Result Unstructured Data: Test Result:conscious patient, not oriented in time and space; Comments: stupefaction, psychomotor retardation, apraxic; Test Date: 20220110; Test Name: SARS-CoV-2 test; Test Result: Positive ; Test Name: abdominal examination; Result Unstructured Data: Test Result:normal; Test Name: pulmonary examination; Result Unstructured Data: Test Result:normal; Test Name: urinary examination; Result Unstructured Data: Test Result:normal | | |

| Medications At Time of Vaccination | History/Allergies |
|---|---|
| | Medical History/Concurrent Conditions: Alcohol use; Deep vein thrombosis; Embolism pulmonary (pulmonary embolism on deep vein thrombosis treated with Previscan) |

# VAERS DETAIL

VAERS ID: 2267942

| Vaccine Type | Vaccine | Manufacturer | Lot | Dose | Route | Site |
|---|---|---|---|---|---|---|
| COVID19 | COVID19 (COVID19 (PFIZER-BIONTECH)) | PFIZER\BIONTECH | 1D020A | 2 | | |

| Event Information | | | |
|---|---|---|---|
| Patient Age | 74 | Sex | F |
| State/Territory | FR | Date Report Completed | |
| Date Vaccinated | 8/5/2021 | Date Report Received | 5/9/2022 |
| Date of Onset | | Date Died | 10/8/2021 |
| Days to Onset | | | |
| Vaccine Administered By | OTH | Vaccine Purchased By | |
| Mfr/Imm Project Number | | Split Type | DEPFIZER INC202200663761 |
| 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 |
|---|
| Aphasia |
| Blood pressure abnormal |
| Creutzfeldt-Jakob disease |
| Disturbance in attention |
| Dizziness |
| Dysphagia |
| Gait inability |
| Interchange of vaccine products |
| Off label use |
| Tachycardia |
| Thrombocytopenia |

## Adverse Event Description

off labe use; interchange of vaccine products; development of CJD (Creutzfeldt-Jakob disease); brain fog; finding words; changing blood pressure, too high, too low; Heart palpitations; loss of ability to walk; thrombocytopes; dizziness; loss of ability to swallowing; This is a spontaneous report received from a non-contactable reporter(s) (Consumer or other non HCP) from the Regulatory Authority. Regulatory number: DE-PEI-CADR2022293438. Other Case identifier(s): DE-CADRPEI-2022293438, DE-PEI-202200106508.  A 74-year-old female patient received BNT162b2 (COMIRNATY), on 05Aug2021 as dose 2 (initial pfizer dose), 0.3 ml single (Lot number: 1D020A) at the age of 74 years for covid-19 immunisation. The patient's relevant medical history included: "Anaemia" (ongoing); "Lipo-lymphedema" (ongoing); "Cardiac insufficiency" (ongoing). The patient's concomitant medications were not reported. Vaccination his-tory included: vaxzevria (1st dose), administration date: 04May2021, for COVID-19 immunisation. The following information was reported: OFF LABEL USE (death), outcome "fatal", described as "off label use"; INTERCHANGE OF VACCINE PRODUCTS (death), outcome "fatal"; CREUTZFELDT-JAKOB DISEASE (death), outcome "fatal", described as "development of CJD (Creutzfeldt-Jakob disease)"; DISTURBANCE IN ATTENTION (death), outcome "fatal", described as "brain fog"; APHASIA (death), outcome "fatal", described as "finding words"; BLOOD PRESSURE ABNORMAL (death), outcome "fatal", described as "changing blood pressure, too high, too low"; TACHYCARDIA (death), outcome "fatal", described as "Heart palpitations"; GAIT INABILITY (death), outcome "fatal", described as "loss of ability to walk"; THROMBOCYTOPENIA (medically significant), outcome "unknown", described as "thrombocytopes"; DIZZINESS (non-serious), outcome "unknown"; DYSPHAGIA (non-serious), outcome "unknown", described as "loss of ability to swallowing". The patient date of death was 08Oct2021. Reported cause of death: "Creutzfeld-Jacob disease", "Disturbance in attention", "Aphasia", "Blood pressure abnormal", "Tachycardia", "Gait inability". It was not reported if an autopsy was performed. It was reported that, information on risk factors or previous illnesses. Heart failure, anemia, lipolymphoedema. Date of death 08Oct2021. Death by Creutzfeldt Jakob 8 weeks after the 2nd vaccination. Between the 2nd vaccination and death there is a continuous decline in skills. Swallow, Talk, Walk, Speak. Full description as reported for all reported events: Heart palpitations, brain fog, thrombocytopes., changing blood pressure, too high, too low, finding words, dizziness, loss of ability to walk, swallowing, speech, development of CJD (Creutzfeldt-Jakob disease), death. Assessment D. Unclassifiable by PEI for: Concentration ability impaired, Tachycardia, Word finding difficulty, Blood pressure abnormal, Gait inability, Creutzfeld-Jacob disease.  Sender Comment: Do you or the person concerned have any known allergies? If yes, which? No.  No follow-up attempts are possible. No further information is expected.; Reported Cause(s) of Death: Disturbance in attention; Aphasia; Blood pressure abnormal; Tachycardia; Gait inability; Creutzfeld-Jacob disease

| Lab Data | Current Illness | Adverse Events After Prior Vaccinations |
|---|---|---|
| | Anaemia; Cardiac insufficiency; Lipo-lymphedema | |

| Medications At Time of Vaccination | History/Allergies |
|---|---|
| | |

# VAERS DETAIL

VAERS ID: 2270400

| Vaccine Type | Vaccine | Manufacturer | Lot | Dose | Route | Site |
|---|---|---|---|---|---|---|
| COVID19 | COVID19 (COVID19 (PFIZER-BIONTECH)) | PFIZER\BIONTECH | FC0681 | 2 | | |

| Event Information | | | |
|---|---|---|---|
| Patient Age | | Sex | F |
| State/Territory | FR | Date Report Completed | |
| Date Vaccinated | 5/25/2021 | Date Report Received | 5/11/2022 |
| Date of Onset | 12/1/2021 | Date Died | 1/15/2022 |
| Days to Onset | 190 | | |
| Vaccine Administered By | OTH | Vaccine Purchased By | |
| Mfr/Imm Project Number | | Split Type | SEPFIZER INC202200673652 |
| 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 |
|---|
| Autopsy |
| Creutzfeldt-Jakob disease |
| Electroencephalogram |
| Investigation |
| Magnetic resonance imaging |

## Adverse Event Description

Creutzfeldt-Jakob disease; This is a spontaneous report received from a contactable reporter(s) (Physician) from the Agency Agency-WEB. Regulatory number: SE-MPA-2022-013996. Other Case identifier(s): SE-VISMA-1649937722956. A 70-year-old female patient received BNT162b2 (COMIRNATY), on 25May2021 as dose 2, single (Lot number: FC0681) for covid-19 immunisation. The patient's relevant medical history included: "Chronic obstructive pulmonary disease" (ongoing); "Rheumatoid arthritis" (ongoing); "Asthma" (ongoing). Concomitant medication(s) included: METHOTREXATE ORION [METHOTREXATE SODIUM], start date: 28Apr2021; BRICANYL TURBUHALER, start date: 09Mar2021; FLUTIDE [FLUTICASONE PROPIONATE], start date: 09Mar2021; RISEDRONAT ACTAVIS, start date: 15Jan2021; ONBREZ BREEZHALER; PANODIL; SERTRALIN BLUEFISH. Past drug history included: Nsaid, reaction(s): "Adverse drug reaction", notes: She have had an adverse drug reaction when using NSAID at an unknown time. Vaccination history included: comirnaty (1st dose, Lot: unknown), administration date: 15Apr2021, for COVID-19 immunisation. The following information was reported: CREUTZFELDT-JAKOB DISEASE (death, hospitalization) with onset 01Dec2021, outcome "fatal". The patient underwent the following laboratory tests and procedures: Electroencephalogram: unknown results; lumbar punction: unknown results; Magnetic resonance imaging: unknown results; Autopsy: Creutzfeldt-Jakob disease (CJD) histiotype MM/MV1,, notes: Creutzfeldt-Jakob disease (CJD) histiotype MM/MV1, 14-3-3 was found in the spinal liquor and finally a high quota of Tau/P-tau. The patient date of death was 15Jan2022. Reported cause of death: "Creutzfeldt-Jakob disease". The autopsy revealed "the neuropathological autopsy report revealed signs as seen in creutzfeldt-jakob disease (cjd) histiotype mm/mv1, 14-3-3 was found in the spinal liquor and finally a high quota of tau/p-tau." (creutzfeldt-jakob disease). Clinical course information: She have had an adverse drug reaction when using NSAID at an unknown time. Reported suspected adverse event was Creutzfeldt-Jakob disease debuting 190 days after the second dose of Comirnaty. According to the reporter the woman suddely went poorly with cognitive difficulties, bad sleep, anxiety and a for her abnormal behaviour. The first signs of Creutzfeldt-Jakob disease debuted earlier the same day as dose 3 of Comirnaty was administered, prior to the vaccination. The woman was brougt to the hospital after an unknown time period due to sessions of cramps, followed by progressive neurological deterioration of higher cerebral functions. She passed away 235 days (approximately 7,5 months) after the second dose was administered. By then they had perfomed MRI, lumbar punction, EEG etc. The neuropathological autopsy report revealed signs as seen in Creutzfeldt-Jakob disease (CJD) histiotype MM/MV1, 14-3-3 was found in the spinal liquor and finally a high quota of Tau/P-tau. CJD was reported as the cause of death. No follow-up attempts are possible. No further information is expected.; Reported Cause(s) of Death: Creutzfeldt-Jakob disease; Autopsy-determined Cause(s) of Death: The neuropathological autopsy report revealed signs as seen in Creutzfeldt-Jakob disease (CJD) histiotype MM/MV1, 14-3-3 was found in the spinal liquor and finally a high quota of Tau/P-tau.

| Lab Data | Current Illness | Adverse Events After Prior Vaccinations |
|---|---|---|
| Test Name: EEG etcetera; Result Unstructured Data: Test Result:unknown results; Test Name: lumbar punction; Result Unstructured Data: Test Result:unknown results; Test Name: MRI; Result Unstructured Data: Test Result:unknown results; Test Name: neuropathological autopsy; Result Unstructured Data: Test Result:Creutzfeldt-Jakob disease (CJD) histiotype MM/MV1,; Comments: Creutzfeldt-Jakob disease (CJD) histiotype MM/MV1, 14-3-3 was found in the spinal liquor and finally a high quota of Tau/P-tau | Asthma; Chronic obstructive pulmonary disease; Rheumatoid arthritis | |

| Medications At Time of Vaccination | History/Allergies |
|---|---|
| METHOTREXATE ORION [METHOTREXATE SODIUM]; BRICANYL TURBUHALER; FLUTIDE [FLUTICASONE PROPIONATE]; RISEDRONAT ACTAVIS; ONBREZ BREEZHALER; PANODIL; SERTRALIN BLUEFISH | |

# VAERS DETAIL

VAERS ID: 2296679

| Vaccine Type | Vaccine | Manufacturer | Lot | Dose | Route | Site |
|---|---|---|---|---|---|---|
| COVID19 | COVID19 (COVID19 (PFIZER-BIONTECH)) | PFIZER\BIONTECH | FF2834 | 3 | OT | |

| Event Information | | | |
|---|---|---|---|
| Patient Age | | Sex | M |
| State/Territory | FR | Date Report Completed | |
| Date Vaccinated | 11/18/2021 | Date Report Received | 5/26/2022 |
| Date of Onset | 12/2/2021 | Date Died | |
| Days to Onset | 14 | | |
| Vaccine Administered By | OTH | Vaccine Purchased By | |
| Mfr/Imm Project Number | | Split Type | ATPFIZER INC202200751892 |
| 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 | Yes |

| Symptoms |
|---|
| Aspiration |
| Ataxia |
| Autopsy |
| Creutzfeldt-Jakob disease |
| CSF test |
| Dementia with Lewy bodies |
| Dizziness |
| Dysphagia |
| Fall |
| Gait disturbance |
| General physical health deterioration |

## Adverse Event Description

Suspected aspiration in dysphagia; Suspected aspiration in dysphagia; recurrent falls; further deterioration with complete need for care; finally diagnosed with Creutzfeldt-Jakob disease; in case of deterioration from Feb2022 neurolog. Clarification with suspected Lewy body dementia; About 1 week after the 3rd vaccination (Comirnaty), dizziness attacks; ataxic gait disorders; ataxic gait disorders; This is a spontaneous report received from a contactable reporter(s) (Physician) from the Regulatory Authority, number: AT-BASGAGES-2022-061837 (BASGAGES). An 80-year-old male patient received BNT162b2 (COMIRNATY), on 18Nov2021 as dose 3 (booster), single (Lot number: FF2834) intramuscular for covid-19 immunisation. The patient's relevant medical history included: "Intervertebral disc prolapse" (unspecified if ongoing), notes: disc prolapse lumbar spine; "Barrett's esophagitis" (unspecified if ongoing), notes: suspected Barrett's mucosa; "Meningioma" (unspecified if ongoing), notes: small meningioma cerebellopontine angle left; "Prostate cancer", start date: Aug2021 (not ongoing); "Condition after surgery prostate carcinoma", start date: Aug2021 (not ongoing). The patient's concomitant medications were not reported. Vaccination history included: Covid-19 vaccine (DOSE 1, MANUFACTURER UNKNOWN), for Covid-19 immunization; Covid-19 vaccine (DOSE 2, MANUFACTURER UNKNOWN), for Covid-19 immunization. The following information was reported: DIZZINESS (medically significant) with onset 02Dec2021, outcome "not recovered", described as "About 1 week after the 3rd vaccination (Comirnaty), dizziness attacks"; ATAXIA (medically significant), GAIT DISTURBANCE (medically significant) all with onset 02Dec2021, outcome "not recovered" and all described as "ataxic gait disorders"; DEMENTIA WITH LEWY BODIES (medically significant) with onset Feb2022, outcome "not recovered", described as "in case of deterioration from Feb2022 neurolog. Clarification with suspected Lewy body dementia"; CREUTZFELDT-JAKOB DISEASE (death, medically significant) with onset May2022, outcome "fatal", described as "finally diagnosed with Creutzfeldt-Jakob disease"; ASPIRATION (hospitalization), DYSPHAGIA (hospitalization) all with onset 2022, outcome "not recovered" and all described as "Suspected aspiration in dysphagia"; FALL (medically significant), outcome "not recovered", described as "recurrent falls"; GENERAL PHYSICAL HEALTH DETERIORATION (medically significant), outcome "unknown", described as "further deterioration with complete need for care". The event "about 1 week after the 3rd vaccination (comirnaty), dizziness attacks" required physician office visit. The patient underwent the following laboratory tests and procedures: Autopsy: (May2022) unknown results; CSF test: (May2022) suspected Creutzfeldt-Jakob disease. The patient date of death was unknown. Reported cause of death: "Creutzfeldt-Jakob disease". Clinical course: From Dec2021 (about 1 week after the 3rd vaccination) dizziness attacks and atactic gait disturbance, initially internist. Polyneuropathy suspected with worsening from Feb2022 neurological clarification with suspected Lewy body dementia, liquorpunctate result still pending, further deterioration with complete need for care, finally inpatient admission due to Suspected aspiration in dysphagia. FU information on 19May2022: an autopsy was performed due to of the specifications of the Epidemic Act and was carried out, the autopsy result has not yet been included because, according to information from the pathology department, the neuropathological diagnosis in the corresponding reference center takes a few months(!) (at least the transmission of the diagnosis). Clinically, the suspected CJD was given as the cause of death (this was clinically consistent with the laboratory chemical liquor tests). Text for Relevant Medical History and Concurrent Conditions (not including reaction / event): Condition after surgery prostate carcinoma (Aug2021), small meningioma cerebellopontine angle left, disc prolapse lumbar spine, suspected Barrett's mucosa. Event: Lightheadedness / Event as reported by primary source: About 1 week after the 3rd vaccination (Comirnaty), dizziness attacks and ataxic gait disturbances with recurrent falls occurred. Creutzfeldt-Jakob disease Stop Date/Time: 11May2022, Outcome: Fatal. No follow-up attempts are possible. No further information is expected.; Reported Cause(s) of Death: Creutzfeldt-Jakob disease

| Lab Data | Current Illness | Adverse Events After Prior Vaccinations |
|---|---|---|
| Test Date: 202205; Test Name: Autopsy results; Result Unstructured Data: Test Result:unknown results; Test Date: 202205; Test Name: liquorpunctate results; Result Unstructured Data: Test Result:suspected Creutzfeldt-Jakob disease | | |

| Medications At Time of Vaccination | History/Allergies |
| --- | --- |
| | Medical History/Concurrent Conditions: Barrett's esophagitis (suspected Barrett's mucosa); Intervertebral disc prolapse (disc prolapse lumbar spine); Meningioma (small meningioma cerebellopontine angle left); Prostate cancer; Prostatic operation |

# VAERS DETAIL

VAERS ID: 2313180

| Vaccine Type | Vaccine | Manufacturer | Lot | Dose | Route | Site |
|---|---|---|---|---|---|---|
| COVID19 | COVID19 (COVID19 (PFIZER-BIONTECH)) | PFIZER\BIONTECH | FC3180 | 2 | UN | UN |

| Event Information | | | |
|---|---|---|---|
| Patient Age | 72 | Sex | M |
| State/Territory | MA | Date Report Completed | |
| Date Vaccinated | 8/6/2021 | Date Report Received | 6/8/2022 |
| Date of Onset | 3/14/2022 | Date Died | 3/14/2022 |
| Days to Onset | 220 | | |
| Vaccine Administered By | PUB | Vaccine Purchased By | |
| Mfr/Imm Project Number | | Split Type | |
| 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 |
|---|
| Creutzfeldt-Jakob disease |
| Death |
| Laboratory test |
| Lumbar puncture abnormal |

| Adverse Event Description |
|---|
| He got Creutzfeldt-Jakob disease (CJD) and died a horrific death. |

| Lab Data | Current Illness | Adverse Events After Prior Vaccinations |
|---|---|---|
| Spinal tap confirmed CJD after he died. They studied his brain and it was ruled spontaneous; not genetic. | | |

| Medications At Time of Vaccination | History/Allergies |
|---|---|
| | |

# VAERS DETAIL

VAERS ID: 2312136

| Vaccine Type | Vaccine | Manufacturer | Lot | Dose | Route | Site |
|---|---|---|---|---|---|---|
| COVID19 | COVID19 (COVID19 (PFIZER-BIONTECH)) | PFIZER\BIONTECH | PCA0020 | 3 | OT | RA |

| Event Information | | | |
|---|---|---|---|
| Patient Age | | Sex | M |
| State/Territory | FR | Date Report Completed | |
| Date Vaccinated | 12/9/2021 | Date Report Received | 6/8/2022 |
| Date of Onset | 1/1/2022 | Date Died | 5/6/2022 |
| Days to Onset | 23 | | |
| Vaccine Administered By | OTH | Vaccine Purchased By | |
| Mfr/Imm Project Number | | Split Type | FRPFIZER INC202200794900 |
| 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 |
|---|
| Amnesia |
| Borrelia test |
| Cognitive disorder |
| Creutzfeldt-Jakob disease |
| CSF protein |
| Cytomegalovirus test |
| Disorientation |
| Electroencephalogram |
| Enterovirus test |
| Epstein-Barr virus test |
| Hallucination |
| Herpes simplex test |
| Human herpes virus 6 serology |
| Lumbar puncture |
| Magnetic resonance imaging head |
| Persecutory delusion |
| Physical examination |
| Varicella virus test |
| Viral test |
| Visual impairment |

## Adverse Event Description

Spatial disorientation; Memory loss; visual disturbances; Hallucination; Persecution syndrome; rapidly evolving cognitive disorders; Creutzfeld-Jacob disease; This is a spontaneous report received from a contactable reporter(s) (Physician) from the Regulatory Authority. Regulatory number: FR-AFSSAPS-AM20221504. A 66-year-old male patient received BNT162b2 (COMIRNATY), on 09Dec2021 as dose 3 (booster), single (Lot number: PCA0020) intramuscular, in right deltoid for covid-19 immunization; perindopril (PERINDOPRIL), (Lot number: Unknown) till 23Apr2022 at 2 mg daily for hypertension; influenza vaccine inact sag 4v (INFLUVAC TETRA), on 29Oct2021 (Lot number: Z3608122) intramuscular for influenza immunisation. The patient's relevant medical history included: "Memory disturbance (excl dementia)" (unspecified if ongoing), notes: , anterograde memory problems for 3 years; "Bronchitis" (unspecified if ongoing); "Arterial hypertension" (unspecified if ongoing); "Coxarthrosis" (unspecified if ongoing). The patient's concomitant medications were not reported. Vaccination history included: comirnaty (dose 1, lot ET6956, right deltoid), administration date: 24Apr2021, for COVID-19 immunisation; comirnaty (dose 2, lot FC1526, right deltoid), administration date: 04Jun2021, for COVID-19 immunization. The following information was reported: CREUTZFELDT-JAKOB DISEASE (death, hospitalization) with onset Jan2022, outcome "fatal", described as "Creutzfeld-Jacob disease"; HALLUCINATION (hospitalization, medically significant) with onset 25Apr2022, outcome "unknown"; AMNESIA (hospitalization) with onset 25Apr2022, outcome "unknown", described as "Memory loss"; PERSECUTORY DELUSION (hospitalization) with onset 25Apr2022, outcome "unknown", described as "Persecution syndrome"; COGNITIVE DISORDER (hospitalization) with onset 25Apr2022, outcome "unknown", described as "rapidly evolving cognitive disorders"; VISUAL IMPAIRMENT (hospitalization) with onset 25Apr2022, outcome "unknown", described as "visual disturbances"; DISORIENTATION (hospitalization), outcome "unknown", described as "Spatial disorientation". The patient was hospitalized for creutzfeldt-jakob disease, cognitive disorder, disorientation (start date: 25Apr2022). The patient underwent the following laboratory tests and procedures: Borrelia test: (26Apr2022) negative; CSF protein (0.15-0.45): (26Apr2022) 0.8 g/l, notes: hyperproteinorachia; Cytomegalovirus test: (26Apr2022) negative; Electroencephalogram: (25Apr2022) theta rhythms at 6 cycles/sec, notes: background activity characterized by theta rhythms at 6 cycles/sec, delta slow wave overloads. Globally slowed tracing, triphasic anomalies predominant on the posterior regions, compatible with Creutzfeld Jakob disease; (18May2022) clear worsening of the EEG tracing, notes: clear worsening of the EEG tracing, absence of argument for a seizure or status epilepticus; Enterovirus test: (26Apr2022) negative; Epstein-Barr virus test: (26Apr2022) negative; Herpes simplex test: (26Apr2022) Negative; (26Apr2022) negative; Human herpes virus 6 serology: (26Apr2022) negative; Lumbar puncture: (26Apr2022) crystal clear appearance, notes: - absence of atypical cells - 14-3-3 protein assay pending; Magnetic resonance imaging head: (23Apr2022) posterior cortical hypersignals, notes: posterior cortical hypersignals, absence of expansive process, no hemorrhage, vascular leukopathy and bilateral hippocampal atrophy stage 4 (scheltens); on clinical admission: (25Apr2022) patient alert, disoriented in time and space, notes: intact cranial pairs, no pyramidal syndrome, no extrapyramidal syndrome, no cerebellar syndrome, no myoclonus. Praxical and visio-constructive disorders. Perindopril stopped on entry; Varicella virus test: (26Apr2022) negative; Viral test: (26Apr2022) negative. The action taken for perindopril was dosage permanently withdrawn on 23Apr2022. The patient date of death was 06May2022. Reported cause of death: "Creutzfeld-Jacob disease". It was not reported if an autopsy was performed. Clinical information: 66-year-old patient with a history of hypertension, anterograde memory problems for 3 years. He is treated long term with Perindopril only. The patient was hospitalized on 25Apr2022 due to the onset of rapidly evolving cognitive disorders (ambulation, several episodes of spatial disorientation, memory loss) and difficult home care for 3 months. Concept of visual disturbances, hallucination, persecution syndrome. No follow-up attempts are possible. No further information is expected.; Reported Cause(s) of Death: Creutzfeld-Jacob disease

| Lab Data | Current Illness | Adverse Events After Prior Vaccinations |
|---|---|---|
| Test Date: 20220426; Test Name: Lyme serology; Test Result: Negative ; Test Date: 20220426; Test Name: hyperproteinorachia; Result Unstructured Data: Test Result:0.8 g/l; Comments: hyperproteinorachia; Test Date: 20220426; Test Name: CMV virus; Test Result: Negative ; Test Date: 20220425; Test Name: EEG; Result Unstructured Data: Test Result:theta rhythms at 6 cycles/sec; Comments: background activity characterized by theta rhythms at 6 cycles/sec, delta slow wave overloads. Globally slowed tracing, triphasic anomalies predominant on the posterior regions, compatible with Creutzfeld Jakob disease.; Test Date: 20220518; Test Name: EEG; Result Unstructured Data: Test Result:clear worsening of the EEG tracing; Comments: clear worsening of the EEG tracing, absence of argument for a seizure or status epilepticus.; Test Date: 20220426; Test Name: enterovirus; Test Result: Negative ; Test Date: 20220426; Test Name: EBV; Test Result: Negative ; Test Date: 20220426; Test Name: HSV-1; Test Result: Negative ; Test Date: 20220426; Test Name: HSV-2; Test Result: Negative ; Test Date: 20220426; Test Name: HHV-6; Test Result: Negative ; Test Date: 20220426; Test Name: Sampling of cerebrospinal fluid on lumbar puncture; Result Unstructured Data: Test Result:crystal clear appearance; Comments: - absence of atypical cells - 14-3-3 protein assay pending; Test Date: 20220423; Test Name: Brain MRI; Result Unstructured Data: Test Result:posterior cortical hypersignals; Comments: posterior cortical hypersignals, absence of expansive process, no hemorrhage, vascular leukopathy and bilateral hippocampal atrophy stage 4 (scheltens).; Test Date: 20220425; Test Name: on clinical admission; Result Unstructured Data: Test Result:patient alert, disoriented in time and space; Comments: intact cranial pairs, no pyramidal syndrome, no extrapyramidal syndrome, no cerebellar syndrome, no myoclonus. Praxical and visio-constructive disorders. Perindopril stopped on entry.; Test Date: 20220426; Test Name: VZV; Test Result: Negative ; Test Date: 20220426; Test Name: parechovirus; Test Result: Negative | | |

| Medications At Time of Vaccination | History/Allergies |
|---|---|
| PERINDOPRIL | Medical History/Concurrent Conditions: Arterial hypertension; Bronchitis; Coxarthrosis; Memory disturbance (excl dementia) (, anterograde memory problems for 3 years) |

# VAERS DETAIL

VAERS ID: 2326653

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

| Event Information | | | |
|---|---|---|---|
| Patient Age | | Sex | F |
| State/Territory | | Date Report Completed | |
| Date Vaccinated | 9/21/2021 | Date Report Received | 6/22/2022 |
| Date of Onset | | Date Died | |
| Days to Onset | | | |
| Vaccine Administered By | UNK | Vaccine Purchased By | |
| Mfr/Imm Project Number | | Split Type | USPFIZER INC202200851089 |
| 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 | Yes |

| Symptoms |
|---|
| Brain scan normal |
| Creutzfeldt-Jakob disease |
| Death |
| Disease progression |
| Gait inability |
| Scan brain |
| Stress |
| Tremor |

## Adverse Event Description

died within five months of the second dose.; cjd; her left hand and side began to tremble; stress; disease progressed; not being able to sit and walk independently; significant changes in the right side of her brain; This is a literature report for the following literature source(s): "Studies suggest that there is a link between Covid-19 - "vaccines" and a rapidly evolving, incurable and deadly disease, which is known as Creutzfeldt-Jakob disease.". A female patient received BNT162b2 (BNT162B2), on 21Sep2021 as dose 2, single (Batch/Lot number: unknown) for covid-19 immunisation. The patient's relevant medical history and concomitant medications were not reported. Vaccination history included: BNT162b2 (first dose of Pfizer on 29Aug2021), administration date: 29Aug2021, for COVID-19 immunization. The following information was reported: DEATH (death), outcome "fatal", described as "died within five months of the second dose."; CREUTZFELDT-JAKOB DISEASE (medically significant), outcome "unknown", described as "cjd"; TREMOR (non-serious), outcome "unknown", described as "her left hand and side began to tremble"; STRESS (non-serious), outcome "unknown"; DISEASE PROGRESSION (non-serious), outcome "unknown", described as "disease progressed"; GAIT INABILITY (non-serious), outcome "unknown", described as "not being able to sit and walk independently"; BRAIN SCAN NORMAL (non-serious), outcome "unknown", described as "significant changes in the right side of her brain". The event "stress" required physician office visit. The patient underwent the following laboratory tests and procedures: Scan brain: significant changes in the right side of her brain, notes: The scans confirmed that (Name withheld) had significant changes in the right side of her brain. Therapeutic measures were taken as a result of stress. The date and cause of death for the patient were unknown. Clinical information: Please see attached a spontaneous case sent to us by a Pfizer colleague who reviewed local websites (withheld). This is a spontaneous report published on a (website withheld) and reported by a Pfizer colleague. I am attaching the translation of the article in English. At your disposal, COVID 'vaccines' linked to new type of incurable, lethal degenerative brain disorder Studies suggest that there is a link between Covid-19 - "vaccines" and a rapidly evolving, incurable and deadly disease, which is known as Creutzfeldt-Jakob disease.(Name withheld) Lawyer at (Organization withheld) and journalist of The Defender. (Organization withheld) 07Jun2022 (Web link withheld) Studies suggest that there is a link between an incurable and fatal disease known as Creutzfeldt-Jakob disease (CJD) and COVID-19 vaccines. Researchers believe that the area of the original spike protein of (Place withheld) variant of COVID-19 virus was incorporated into mRNA "vaccines"- and carrier adenovirus "vaccines" administered to billions of people can cause a new type of rapidly evolving sporadic CJD. According to the (Clinic withheld), Creutzfeldt-Jakob disease (CJD) is a degenerative disorder of the brain [which turns the brain into a mizithra] and leads to dementia and, ultimately, to death. Although the Omicron variant has no region in its spike protein, the current COVID-19 vaccines continue to use the genetic material including the region of the (place withheld) parent strain. A study published in May2022 on the relationship of the COVID-19 'vaccine' and CJD, identified a new form of sporadic CJD that appeared within days of taking a first or second dose of COVID-19 vaccines of Pfizer and Moderna. The researchers analysed 26 cases of Creutzfeldt-Jakob disease (CJD) and found that the first symptoms appeared on average 11.38 days after the injection of the COVID-19 'vaccine'. By the time the study was published, of the 26 cases, 20 had died and 6 were still alive. As the researchers wrote: "The 20 deaths occurred 4.76 months after injection. Among them, 8 of them led to sudden death (2.5 months); This confirms the radically different nature of this new form of CJD, while the classical form takes several decades to manifest itself." Dr. (Name withheld), lead author of the study, on 06Jun said in The (publication withheld) that all 26 cases led to death. According to the Centres for Disease Control and Prevention (CDC), diseases are a family of rare progressive neurodegenerative disorders affecting humans, and livestock. Diseases are usually rapidly evolving and always fatal. Although appear naturally in the brain and are usually harmless, they can be disturbed or not folded normally, affecting nearby and causing a change in their structure and behavior; The abnormal folding of proteins ' leads to brain damage and characteristic signs and symptoms of Creutzfeldt-Jakob disease (CJD)", says the website of the CDC. Sporadic Creutzfeldt-Jakob (CJD) occurs when a person becomes infected without obvious Reason. Once a single is contaminated, it will develop into another and there is no cure that can it can stop it.The region of the original spike protein of the (withheld) virus strain that exists in all COVID "vaccines", can interact with human Cells. Although the Omicron variant has no area in its spike protein, researchers said other variants of COVID-19, including the maternal (withheld) strain used in vaccines currently administered, have. As the researchers wrote: "We are now studying the first cases of patients with Omicron, in particular. In all these cases, the area has disappeared." However, the spike protein gene information of the (Withheld) virus variant including the region were incorporated into the 'vaccines' mRNA of Pfizer and the Moderna and "vaccines" with carrier genetically modified monkey adenovirus virus of AstraZeneca and Johnson & Johnson. "We have also proven whereas the Pfizer and Moderna mRNA injections also contain the same area. The same applies to all other "vaccines" -SARS-CoV2, because all are made from the Spike sequence of the (Withheld) SARS-CoV2 virus, which we showed that contains the area." With the mRNA "vaccines"-, once the mRNA is incorporated into the cells, the cell converts mRNA guidelines into a COVID-19 spike protein that tricks cells into to believe that it is infected, so that the body creates an immune memory against a piece of the virus. With the

"vaccines" with carrier a genetically modified monkey adenovirus, its DNA spike protein is transferred to the cell and then to the nucleus where it is stored all human DNA. After the DNA is transcribed into mRNA and converted to spike protein; An (Withheld) study of 2022, published in Microorganisms showed that the area of the SARS-CoV-2 spike protein incorporated in the COVID-19 "vaccines" is capable of interaction with human cells; Although the CDC repeats unsubstantiated that COVID-19 "vaccines" "cannot to change our DNA", studies show that mRNA can be converted into DNA and incorporated into the human genome. An (Withheld) study of 2021, titled: "Worse than the disease? Review of some possible unintended consequences of mRNA vaccines against COVID-19," he hypothesized that a incorrect folding of the spike protein could create an incorrect folded saw area, which can interact with a healthy to cause damage, leading to CJD disease; (published in the Journal of Vaccine, Practice, and Research (Withheld) An case report published in 2021, suddenly identified cases of CJD that appeared after vaccination with vaccines Pfizer, Moderna and AstraZeneca, suggesting a link between vaccination and disease.Creutzfeldt-Jakob Disease After the COVID-19 Vaccination, Turk J Intensive Care, Dec2021.(Link Withheld) A study published in 2021 in Microbiology & Infectious Diseases found a possible relationship between the Pfizer "vaccine" and disease in humans. ((Name withheld) COVID-19 RNA Based Vaccines and the Risk of Disease. Microbial Infect Dis. 2021; 5(1): 1-3. (Link Withheld) Despite the existence of new variants of SARS-COV-2, people still receive the COVID-19 "vaccines" developed with the spike protein of the parent variant of the virus of (Withheld). Many cases of CJD disease were reported in the U.S. Among the case reports of Creutzfeldt-Jakob disease (CJD) in the US in Mar2022, one was about 64-year-old (Name withheld) battle with CJD disease, which developed a few days after the second dose of Pfizer's "vaccine" for COVID-19. The report stated: "We cite the case of a 64-year-old woman, who has a rapidly declining loss of memory, behavioural changes, headaches and gait disorders about a week after the administration of the second dose of the new mRNA of Pfizer-BioNTech-Covid-19 "vaccine". After extensive research, definitive evidence identified the fatal diagnosis of sporadic Creutzfeldt-Jakob disease'. In an interview with The Defender in Aug2021, (Name withheld) daughter, (Name withheld), said that her mother's regression was heart breaking: From being able to work and do normal daily activities ended up not being able to walk, talk or control the movement of her body; She felt that her head was about to "explode" and died within three months of taking the second dose of Pfizer. In a written statement to The Defender, the doctor of (Name withheld) said: "In her case, possible side effects that could occur after the administration of the new Covid 19 "vaccine" are identified. Clinicians should take into account their differential diagnoses when a patient has rapidly progressing dementia, particularly after a recent vaccination, neurodegenerative diseases such as disease (e.g. sporadic Creutzfeldt-Jakob disease), autoimmune encephalitis, infections, non-epileptic seizures, toxic-metabolic disorders, etc.; Although there is currently no cure for the sporadic Creutzfeldt-Jakob disease (sCJD), early diagnosis is vital to avoid unnecessary administration of drugs for suspected psychological or neurological disorders; In addition, monitoring of side effects could potentially lead to further understanding of both the new mRNA "vaccine"- for COVID-19 and the etiologic of sCJD. Most importantly, recognizing the adverse effects provides individuals with vital important information to make a more informed decision about their health." (Name withheld), in an interview with The Defender, said that his mother, (Name withheld), knew that the Creutzfeldt-Jakob's disease was associated with Moderna's "vaccine". (Name withheld) made her first dose of Moderna on 16Feb2021 and did not report any complaints. But soon after the second dose on 17Mar, "felt different." Her symptoms began with numbness that spread from the hand where the injection was made to the entire left side of her body; She complained that something was wrong with her. Her brain could not combine her thoughts, understand things, developed diplopia and blindness and began to have hallucinations. The doctors initially thought that (Name withheld) had suffered a stroke due to... Anxiety. The MRIs later showed that there were abnormalities in her cerebellum. Her condition progressed quickly and she was eventually diagnosed with Creutzfeldt-Jakob disease (CJD) and they gave her days of life. She died within months of taking the second dose of Moderna. Her doctors submitted a report to the Vaccine Adverse Event Reporting System of CDC (VAERSID#). But, to date, the CDC have not communicated with the family despite an autopsy that confirmed that her death was caused by CJD-disease that manifested itself after the COVID-19"vaccine". (Name withheld), in an interview with The Defender, said that his wife, (Name withheld), showed the CJD disease after Pfizer's COVID-19 "vaccine" and died within five months of the second dose. She did her first dose of Pfizer on 29Aug2021 and her second dose on 21Sep2021. Her husband remained unvaccinated, but (Name withheld) had to be vaccinated compulsorily because of her professional employment. Four days after the second dose, (Name withheld) experienced the first episode of a "sudden" strange event that he could not explain." She started to have more episodes and her left hand and side began to tremble. On 13Oct2021, (Name withheld) returned to the doctor, who prescribed Xanax for the... stress. (!!!) The disease progressed rapidly to the point of not being able to sit and walk independently. The scans confirmed that (Name withheld) had significant changes in the right side of her brain. A new medical team did a systematic check on the spine and confirmed that the (Name withheld) had cjd. Until that moment, (Name withheld) could not get out of bed. "Your brain just disappears. It's crazy. You have a completely healthy body and your brain dies within a few months," said (Name withheld) who was informed that his wife will not recover. (Name withheld) died on 21Feb five months after her second dose of Pfizer. According to the latest data of the reference system of the side effects of vaccines (VAERS), as of 14Dec2021, 56 cases of rapid onset of the disease have been reported CJD after COVID-19 "vaccines". As has been shown, in federal reporting system of side effects of vaccines (VAERS) only 1% of all side effects of 'vaccines' are reported.  No follow-up attempts are needed; information about lot/batch number cannot be obtained. No further information is expected.; Sender's Comments: Based on the information available , a possible contributory role of the suspect BNT162B2 cannot be excluded for the reported events of death,Creutzfeldt-Jakob disease. 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 within five months of the second dose

| Lab Data | Current Illness | Adverse Events After Prior Vaccinations |
|---|---|---|
| Test Name: The scans confirmed that (Name withheld) had significant changes in the right side of her brain; Result Unstructured Data: Test Result:significant changes in the right side of her brain; Comments: The scans confirmed that (Name withheld) had significant changes in the right side of her brain | | |

| Medications At Time of Vaccination | History/Allergies |
|---|---|
| | |

# VAERS DETAIL

VAERS ID: 2326795

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

| Event Information | | | |
|---|---|---|---|
| Patient Age | | Sex | F |
| State/Territory | | Date Report Completed | |
| Date Vaccinated | | Date Report Received | 6/22/2022 |
| Date of Onset | | Date Died | |
| Days to Onset | | | |
| Vaccine Administered By | UNK | Vaccine Purchased By | |
| Mfr/Imm Project Number | | Split Type | USPFIZER INCPV20220000477 |
| 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 |
|---|
| Amnesia |
| Behaviour disorder |
| Creutzfeldt-Jakob disease |
| Death |
| Gait disturbance |
| Headache |

## Adverse Event Description

died within three months of taking the second dose of Pfizer; CJD disease; loss of memory; behavioral changes; headache; gait disorder; This is a literature report. A 64-year-old female patient received BNT162b2 (BNT162B2), as dose 2, single (Batch/Lot number: unknown) for covid-19 immunisation. The patient's relevant medical history and concomitant medications were not reported. Vaccination history included: Covid-19 vaccine (DOSE: 1), for COVID-19 immunization. The following information was reported: DEATH (death, medically significant), outcome "fatal", described as "died within three months of taking the second dose of Pfizer"; CREUTZFELDT-JAKOB DISEASE (medically significant), outcome "unknown", described as "CJD disease"; AMNESIA (non-serious), outcome "unknown", described as "loss of memory"; BEHAVIOUR DISORDER (non-serious), outcome "unknown", described as "behavioral changes"; HEADACHE (non-serious), outcome "unknown"; GAIT DISTURBANCE (non-serious), outcome "unknown", described as "gait disorder". The date and cause of death for the patient were unknown. Please see attached a spontaneous case sent to RA by a Pfizer colleague who reviewed local websites (withheld). This is a spontaneous report published on a (website withheld) and reported by a Pfizer colleague. I am attaching the translation of the article. At your disposal, COVID 'vaccines' linked to new type of incurable, lethal degenerative brain disorder. Studies suggest that there is a link between Covid-19 - "vaccines" and a rapidly evolving, incurable and deadly prion disease, which is known as Creutzfeldt-Jakob disease.(Name withheld) Lawyer at (Organization withheld) and journalist. (Organization withheld) 07Jun2022 (withheld) Studies suggest that there is a link between an incurable and fatal prion disease known as Creutzfeldt-Jakob disease (CJD) and COVID-19 vaccines. Researchers believe that the prion area of the original spike protein of (Place withheld) variant of COVID-19 virus was incorporated into mRNA "vaccines"- and carrier adenovirus "vaccines" administered to billions of people can cause a new type of rapidly evolving sporadic CJD. According to the (Clinic withheld), Creutzfeldt-Jakob disease (CJD) is a degenerative disorder of the brain [which turns the brain into a mizithra] and leads to dementia and, ultimately, to death. Although the Omicron variant has no prion region in its spike protein, the current COVID-19 vaccines continue to use the genetic material including the prion region of the (Place withheld) parent strain. A study published on the relationship of the COVID-19 'vaccine' and CJD, identified a new form of sporadic CJD that appeared within days of taking a first or second dose of COVID-19 vaccines of Pfizer and Moderna. The researchers analyzed 26 cases of Creutzfeldt-Jakob disease (CJD) and found that the first symptoms appeared on average 11.38 days after the injection of the COVID-19 'vaccine'. By the time the study was published, of the 26 cases, 20 had died and 6 were still alive. As the researchers wrote: The 20 deaths occurred 4.76 months after injection. Among them, 8 of them led to sudden death (2.5 months); This confirms the radically different nature of this new form of CJD, while the classical form takes several decades to manifest itself." Dr. (Name withheld), lead author of the study, on 06Jun said in The (publication withheld) that all 26 cases led to death. According to the Centers for Disease Control and Prevention (CDC), prion diseases are a family of rare progressive neurodegenerative disorders affecting humans, and livestock. Prion diseases are usually rapidly evolving and always fatal. Although prions appear naturally in the brain and are usually harmless, they can be disturbed or not folded normally, affecting nearby prions and causing a change in their structure and behavior; The abnormal folding of prion proteins ' leads to brain damage and characteristic signs and symptoms of Creutzfeldt-Jakob disease (CJD)", says the website of the CDC. Sporadic Creutzfeldt-Jakob (CJD) occurs when a person becomes infected without obvious Reason. Once a single prion is contaminated, it will develop into another prion and there is no cure that can it can stop it. The Prion region of the original spike protein of the (withheld) virus strain that exists in all COVID "vaccines", can interact with human Cells. Although the Omicron variant has no prion area in its spike protein, researchers said other variants of COVID-19, including the maternal (withheld) strain used in vaccines currently administered, have. As the researchers wrote: "We are now studying the first cases of patients with Omicron, in particular. In all these cases, the Prion area has disappeared." However, the spike protein gene information of the (Withheld) virus variant including the prion region were incorporated into the 'vaccines' mRNA of Pfizer and the Moderna and "vaccines" with carrier genetically modified monkey adenovirus virus of AstraZeneca and Johnson & Johnson. "We have also proven whereas the Pfizer and Moderna mRNA injections also contain the same prion area. The same applies to all other "vaccines" -SARS-CoV2, because all are made from the Spike sequence of the (Withheld) SARS-CoV2 virus, which we showed that contains the Prion area." With the mRNA "vaccines"-, once the mRNA is incorporated into the cells, the cell converts mRNA guidelines into a COVID-19 spike protein that tricks cells into to believe that it is infected, so that the body creates an immune memory against a piece of the virus. With the "vaccines" with carrier a genetically modified monkey adenovirus, its DNA spike protein is transferred to the cell and then to the nucleus where it is stored all human DNA. After the DNA is transcribed into mRNA and converted to spike protein; An (Withheld) study of 2022, published in Microorganisms showed that the prion area of the SARS-CoV-2 spike protein incorporated in the COVID-19 "vaccines" is capable of interaction with human cells; Although the CDC repeats unsubstantiatedly that COVID-19 "vaccines""cannot to change our DNA", studies show that mRNA can be converted into DNA and incorporated into the human genome. An (Withheld) study of 2021, he hypothesized that a incorrect folding of the spike protein could create an incorrect

folded saw area, which can interact with a healthy prion to cause damage, leading to CJD disease. An case report published in 2021, suddenly identified cases of CJD that appeared after vaccination with vaccines Pfizer, Moderna and AstraZeneca, suggesting a link between vaccination and disease. (Link Withheld) A study published in 2021 found a possible relationship between the Pfizer "vaccine" and prion disease in humans. Microbiol Infect Disk, Despite the existence of new variants of SARS-COV-2, people still receive the COVID-19 "vaccines" developed with the spike protein of the parent variant of the virus of (Withheld). Many cases of CJD disease were reported Among the case reports of Creutzfeldt-Jakob disease (CJD) in Mar2022, one was about 64-year-old (Name withheld) battle with CJD disease, which developed a few days after the second dose of Pfizer's "vaccine" for COVID-19. The report stated: "We cite the case of a 64-year-old woman, who has a rapidly declining loss of memory, behavioral changes, headaches and gait disorders about a week after the administration of the second dose of the new mRNA of Pfizer-BioNTech-Covid-19 "vaccine". After extensive research, definitive evidence identified the fatal diagnosis of sporadic Creutzfeldt-Jakob disease'. In an interview in Aug2021, (Name withheld) daughter, (Name withheld), said that her mother's regression was heartbreaking: From being able to work and do normal daily activities ended up not being able to walk, talk or control the movement of her body; She felt that her head was about to "explode" and died within three months of taking the second dose of Pfizer. In a written statement, the doctor of (Name withheld) said: "In her case, possible side effects that could occur after the administration of the new Covid 19 "vaccine" are identified. Clinicians should take into account their differential diagnoses when a patient has rapidly progressing dementia, particularly after a recent vaccination, neurodegenerative diseases such as prion disease (e.g. sporadic creutzfeldt-jakob disease), autoimmune encephalitis, infections, non-epileptic seizures, toxic-metabolic disorders, etc.; Although there is currently no cure for the sporadic creutzfeldt-jakob disease (sCJD), early diagnosis is vital to avoid unnecessary administration of drugs for suspected psychological or neurological disorders; In addition, monitoring of side effects could potentially lead to further understanding of both the new mRNA "vaccine"- for COVID-19 and the etiology of sCJD. Most importantly, recognizing the adverse effects provides individuals with vital important information to make a more informed decision about their health." (Name withheld), in an interview, said that his mother, (Name withheld), knew that the Creutzfeldt-Jakob's disease was associated with Moderna's "vaccine". (Name withheld) made her first dose of Moderna on 16Feb2021 and did not report any complaints. But soon after the second dose on 17Mar, "felt different." Her symptoms began with numbness that spread from the hand where the injection was made to the entire left side of her body; She complained that something was wrong with her. Her brain could not combine her thoughts, understand things, developed diplopia and blindness and began to have hallucinations. The doctors initially thought that (Name withheld) had suffered a stroke due to... Anxiety. The MRIs later showed that there were abnormalities in her cerebellum. Her condition progressed quickly and she was eventually diagnosed with Creutzfeldt-Jakob disease (CJD) and they gave her days of life. She died within months of taking the second dose of Moderna. Her doctors submitted a report to the Vaccine Adverse Event Reporting System of CDC (VAERSID#). But, to date, the CDC have not communicated with the family despite an autopsy that confirmed that her death was caused by CJD-disease that manifested itself after the COVID-19"vaccine". (Name withheld), in an interview, said that his wife, (Name withheld), showed the CJD disease after Pfizer's COVID-19 "vaccine" and died within five months of the second dose. She did her first dose of Pfizer on 29Aug2021 and her second dose on 21Sep2021. Her husband remained unvaccinated, but (Name withheld) had to be vaccinated compulsorily because of her professional employment. Four days after the second dose, (Name withheld) experienced the first episode of a "sudden" strange event that he could not explain." She started to have more episodes and her left hand and side began to tremble. On 13Oct2021, (Name withheld) returned to the doctor, who prescribed Xanax for the... stress. (!!!) The disease progressed rapidly to the point of not being able to sit and walk independently. The scans confirmed that (Name withheld) had significant changes in the right side of her brain. A new medical team did a systematic check on the spine and confirmed that the (Name withheld) had cjd. Until that moment, (Name withheld) could not get out of bed. "Your brain just disappears. It's crazy. You have a completely healthy body and your brain dies within a few months," said (Name withheld) who was informed that his wife will not recover. (Name withheld) died on 21Feb five months after her second dose of Pfizer. According to the latest data of the reference system of the side effects of vaccines (VAERS), as of 14Dec2021, 56 cases of rapid onset of the disease have been reported CJD after COVID-19 "vaccines". As has been shown, in federal reporting system of side effects of vaccines (VAERS) only 1% of all side effects of 'vaccines' are reported.  No follow-up attempts are needed; information about lot/batch number cannot be obtained. No further information is expected.; Sender's Comments: Based on the information available  a possible contributory role of the suspect BNT162B2 cannot be excluded for the reported events of death and Creutzfeldt-Jakob disease . 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 within three months of taking the second dose of Pfizer.

| Lab Data | Current Illness | Adverse Events After Prior Vaccinations |
|---|---|---|
| | | |

| Medications At Time of Vaccination | History/Allergies |
|---|---|
| | |

# VAERS DETAIL

VAERS ID: 2354380

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

| Event Information | | | |
|---|---|---|---|
| Patient Age | | Sex | M |
| State/Territory | FR | Date Report Completed | |
| Date Vaccinated | 5/10/2021 | Date Report Received | 7/2/2022 |
| Date of Onset | 9/1/2021 | Date Died | 12/30/2021 |
| Days to Onset | 114 | | |
| Vaccine Administered By | OTH | Vaccine Purchased By | |
| Mfr/Imm Project Number | | Split Type | FRPFIZER INC202200901063 |
| 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 |
|---|
| Anti-NMDA antibody |
| Creutzfeldt-Jakob disease |
| CSF protein |
| CSF test |
| Electrocardiogram |
| Electroencephalogram |
| HIV test |
| Investigation |
| Magnetic resonance imaging head |
| Neurological examination |
| Protein total |
| Treponema test |

## Adverse Event Description

Creutzfeld-Jacob disease; This is a spontaneous report received from a contactable reporter(s) (Physician) from the regulatory authority-WEB. Regulatory number: FR-AFSSAPS-TO20222203 (RA). A 72-year-old male patient received BNT162b2 (COMIRNATY), on 10May2021 as dose 2, single (Lot number: Unknown) intramuscular for covid-19 immunisation. The patient's relevant medical history included: "Cholecystectomy" (unspecified if ongoing); "Cataract bilateral NOS" (unspecified if ongoing); "Colon cancer", start date: 1994 (unspecified if ongoing); "Pseudomonas aeruginosa prostatitis", start date: Dec2021 (unspecified if ongoing). Concomitant medication(s) included: LANSOPRAZOLE; TRANXENE; AMLOR; CEFTRIAXONE; FRAGMINE. Vaccination history included: Covid-19 vaccine (Dose 1, manufacturer unknown), for COVID-19 IMMUNISATION. The following information was reported: CREUTZFELDT-JAKOB DISEASE (death) with onset Sep2021, outcome "fatal", described as "Creutzfeld-Jacob disease". The patient underwent the following laboratory tests and procedures: Anti-NMDA antibody: (11Jan2022) Negative; CSF protein: (22Dec2021) 0.5 g/l, notes: proteinorachia, without nucleated element, without oligoclonal band; CSF test: (11Jan2022) reveals the presence of a positive 14-3-3 protein,, notes: reveals the presence of a positive 14-3-3 protein, increased TAU/TAU-phosphorylated protein, lowered AB1.42 protein in favor of Creutzfeld-Jacob disease; Electrocardiogram: (30Nov2021) absense-like status, notes: reveals continuous wave spikes at a rate of 3 cycles/second suggesting absence-like status. Implementation of treatment with valproic acid (DEPAKINE); Electroencephalogram: (22Dec2021) Periodic Triphasic Complexes; HIV test: (11Jan2022) Negative; AB1.42 protein (normal high range 600): (11Jan2022) 541 pg/mL; anti-AMPAR: (11Jan2022) Negative; (11Jan2022) Negative; (11Jan2022) Negative; (11Jan2022) Negative; (11Jan2022) Negative; (11Jan2022) Negative; (unspecified date) hypertonia of the four limbs, notes: Gradual worsening of the clinical picture in a few days with hypertonia of the four limbs, myoclonus of the right quadriceps and the right upper limb, tremor, automatic crumbling; (11Jan2022) Positive; TAU protein (normal high range 450): (11Jan2022) 30700 pg/mL, notes: increased; Magnetic resonance imaging head: (22Dec2021) 1st hypothesis Creutzfeld-Jacob disease, notes: Hypersignal in diffusion of the cortex reaching the right parietal, temporal, frontal and insular lobes of the head of the right caudate nucleus, which should suggest in the 1st hypothesis Creutzfeld-Jacob disease.No symptoms suggestive of autoimmune encephalitis. Fazekas grade 2 leukopathy; Neurological examination: (25Nov2021) impairment of all cognitive functions, notes: reveals impairment of all cognitive functions: orientation in time and space, memory of recent events and old events. Inability of the patient to perform simple gestures. Hypothesis of rapidly evolving dementia; (Dec2021) akinetic mutism, notes: with no understanding of language. The patient does not execute any command; no motor deficit in all four limbs, non-explorable eye movement, blinking of the eyelids in the threat test, symmetrical and normo-reactive pupils, osteotendinous reflexes present and symmetrical, the plantar cutaneous reflexes being in flexion; Protein total (normal high range 60): (11Jan2022) 320 pg/mL; Treponema test: (11Jan2022) Negative. Therapeutic measures were taken as a result of creutzfeldt-jakob disease. The patient date of death was 30Dec2021. Reported cause of death: "Creutzfeld-Jacob disease". It was not reported if an autopsy was performed. Clinical course: It was reported that in Dec2021 Patient hospitalized for Pseudomonas aeruginosa prostatitis. Transfer in neurology in front of a clinical picture evoking a possibly auto-immune encephalitis. A hypothesis of Creutzfeld-Jacob disease is preferred. In the absence of a causal factor (transplant, growth hormone), a genetic test for the disease is requested. According to the patient's wife, the symptoms would have started in Sep2021, that is 4 months after the Dose 2 Comirnaty. 25Dec2021: Installation of a coma, implementation of midazolam (HYPNOVEL) PSE for antiepileptic purposes. 30Dec2021: Patient died overnight. In view of the clinical picture and the biological results, a diagnosis of Creutzfeld-Jacob disease was retained. Waiting for genetic test results. Follow-up attempts are completed. No further information is expected.; Reported Cause(s) of Death: Creutzfeld-Jacob disease

| Lab Data | Current Illness | Adverse Events After Prior Vaccinations |
|---|---|---|
| Test Date: 20220111; Test Name: anti-NMDAR; Test Result: Negative ; Test Date: 20211222; Test Name: cerebrospinal fluid; Result Unstructured Data: Test Result:0.5 g/l; Comments: proteinorachia, without nucleated element, without oligoclonal band.; Test Date: 20220111; Test Name: CSF analysis; Result Unstructured Data: Test Result:reveals the presence of a positive 14-3-3 protein,; Comments: reveals the presence of a positive 14-3-3 protein, increased TAU/TAU-phosphorylated protein, lowered AB1.42 protein in favor of Creutzfeld-Jacob disease; Test Date: 20211130; Test Name: ECG; Result Unstructured Data: Test Result:absense-like status; Comments: reveals continuous wave spikes at a rate of 3 cycles/second suggesting absence-like status. Implementation of treatment with valproic acid (DEPAKINE).; Test Date: 20211222; Test Name: EEG; Result Unstructured Data: Test Result:Periodic Triphasic Complexes; Test Date: 20220111; Test Name: HIV serology; Test Result: Negative ; Test Date: 20220111; Test Name: AB1.42 protein; Result Unstructured Data: Test Result:541 pg/mL; Test Date: 20220111; Test Name: anti-AMPAR; Test Result: Negative ; Test Date: 20220111; Test Name: anti-CASPR2; Test Result: Negative ; Test Date: 20220111; Test Name: anti-GABAR; Test Result: Negative ; Test Date: 20220111; Test Name: anti-neurophil antibodies; Test Result: Negative ; Test Date: 20220111; Test Name: Anti-onconeuronal antibodies; Test Result: Negative ; Test Date: 20220111; Test Name: DPPX; Test Result: Negative ; Test Name: investigation; Result Unstructured Data: Test Result:hypertonia of the four limbs; Comments: Gradual worsening of the clinical picture in a few days with hypertonia of the four limbs, myoclonus of the right quadriceps and the right upper limb, tremor, automatic crumbling.; Test Date: 20220111; Test Name: protein 14-3-3; Test Result: Positive ; Test Date: 20220111; Test Name: TAU protein; Result Unstructured Data: Test Result:30700 pg/mL; Comments: increased; Test Date: 20211222; Test Name: Brain MRI; Result Unstructured Data: Test Result:1st hypothesis Creutzfeld-Jacob disease; Comments: Hypersignal in diffusion of the cortex reaching the right parietal, temporal, frontal and insular lobes of the head of the right caudate nucleus, which should suggest in the 1st hypothesis Creutzfeld-Jacob disease. No symptoms suggestive of autoimmune encephalitis. Fazekas grade 2 leukopathy.; Test Date: 20211125; Test Name: neurological examination; Result Unstructured Data: Test Result:impairment of all cognitive functions; Comments: reveals impairment of all cognitive functions: orientation in time and space, memory of recent events and old events. Inability of the patient to perform simple gestures. Hypothesis of rapidly evolving dementia.; Test Date: 202112; Test Name: neurological examination; Result Unstructured Data: Test Result:akinetic mutism; Comments: with no understanding of language. The patient does not execute any command; no motor deficit in all four limbs, non-explorable eye movement, blinking of the eyelids in the threat test, symmetrical and normo-reactive pupils, osteotendinous reflexes present and symmetrical, the plantar cutaneous reflexes being in flexion.; Test Date: 20220111; Test Name: TAU-phophorylated protein; Result Unstructured Data: Test Result:320 pg/mL; Test Date: 20220111; Test Name: Syphilis test; Test Result: Negative | | |

| Medications At Time of Vaccination | History/Allergies |
|---|---|
| LANSOPRAZOLE; TRANXENE; AMLOR; CEFTRIAXONE; FRAGMINE | Medical History/Concurrent Conditions: Cataract bilateral NOS; Cholecystectomy; Colon cancer; Pseudomonas aeruginosa infection NOS |

# VAERS DETAIL

VAERS ID: 2361138

| Vaccine Type | Vaccine | Manufacturer | Lot | Dose | Route | Site |
|---|---|---|---|---|---|---|
| COVID19 | COVID19 (COVID19 (PFIZER-BIONTECH)) | PFIZER\BIONTECH | EW0172 | 1 | SYR | |
| COVID19 | COVID19 (COVID19 (PFIZER-BIONTECH)) | PFIZER\BIONTECH | EW0179 | 2 | | |
| COVID19 | COVID19 (COVID19 (PFIZER-BIONTECH)) | PFIZER\BIONTECH | FE3594 | 3 | SYR | |

| Event Information | | | |
|---|---|---|---|
| Patient Age | 71 | Sex | M |
| State/Territory | MI | Date Report Completed | |
| Date Vaccinated | 5/17/2021 | Date Report Received | 7/7/2022 |
| Date of Onset | 8/1/2021 | Date Died | 4/21/2022 |
| Days to Onset | 76 | | |
| Vaccine Administered By | PUB | Vaccine Purchased By | |
| Mfr/Imm Project Number | | Split Type | |
| Recovered | N | Serious | |

| Event Categories | |
|---|---|
| Death | Yes |
| Life Threatening | No |
| Permanent Disability | No |
| Congenital Anomaly/Birth Defect | No |
| Hospitalized | Yes |
| Days in Hospital | 22 |
| Existing Hospitalization Prolonged | No |
| Emergency Room/Office Visit | No |
| Emergency Room | No |
| Office Visit | Yes |

| Symptoms |
|---|
| Cognitive disorder |
| Creutzfeldt-Jakob disease |
| Death |
| Feeding disorder |
| Gait inability |
| Impaired driving ability |
| Impaired self-care |
| Laboratory test |
| Lumbar puncture abnormal |
| Memory impairment |

## Adverse Event Description

My Dad started experiencing symptoms of CJD Creutfeldt Jakob Disease within months of the 2nd vaccine dose. He  was unable to sleep, he also had coordination issues and double vision. After receiving his booster on 12/16/21, he went drastically downhill within one week, He became unable to walk unassisted, had memory and cognitive issues, had trouble feeding and caring for himself, He could no longer drive. or be left alone for long periods of time. After seeing multiple specialists through January 2022, he was hospitalized and a Lumbar punch was performed. Three weeks later on Feb 28th, 2022 his test results returned positive for CJD. My Dad came home from the hospital on hospice and passed on 4/21/2022.

| Lab Data | Current Illness | Adverse Events After Prior Vaccinations |
|---|---|---|
| A multitude of tests were run between Dec 2021 & Feb 2022. Dad's Lumbar punch was performed 2/8/22 | | |

| Medications At Time of Vaccination | History/Allergies |
|---|---|
| | |
| | Iodine & Shellfish |

# VAERS DETAIL

VAERS ID: 2386076

| Vaccine Type | Vaccine | Manufacturer | Lot | Dose | Route | Site |
|---|---|---|---|---|---|---|
| COVID19 | COVID19 (COVID19 (PFIZER-BIONTECH)) | PFIZER\BIONTECH | FF4213 | 2 | OT | |

| Event Information | | | |
|---|---|---|---|
| Patient Age | | Sex | F |
| State/Territory | FR | Date Report Completed | |
| Date Vaccinated | 7/18/2021 | Date Report Received | 7/23/2022 |
| Date of Onset | 8/1/2021 | Date Died | |
| Days to Onset | 14 | | |
| Vaccine Administered By | OTH | Vaccine Purchased By | |
| Mfr/Imm Project Number | | Split Type | ITPFIZER INC202200982502 |
| Recovered | N | Serious | |

| Event Categories | |
|---|---|
| Death | No |
| Life Threatening | Yes |
| 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 X-ray |
| Bladder catheterisation |
| Blood glucose increased |
| Cachexia |
| Chest X-ray |
| Computerised tomogram |
| Computerised tomogram head |
| Confusional state |
| Creutzfeldt-Jakob disease |
| CSF test |
| Discomfort |
| Electrocardiogram |
| Electroencephalogram |
| Encephalopathy |
| Epilepsy |
| Faecaloma |
| Fatigue |
| Hydronephrosis |
| Hypertension |
| Insomnia |
| Magnetic resonance imaging head |
| Menstrual disorder |
| Nephrolithiasis |
| Organic brain syndrome |
| Pain in extremity |
| Renal cyst |
| Tachycardia |
| Uterine leiomyoma |

## Adverse Event Description

Both kidneys show mild hydronephrosis; inferior calyceal microcalculus of the left kidney; Colic coprostasis; 33 mm posterior uterine subserous fibroma; left renal cortical cyst; depleted, catheterized bladder; Creutzfeld-Jacob disease; mental confusion; epileptic seizures; unstoppable physiological wasting; psycho-organic syndrome; ischemic vascular encephalopathy; arterial hypertension; pain in the lower limbs; fatigue; insomnia; tachycardia; high blood sugar; discontinuation of the menstrual cycle; lady began to show discomfort after receiving the covid vaccine, last summer; This is a spontaneous report received from a contactable reporter(s) (Consumer or other non HCP) from the Regulatory Authority-WEB. Regulatory number: IT-MINISAL02-875105 (RA). A 47-year-old female patient received BNT162b2 (COMIRNATY), on 13Jun2021 as dose 1, single (Batch/Lot number: unknown) and on 18Jul2021 as dose 2, 0.3 ml, single (Lot number: FF4213) intramuscular for covid-19 immunisation; coviD-19 vaccine mrna (mrna 1273) (MODERNA COVID-19 VACCINE), on 22Dec2021 as dose 3 (booster), single (Lot number: 017G21A) for covid-19 immunisation. The patient's relevant medical history and concomitant medications were not reported. The following information was reported: MENSTRUAL DISORDER (non-serious) with onset 2021, outcome "unknown", described as "discontinuation of the menstrual cycle"; EPILEPSY (hospitalization, medically significant) with onset 2021, outcome "unknown", described as "epileptic seizures"; FATIGUE (non-serious) with onset 2021, outcome "unknown"; BLOOD GLUCOSE INCREASED (non-serious) with onset 2021, outcome "unknown", described as "high blood sugar"; INSOMNIA (non-serious) with onset 2021, outcome "unknown"; DISCOMFORT (non-serious) with onset 2021, outcome "unknown", described as "lady began to show discomfort after receiving the covid vaccine, last summer"; CONFUSIONAL STATE (hospitalization) with onset 2021, outcome "unknown", described as "mental confusion"; PAIN IN EXTREMITY (non-serious) with onset 2021, outcome "unknown", described as "pain in the lower limbs"; TACHYCARDIA (non-serious) with onset 2021, outcome "unknown"; CACHEXIA (hospitalization, medically significant) with onset 2021, outcome "unknown", described as "unstoppable physiological wasting"; CREUTZFELDT-JAKOB DISEASE (hospitalization, medically significant, life threatening) with onset Aug2021, outcome "not recovered", described as "Creutzfeld-Jacob disease"; HYDRONEPHROSIS (hospitalization, medically significant), outcome "unknown", described as "Both kidneys show mild hydronephrosis"; NEPHROLITHIASIS (hospitalization, medically significant), outcome "unknown", described as "inferior calyceal microcalculus of the left kidney"; FAECALOMA (hospitalization, medically significant), outcome "unknown", described as "Colic coprostasis"; UTERINE LEIOMYOMA (hospitalization), outcome "unknown", described as "33 mm posterior uterine subserous fibroma"; RENAL CYST (hospitalization), outcome "unknown", described as "left renal cortical cyst"; BLADDER CATHETERISATION (hospitalization), outcome "unknown", described as "depleted, catheterized bladder"; ORGANIC BRAIN SYNDROME (hospitalization), outcome "unknown", described as "psycho-organic syndrome"; ENCEPHALOPATHY (medically significant), outcome "unknown", described as "ischemic vascular encephalopathy"; HYPERTENSION (non-serious), outcome "unknown", described as "arterial hypertension". The patient was hospitalized for organic brain syndrome (start date: 18Mar2022, discharge date: 24Mar2022, hospitalization duration: 6 day(s)). The patient underwent the following laboratory tests and procedures: Abdominal X-ray: (14Jun2022) Gas overdistension of the colic, notes: and tenual intestinal loops with visible levels at the left colic flexure. Colic fecal residues. Not free air in the abdomen; Chest X-ray: (14Jun2022) No evident, notes: pleuroparenchymal lesions in place; Computerised tomogram: (06Jun2022) examination performed before and after, notes: contrast medium injection. Skull and neck: no evident tomodensitometry alterations of the nervous tissue nor pathological impregnations after contrast medium. Non lymphadenomegaly of the lymphocenters of the neck. Chest: no focal lesions of the lung parenchyma. No mediastinal lymphadenomegaly or pleural effusion evident. Abdomen and pelvis: nothing to report on the liver, spleen, pancreas, adrenal glands. Both kidneys show mild hydronephrosis (renal pelvis AP diameter about 20 mm), in the absence of documentable obstacles to urinary outflow; 1 1 mm left renal cortical cyst, inferior calyceal microcalculus of the left kidney. No evident abdominal-pelvic lymphadenomegaly. Do not ascites in the abdomen. Colic coprostasis. 33 mm posterior uterine subserosal fibroma. depleted, catheterized bladder; Computerised tomogram head: (04Jun2022) examination performed without injection of, notes: contrast medium in a patient with reported allergic diathesis in the absence of desensitizing therapy. No evident focal or diffuse densitometric alterations of the supra and subtentorial brain tissue currently detectable with the method in use. Slight dimensional asymmetry of the ventricular system due to left prevalence. Unaffected median axis; CSF test: (16Jun2022) Beta 1-42: 351 pg / ml (vn greater than 500, notes: pg / ml),Amyloid Beta 1 - 40: 4456 pg / ml (vn 4532 - 20116), total TAU: 600 pg / ml (vn between 21 and 51 years lower than 300), PhosphoTAU 181 16 pg / ml (vn lower than 60), ABeta 42 / ABeta 40 ratio 0.08 cut-off higher than 0.05, TAU / PTau ratio: 37.5 cut-off lower than 25; (07Jun2022) WBC: 3 (reference values ??lower than 5),, notes: Total Proteins: 40 mg / dl (reference values ??lower than 40), Glucose 152 mg / dl, Glucose liquor / serum: 0.8 (reference values ??higher than 0.6), Lactate 14 (reference values ??10-22); Electrocardiogram: (12Jun2022) sinus tachycardia at 123 bpm., notes: Nonspecific anomalies of ventricular repolarization; Electroencephalogram: (03Jun2022) unstable alpha background activity,, notes: with recurrence of theta sequences, substantially symmetrical, normovolted, poorly reactive., prevalent sharp theta activity in the bilateral front-temporal area, more evident and slow on the right, in which isolated triphasic figures are inscribed. SLI without modifications of the activity already described. Conclusions: acts; (08Jun2022) diffusely slowed trace., notes: Basic activity with an unstable, poorly modulated mean alpha rhythm, with a prevalence of slow activity (polymorphic theta with sharp morphology) present mainly in the bilateral frontal and right occipital leads. Presence of isolated biphasic and triphasic peaks without periodicity characters. The light stimulus does not modify the trace; Magnetic resonance imaging head: (11Jun2022) examination performed before and after, notes: administration of i.v. contrast medium in suspected CreutzfeldJakob disease. There are no appreciable alterations of the signal in particular in the DWI sequence or in FLAIR referable to the diagnostic suspicion. Some areas of gliotic nature are appreciated in correspondence of the deep and subcotial frontal white matter bilaterally and in correspondence of the left external capsule, on a microangiopathic basis. Ventricular system on axis, not dilated. No evident alterations of the signal in the medullary field or impregnations of pathological significance; Blood glucose increased: (unspecified date) Blood sugar high. Clinical course: 30Jun2022 follow up information: the reporter was asked whether the diagnosis relating to the reported adverse reaction Creutzfeldt-Jakob disease was made by a doctor or following hospitalization and, if so, to submit the relevant documentation. 01Jul2022 follow up information: following the request, the reporter sent the letter of discharge following the patient's last hospitalization from 01Jun2022 to 22Jun2022, adding that the patient was then transferred to the Hospice in PRIVACY where she is currently hospitalized. I confirm that the lady began to show discomfort after receiving the covid vaccine, last summer, before this she has always been an active and dynamic person, in strength. From the discharge letter it was clear that the patient had previously been hospitalized from 18Mar2022 to 24Mar2022 due to the appearance, a few days before admission, of confusion, behavioral disorders, artistic automatisms during sleep, short-term memory deficit, enough to require the assistance of family members in the activities of daily life. She was discharged on 24Mar2022 with a diagnosis of psycho-organic syndrome. Lesional epilepsy, ischemic vascular encephalopathy; arterial hypertension. Since then reported general worsening of general and mental conditions, with confusion and disorientation. She would have fed very little with marked weight loss; reported loss of sphincter control. During the last hospitalization from 01Jun2022 to 22Jun2022, the patient was also subjected to diagnostic spinal taps for the search for neurodegeneration markers which were altered especially as regards the Tau protein and the Tau / FosfoTAU ratio; she was following dispatch of Liquor and blood to the Higher Institute of Health for Prion Protein Research in the suspicion based on clinical and Creuzfeldt-Jakob Disease Laboratory data. At discharge, the patient presents a clinical picture characterized by a sleep state, marked hypotonia and diffuse hypotrophy, was unable to acquire an upright position and walk independently, diffuse hyperreflexia, responds inconstantly to some simple questions and not always correctly, absent spontaneous speech, in the last days visual hallucinations (the patient tries to take objects that are not there), distal myoclonic shots especially of the lower limbs. She was fed orally by the healthcare assistants because the patient does not feed spontaneously. During the hospitalization she constantly presented high blood glucose values ??for which insulin therapy was introduced with improvement of the same. The information on the batch/lot number for BNT162b2 has been requested and will be submitted if and when received.; Sender's Comments: Linked Report(s) : IT-PFIZER INC-202200990184 same patient, different vaccine doses;

| Lab Data | Current Illness | Adverse Events After Prior Vaccinations |
| --- | --- | --- |
| Test Date: 20220614; Test Name: Abdomen x-ray; Result Unstructured Data: Test Result:Gas overdistension of the colic; Comments: and tenual intestinal loops with visible levels at the left colic flexure. Colic fecal residues. Not free air in the abdomen.; Test Date: 20220614; Test Name: Chest X-ray; Result Unstructured Data: Test Result:No evident; Comments: pleuroparenchymal lesions in place.; Test Date: 20220606; Test Name: CT total body; Result Unstructured Data: Test Result:examination performed before and after; Comments: contrast medium injection. Skull and neck: no evident tomodensitometry alterations of the nervous tissue nor pathological impregnations after contrast medium. Non lymphadenomegaly of the lymphocenters of the neck. Chest: no focal lesions of the lung parenchyma. No mediastinal lymphadenomegaly or pleural effusion evident. Abdomen and pelvis: nothing to report on the liver, spleen, pancreas, adrenal glands. Both kidneys show mild hydronephrosis (renal pelvis AP diameter about 20 mm), in the absence of documentable obstacles to urinary outflow; 1 1 mm left renal cortical cyst, inferior calyceal microcalculus of the left kidney. No evident abdominal-pelvic lymphadenomegaly. Do not ascites in the abdomen. Colic coprostasis. 33 mm posterior uterine subserosal fibroma. depleted, catheterized bladder.; Test Date: 20220604; Test Name: CT head; Result Unstructured Data: Test Result:examination performed without injection of; Comments: contrast medium in a patient with reported allergic diathesis in the absence of desensitizing therapy. No evident focal or diffuse densitometric alterations of the supra and subtentorial brain tissue currently detectable with the method in use. Slight dimensional asymmetry of the ventricular system due to left prevalence. Unaffected median axis.; Test Date: 20220616; Test Name: Biomarker neurodegeneration on CSF; Result Unstructured Data: Test Result:Beta 1-42: 351 pg / ml (vn greater than 500; Comments: pg / ml),Amyloid Beta 1 - 40: 4456 pg / ml (vn 4532 - 20116), total TAU: 600 pg / ml (vn between 21 and 51 years lower than 300), PhosphoTAU 181 16 pg / ml (vn lower than 60), ABeta 42 / ABeta 40 ratio 0.08 cut-off higher than 0.05, TAU / PTau ratio: 37.5 cut-off lower than 25.; Test Date: 20220607; Test Name: Chemical-physical examination of the liquor; Result Unstructured Data: Test Result:WBC: 3 (reference values ?? lower than 5),; Comments: Total Proteins: 40 mg / dl (reference values ??lower than 40), Glucose 152 mg / dl, Glucose liquor / serum: 0.8 (reference values ??higher than 0.6), Lactate 14 (reference values ??10-22).; Test Date: 20220612; Test Name: ECG; Result Unstructured Data: Test Result:sinus tachycardia at 123 bpm.; Comments: Nonspecific anomalies of ventricular repolarization; Test Date: 20220603; Test Name: EEG; Result Unstructured Data: Test Result:unstable alpha background activity,; Comments: with recurrence of theta sequences, substantially symmetrical, normovolted, poorly reactive., prevalent sharp theta activity in the bilateral front-temporal area, more evident and slow on the right, in which isolated triphasic figures are inscribed. SLI without modifications of the activity already described. Conclusions: acts; Test Date: 20220608; Test Name: EEG; Result Unstructured Data: Test Result:diffusely slowed trace.; Comments: Basic activity with an unstable, poorly modulated mean alpha rhythm, with a prevalence of slow activity (polymorphic theta with sharp morphology) present mainly in the bilateral frontal and right occipital leads. Presence of isolated biphasic and triphasic peaks without periodicity characters. The light stimulus does not modify the trace.; Test Date: 20220611; Test Name: RM encefalo; Result Unstructured Data: Test Result:examination performed before and after; Comments: administration of i.v. contrast medium in suspected CreutzfeldJakob disease. There are no appreciable alterations of the signal in particular in the DWI sequence or in FLAIR referable to the diagnostic suspicion. Some | | |

| | | |
|---|---|---|
| areas of gliotic nature are appreciated in correspondence of the deep and subcotial frontal white matter bilaterally and in correspondence of the left external capsule, on a microangiopathic basis. Ventricular system on axis, not dilated. No evident alterations of the signal in the medullary field or impregnations of pathological significance.; Test Name: Blood sugar; Result Unstructured Data: Test Result:Blood sugar high | | |

| Medications At Time of Vaccination | History/Allergies |
|---|---|
| | |

# VAERS DETAIL

VAERS ID: 2392387

| Vaccine Type | Vaccine | Manufacturer | Lot | Dose | Route | Site |
|---|---|---|---|---|---|---|
| COVID19 | COVID19 (COVID19 (MODERNA)) | MODERNA | 057G21A | UNK | OT | |

| Event Information | | | |
|---|---|---|---|
| Patient Age | 62 | Sex | M |
| State/Territory | FR | Date Report Completed | |
| Date Vaccinated | 12/6/2021 | Date Report Received | 7/27/2022 |
| Date of Onset | 1/1/2022 | Date Died | 5/13/2022 |
| Days to Onset | 26 | | |
| Vaccine Administered By | UNK | Vaccine Purchased By | |
| Mfr/Imm Project Number | | Split Type | FRMODERNATX, INC.MOD20226 |
| 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 |
|---|
| Creutzfeldt-Jakob disease |
| SARS-CoV-2 test |

## Adverse Event Description

Creutzfeldt-Jakob disease; This case was received via Regulatory Agency (Reference number: FR-AFSSAPS-AM20221798) on 22-Jul-2022 and was forwarded to Moderna on 22-Jul-2022. This regulatory authority case was reported by a consumer and describes the occurrence of CREUTZFELDT-JAKOB DISEASE (Creutzfeldt-Jakob disease) in a 62-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 057G21A) for Revaccination with different COVID-19 vaccine. Co-suspect products included non-company products NEBIVOLOL HYDROCHLORIDE (TEMERIT) for Hypertension arterial, FENOFIBRATE for Dyslipidaemia, ACETYLSALICYLATE LYSINE (KARDEGIC) for Disease coronary artery and AMLODIPINE BESILATE (AMLOR) for Hypertension arterial. The patient's past medical history included COVID-19 (17/04/2022). Concurrent medical conditions included Coronaropathy, Dyslipidemia and Arterial hypertension. Concomitant products included COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19) (VAXZEVRIA) for an unknown indication. On 06-Dec-2021, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On an unknown date, the patient started NEBIVOLOL HYDROCHLORIDE (TEMERIT) (Oral) 1.25 milligram once a day, FENOFIBRATE (Oral) 200 milligram once a day, ACETYLSALICYLATE LYSINE (KARDEGIC) (Oral) 75 milligram once a day and AMLODIPINE BESILATE (AMLOR) (Oral) 1 dosage form once a day. In January 2022, the patient experienced CREUTZFELDT-JAKOB DISEASE (Creutzfeldt-Jakob disease) (seriousness criterion death). The last dose administered for NEBIVOLOL HYDROCHLORIDE (TEMERIT) was on 13-May-2022, FENOFIBRATE (FENOFIBRATE) was on 13-May-2022, ACETYLSALICYLATE LYSINE (KARDEGIC) was on 13-May-2022 and for AMLODIPINE BESILATE (AMLOR) was on 13-May-2022. The patient died on 13-May-2022. The reported cause of death was Creutzfeldt-Jakob disease. It is unknown if an autopsy was performed. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 17-Apr-2022, SARS-CoV-2 test: (Positive) Positive. Dosage text for suspect product Spikevax was reported as R1. Treatment medications were not provided. Company Comment: This regulatory authority case concerns a 62-year-old male patient, with relevant medical conditions coronary artery disease, dyslipidemia, and hypertension, who experienced unexpected, serious fatal event Creutzfeldt-Jakob Disease, around one month following vaccination with a dose of mRNA-1273. Clinical course, treatment details and circumstances surrounding death were not reported. The patient died around 5 months after vaccination. The cause of death was reported as Creutzfeldt-Jakob Disease; it was unknown if an autopsy was done. The patient was also taking nebivolol (Temerit) and amlodipine (Amlor) for hypertension, fenofibrate for dyslipidemia, and acetylsalicylate lysine (Kardegic) for coronary artery disease at the time of death. Additionally, he previously received 2 doses of a different Covid19 vaccine Vaxzevria (interchange of vaccine products). The patient's age could be a risk factor for Creutzfeldt-Jakob Disease. His concurrent illnesses (coronary artery disease, dyslipidemia, hypertension) could be confounding factors for the fatal outcome. The benefit risk relationship of mRNA-1273 is not affected by this report. Event seriousness is assessed as per regulatory authority's report.; Sender's Comments: This regulatory authority case concerns a 62-year-old male patient, with relevant medical conditions coronary artery disease, dyslipidemia, and hypertension, who experienced unexpected, serious fatal event Creutzfeldt-Jakob Disease, around one month following vaccination with a dose of mRNA-1273. Clinical course, treatment details and circumstances surrounding death were not reported. The patient died around 5 months after vaccination. The cause of death was reported as Creutzfeldt-Jakob Disease; it was unknown if an autopsy was done. The patient was also taking nebivolol (Temerit) and amlodipine (Amlor) for hypertension, fenofibrate for dyslipidemia, and acetylsalicylate lysine (Kardegic) for coronary artery disease at the time of death. Additionally, he previously received 2 doses of a different Covid19 vaccine Vaxzevria (interchange of vaccine products). The patient's age could be a risk factor for Creutzfeldt-Jakob Disease. His concurrent illnesses (coronary artery disease, dyslipidemia, hypertension) could be confounding factors for the fatal outcome. The benefit risk relationship of mRNA-1273 is not affected by this report. Event seriousness is assessed as per regulatory authority's report.; Reported Cause(s) of Death: Creutzfeldt-Jakob disease

| Lab Data | Current Illness | Adverse Events After Prior Vaccinations |
|---|---|---|
| Test Date: 20220417; Test Name: SARS-CoV-2 test; Test Result: Positive ; Result Unstructured Data: Positive | | |

| Medications At Time of Vaccination | History/Allergies |
|---|---|
| VAXZEVRIA; AMLOR; KARDEGIC; FENOFIBRATE; TEMERIT | Medical History/Concurrent Conditions: Arterial hypertension; Coronaropathy; COVID-19 (17/04/2022); Dyslipidemia |

# VAERS DETAIL

VAERS ID: 2421529

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

| Event Information | | | |
|---|---|---|---|
| Patient Age | 62 | Sex | M |
| State/Territory | FR | Date Report Completed | |
| Date Vaccinated | 6/11/2021 | Date Report Received | 8/27/2022 |
| Date of Onset | 6/1/2021 | Date Died | |
| Days to Onset | | | |
| Vaccine Administered By | OTH | Vaccine Purchased By | |
| Mfr/Imm Project Number | | Split Type | FRPFIZER INC202201070806 |
| 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 | Yes |

| Symptoms |
|---|
| Affect lability |
| Antibody test |
| Antinuclear antibody |
| Aphasia |
| Blood thyroid stimulating hormone |
| Cerebellar syndrome |
| Cognitive disorder |
| Creutzfeldt-Jakob disease |
| CSF protein increased |
| Death |
| Dysgraphia |
| Electroencephalogram |
| Electromyogram |
| Emotional disorder |
| Endocrine test |
| Extrapyramidal disorder |
| Immunisation |
| Infection |
| Insomnia |
| Lumbar puncture |
| Magnetic resonance imaging |
| Magnetic resonance imaging head |
| Memory impairment |
| Montreal cognitive assessment |
| Myoclonus |
| Nervous system disorder |
| Neuropsychological test |
| Protein total |
| Urogram |

## Adverse Event Description

static and dynamic cerebellar syndrome; Dysexecutive cognitive disorders; emotional impairment; myoclonus; left extrapyramidal syndrome; neurological disorders; difficulties in writing; emotional instability with annoyance; aphasia; Insomnia; Creutzfeld-Jacob disease; Death; memory difficulties; This is a spontaneous report received from a contactable reporter(s) (Physician) from the Regulatory Authority. Regulatory number: FR-AFSSAPS-PS20221616. A 62-year-old male patient received BNT162b2 (COMIRNATY), on 11Jun2021 as dose 2, single (Lot number: Unknown) at the age of 62 years intramuscular for covid-19 immunisation. The patient's relevant medical history included: "memory problems", start date: 2016 (unknown if ongoing), notes: with very insidious onset of concentration problems and increased , impulsiveness with attention deficit. The patient's concomitant medications were not reported. Vaccination history included: comirnaty (DOSE 1, Route of Administration: IM), administration date: 30Apr2021, for COVID-19 vaccination, reaction(s): "neurological disorders". The following information was reported: INSOMNIA (hospitalization) with onset 11Jun2021, outcome "unknown"; APHASIA (hospitalization) with onset 11Jun2021, outcome "unknown"; DYSGRAPHIA (hospitalization) with onset 11Jun2021, outcome "unknown", described as "difficulties in writing"; AFFECT LABILITY (hospitalization) with onset 11Jun2021, outcome "unknown", described as "emotional instability with annoyance"; MEMORY IMPAIRMENT (non-serious) with onset 11Jun2021, outcome "unknown", described as "memory difficulties"; NERVOUS SYSTEM DISORDER (hospitalization, medically significant) with onset 11Jun2021, outcome "unknown", described as "neurological disorders"; CREUTZFELDT-JAKOB DISEASE (hospitalization, medically significant) with onset Jun2021, outcome "not recovered", described as "Creutzfeld-Jacob disease"; COGNITIVE DISORDER (hospitalization) with onset 01Dec2021, outcome "unknown", described as "Dysexecutive cognitive disorders"; EMOTIONAL DISORDER (hospitalization) with onset 01Dec2021, outcome "unknown", described as "emotional impairment"; EXTRAPYRAMIDAL DISORDER (hospitalization) with onset 01Dec2021, outcome "unknown", described as "left extrapyramidal syndrome"; MYOCLONUS (hospitalization) with onset 01Dec2021, outcome "unknown"; CEREBELLAR SYNDROME (hospitalization, medically significant) with onset 01Dec2021, outcome "unknown", described as "static and dynamic cerebellar syndrome"; DEATH (death), outcome "fatal". The events "static and dynamic cerebellar syndrome", "dysexecutive cognitive disorders", "emotional impairment", "myoclonus" and "left extrapyramidal syndrome" required physician office visit. The patient underwent the following laboratory tests and procedures: Antibody test: (unspecified date) Negative; Antinuclear antibody: (unspecified date) negative, no mutation or premutation; Blood thyroid stimulating hormone: (unspecified date) Normal; CSF protein increased: (unspecified date) Found, notes: isolated increase in the tau protein (neurological death marker); Electroencephalogram: (unspecified date) Found, notes: showed a trace suggestive of early encephalopathy, to be rechecked; (01Feb2022) Found, notes: Fluctuating tracing without particularity. No recorded seizure; Electromyogram: (unspecified date) Found, notes: did not show any evidence of peripheral neuropathy or myopathy; Endocrine test: (unspecified date) Vitamins B1, B9 and B12 assays normal; Immunisation: (unspecified date) Found, notes: anti-nuclear, anti-thyroid peroxidase and anti-thyroglobulin antibodies negative; Infection: (unspecified date) Found, notes: Human Immunodeficiency Virus, Hepatitis B virus, Hepatitis C Virus, Syphilis and Lyme serologies negative; Lumbar puncture: (16Mar2022) Found, notes: 0 elements, proteinorachia 0.62, normal glycorachia; isoelectrofocalisation: no specific cerebrospinal fluid band, no intrathecal immunoglobulin G synthesis, 14.3.3 negative. In summary: cerebellar syndrome evolving for about 10 months associated with cognitive disorders of aetiology, which remained undetermined in a 62-year-old male patient. Brain magnetic resonance imaging showing hypersignals of the grey nuclei, mamillary bodies, of the middle frontal cortex already present during the last imaging; Magnetic resonance imaging: (01Feb2022) Found, notes: Multiple hypersignals, diffusion of grey nuclei, mammillary bodies, middle frontal cortex. No translation after injection; Magnetic resonance imaging head: (unspecified date) Found, notes: doubt about diffusion and fluid-attenuated inversion recovery hypersignal of the caudated and lenticular nuclei; Montreal cognitive assessment: (unspecified date) 25/30, notes: score with loss of one point on the Trail Making Test, one point on the cube and three points on memory, with a word recovered on the categorical index and two on multiple options. Fluency limit to 11 words with three words in addition to what he repeated; Neuropsychological test: (01Feb2022) Found, notes: Dysexecutive syndrome mainly reaching the working memory with immediate memory difficulties as a consequence; Protein total: (unspecified date) 0.48 g/l; Protein total: (unspecified date) Negative; Urogram: (unspecified date) Negative. The date and cause of death for the patient were unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained. No further information is expected.; Sender's Comments: Linked Report(s) : FR-PFIZER INC-202201093183 Same patient, drug and different event and dose;; Reported Cause(s) of Death: Unknown cause of death

| Lab Data | Current Illness | Adverse Events After Prior Vaccinations |
|---|---|---|
| Test Name: neuronal antibodies; Result Unstructured Data: Test Result:Negative; Test Name: Fragile X Messenger Ribonucleoprotein 1 mutation; Result Unstructured Data: Test Result:negative, no mutation or premutation; Test Name: Thyroid stimulating hormone; Result Unstructured Data: Test Result:Normal; Test Name: Biomarkers on the Cerebrospinal fluid; Result Unstructured Data: Test Result:Found; Comments: isolated increase in the tau protein (neurological death marker); Test Name: Electroencephalogram; Result Unstructured Data: Test Result:Found; Comments: showed a trace suggestive of early encephalopathy, to be rechecked; Test Date: 20220201; Test Name: Electroencephalogram; Result Unstructured Data: Test Result:Found; Comments: Fluctuating tracing without particularity. No recorded seizure; Test Name: Electromyoneurography; Result Unstructured Data: Test Result:Found; Comments: did not show any evidence of peripheral neuropathy or myopathy; Test Name: metabolic and endocrine level; Result Unstructured Data: Test Result:Vitamins B1, B9 and B12 assays normal; Test Name: Auto-immune; Result Unstructured Data: Test Result:Found; Comments: anti-nuclear, anti-thyroid peroxidase and anti-thyroglobulin antibodies negative; Test Name: infectious level; Result Unstructured Data: Test Result:Found; Comments: Human Immunodeficiency Virus, Hepatitis B virus, Hepatitis C Virus, Syphilis and  Lyme serologies negative; Test Date: 20220316; Test Name: Lumbar puncture; Result Unstructured Data: Test Result:Found; Comments: 0 elements, proteinorachia 0.62, normal glycorachia; isoelectrofocalisation: no  specific cerebrospinal fluid band, no intrathecal immunoglobulin G synthesis, 14.3.3 negative.  In summary: cerebellar syndrome evolving for about 10 months associated with cognitive disorders of aetiology, which remained undetermined in a 62-year-old male patient. Brain magnetic resonance  imaging showing hypersignals of the grey nuclei, mamillary bodies, of the middle frontal cortex already  present during the last imaging; Test Date: 20220201; Test Name: Cerebral magnetic resonance imaging; Result Unstructured Data: Test Result:Found; Comments: Multiple hypersignals, diffusion of grey nuclei, mammillary  bodies, middle frontal cortex. No translation after injection; Test Name: Brain Magnetic Resonance Imaging; Result Unstructured Data: Test Result:Found; Comments: doubt about diffusion and fluid-attenuated inversion recovery  hypersignal of the caudated and lenticular nuclei; Test Name: Montreal Cognitive Assessment; Result Unstructured Data: Test Result:25/30; Comments: score with loss of one point on the Trail Making Test, one point  on the cube and three points on memory, with a word recovered on the categorical index and two on  multiple options. Fluency limit to 11 words with three words in addition to what he repeated.; Test Date: 20220201; Test Name: Neuropsychological assessment; Result Unstructured Data: Test Result:Found; Comments: Dysexecutive syndrome mainly reaching the working memory with  immediate memory difficulties as a consequence; Test Name: hyperproteinorachia; Result Unstructured Data: Test Result:0.48 g/l; Test Name: protein 14-3-3; Result Unstructured Data: Test Result:Negative; Test Name: Thoracic-abdominal-pelvic computed tomography; Result Unstructured Data: Test Result:Negative | | |

| Medications At Time of Vaccination | History/Allergies |
|---|---|
| | Medical History/Concurrent Conditions: Memory deficit (very insidious onset of concentration problems, increased  impulsiveness with attention deficit.) |

# VAERS DETAIL

VAERS ID: 2435709

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

| Event Information | | | |
|---|---|---|---|
| Patient Age | | Sex | U |
| State/Territory | FR | Date Report Completed | |
| Date Vaccinated | | Date Report Received | 9/9/2022 |
| Date of Onset | | Date Died | |
| Days to Onset | | | |
| Vaccine Administered By | OTH | Vaccine Purchased By | |
| Mfr/Imm Project Number | | Split Type | DEPFIZER INCPV20220005755 |
| Recovered | U | Serious | |

| Event Categories | |
|---|---|
| Death | No |
| 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 |
|---|
| Creutzfeldt-Jakob disease |

## Adverse Event Description

Creutzfeldt-Jakob disease as a result of covid vaccination; This is a spontaneous report received from a contactable reporter(s) (Consumer or other non HCP) from License Party. Other Case identifier(s): AE-004611. A patient (no qualifiers provided) received BNT162b2 (COMIRNATY), as dose number unknown, single (Batch/Lot number: unknown) for covid-19 immunisation. The patient's relevant medical history and concomitant medications were not reported. The following information was reported: CREUTZFELDT-JAKOB DISEASE (medically significant), outcome "unknown", described as "Creutzfeldt-Jakob disease as a result of covid vaccination". The information on the batch/lot number for BNT162b2 has been requested and will be submitted if and when received. COMIRNATY is under agreement with BIONTECH SE.

| Lab Data | Current Illness | Adverse Events After Prior Vaccinations |
|---|---|---|
| | | |

| Medications At Time of Vaccination | History/Allergies |
|---|---|
| | |

# VAERS DETAIL

VAERS ID: 2447117

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

| Event Information | | | |
|---|---|---|---|
| Patient Age | 72 | Sex | M |
| State/Territory | FR | Date Report Completed | |
| Date Vaccinated | 4/16/2021 | Date Report Received | 9/16/2022 |
| Date of Onset | 4/16/2021 | Date Died | 7/12/2022 |
| Days to Onset | 0 | | |
| Vaccine Administered By | OTH | Vaccine Purchased By | |
| Mfr/Imm Project Number | | Split Type | BEPFIZER INC202201152731 |
| 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 |
|---|
| Creutzfeldt-Jakob disease |
| Fatigue |
| Gait disturbance |
| Memory impairment |
| Nervous system disorder |

## Adverse Event Description

Gait disorders/Walking disorders; Fatigue; memory disorders; Neurological problem; Creutzfeld-Jacob disease; This is a spontaneous report received from a contactable reporter(s) (Physician) from the Regulatory Authority. Regulatory number: BE-FAMHP-DHH-N2022-118531 (RA). A 72-year-old male patient received BNT162b2 (COMIRNATY), on 16Apr2021 as dose 1, single (Batch/Lot number: unknown) at the age of 72 years, on 21May2021 as dose 2, single (Batch/Lot number: unknown) and on 01Dec2021 as dose 3 (booster), single (Batch/Lot number: unknown) for covid-19 immunisation. The patient's relevant medical history included: "no smoker" (unspecified if ongoing); "no alcohol" (unspecified if ongoing), notes: no alcohol or tobacco. The patient's concomitant medications were not reported. The following information was reported: CREUTZFELDT-JAKOB DISEASE (death, hospitalization, medically significant) with onset 16Apr2021, outcome "fatal", described as "Creutzfeld-Jacob disease"; FATIGUE (death, hospitalization, medically significant) with onset 16Apr2021, outcome "fatal"; GAIT DISTURBANCE (death, hospitalization, medically significant) with onset 16Apr2021, outcome "fatal", described as "Gait disorders/Walking disorders"; NERVOUS SYSTEM DISORDER (death, hospitalization, medically significant) with onset 16Apr2021, outcome "fatal", described as "Neurological problem"; MEMORY IMPAIRMENT (death, hospitalization, medically significant) with onset 16Apr2021, outcome "fatal", described as "memory disorders". Therapeutic measures were not taken as a result of gait disturbance, fatigue, memory impairment, nervous system disorder, creutzfeldt-jakob disease. The patient date of death was 12Jul2022. Reported cause of death: "Creutzfeld-Jacob disease", "gait disorders", "Fatigue", "memory disorders", "Neurological problem". It was not reported if an autopsy was performed. Reporter Comment: Treatment - No, Evolution of the ADR - Death, Examinations - 2 very complete hospitalizations, ADR time relationship - Creutzfeld-Jacob disease and death, ADR description - Progressive decline, walking disorders and memory disorders. No follow-up attempts are possible; information about lot/batch number cannot be obtained. No further information is expected.; Reporter's Comments: Treatment - No, Evolution of the ADR - Death, Examinations - 2 very complete hospitalizations, ADR time relationship - Creutzfeld-Jacob disease and death, ADR description - Progressive decline, walking disorders and memory disorders.; Reported Cause(s) of Death: Creutzfeld-Jacob disease; gait disorders; Fatigue; memory disorders; Neurological problem

| Lab Data | Current Illness | Adverse Events After Prior Vaccinations |
|---|---|---|
| | | |

| Medications At Time of Vaccination | History/Allergies |
|---|---|
| | Medical History/Concurrent Conditions: Abstains from alcohol (no alcohol or tobacco); Non-smoker; Comments: no treatment, no alcohol or tobacco |

# VAERS DETAIL

VAERS ID: 2470001

| Vaccine Type | Vaccine | Manufacturer | Lot | Dose | Route | Site |
|---|---|---|---|---|---|---|
| COVID19 | COVID19 (COVID19 (PFIZER-BIONTECH)) | PFIZER\BIONTECH | 1H049A | 2 | | |

| Event Information | | | |
|---|---|---|---|
| Patient Age | | Sex | M |
| State/Territory | FR | Date Report Completed | |
| Date Vaccinated | 12/1/2021 | Date Report Received | 10/5/2022 |
| Date of Onset | 8/2/2022 | Date Died | |
| Days to Onset | 244 | | |
| Vaccine Administered By | OTH | Vaccine Purchased By | |
| Mfr/Imm Project Number | | Split Type | DEPFIZER INC202201198437 |
| Recovered | N | Serious | |

| Event Categories | |
|---|---|
| Death | No |
| Life Threatening | No |
| Permanent Disability | No |
| Congenital Anomaly/Birth Defect | No |
| Hospitalized | Yes |
| Days in Hospital | 7 |
| Existing Hospitalization Prolonged | No |
| Emergency Room/Office Visit | No |
| Emergency Room | No |
| Office Visit | No |

| Symptoms |
|---|
| Cognitive disorder |
| Creutzfeldt-Jakob disease |
| Depressed mood |
| Investigation |
| Movement disorder |

## Adverse Event Description

Creutzfeld-Jacob disease; Depressed mood; Cognitive disorders; Diagnosed: Creutzfeldt Jakob disease. Severe cognitive disorders, movements such as drinking, no longer able to eat independently. Currently already in the hospice; This is a spontaneous report received from a non-contactable reporter(s) (Consumer or other non HCP) from the Regulatory Authority, number: DE-PEI-CADR2022307703 (RA). Other Case identifier(s): DE-CADRPEI-2022307703 (RA Web portal), DE-PEI-202200140483 (RA). A 69-year-old male patient received BNT162b2 (COMIRNATY), on 01Dec2021 as dose 2, single (Lot number: 1H049A) for covid-19 immunisation. The patient's relevant medical history included: "Prostatic cancer", start date: 2019 (unspecified if ongoing); "Hypertension" (unspecified if ongoing); "Overweight" (unspecified if ongoing). The patient's concomitant medications were not reported. Vaccination history included: Covid-19 vaccine (DOSE 1, MANUFACTURER UNKNOWN), for COVID-19 immunisation. The following information was reported: MOVEMENT DISORDER (hospitalization) with onset 02Aug2022, outcome "recovered with sequelae" (28Sep2022), described as "Diagnosed: Creutzfeldt Jakob disease. Severe cognitive disorders, movements such as drinking, no longer able to eat independently. Currently already in the hospice"; CREUTZFELDT-JAKOB DISEASE (hospitalization, medically significant), outcome "unknown", described as "Creutzfeld-Jacob disease"; DEPRESSED MOOD (hospitalization), outcome "unknown"; COGNITIVE DISORDER (hospitalization), outcome "unknown", described as "Cognitive disorders". The patient was hospitalized for creutzfeldt-jakob disease, depressed mood, movement disorder, cognitive disorder (start date: Aug2022, hospitalization duration: 7 day(s)). The patient underwent the following laboratory tests and procedures: examination: unknown results. RA assessment for all events and Comirnaty is D. Unclassifiable. Sender's comments: Do you or the person concerned have any known allergies? If yes, which?no. Information on risk factors or previous illnesses for prostate cancer in 2019 and high blood pressure / beginning depressive behavior. Increasing cognitive abnormalities with associated motor disorders. At the end of August, the patient was in the hospital for a week for an examination. Mr. PRIVACY has been in the hospice since 21Sep2022. No follow-up attempts are possible. No further information is expected.

| Lab Data | Current Illness | Adverse Events After Prior Vaccinations |
|---|---|---|
| Test Name: examination; Result Unstructured Data: Test Result:unknown results | | |

| Medications At Time of Vaccination | History/Allergies |
|---|---|
| | Medical History/Concurrent Conditions: Hypertension; Overweight; Prostatic cancer |

# VAERS DETAIL

VAERS ID: 2470430

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

| Event Information | | | |
|---|---|---|---|
| Patient Age | | Sex | M |
| State/Territory | FR | Date Report Completed | |
| Date Vaccinated | | Date Report Received | 10/6/2022 |
| Date of Onset | | Date Died | |
| Days to Onset | | | |
| Vaccine Administered By | OTH | Vaccine Purchased By | |
| Mfr/Imm Project Number | | Split Type | TRPFIZER INC202201196318 |
| Recovered | U | Serious | |

| Event Categories | |
|---|---|
| Death | No |
| 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 |
|---|
| Ataxia |
| Cerebral atrophy |
| Cognitive disorder |
| Creutzfeldt-Jakob disease |
| CSF protein |
| Electroencephalogram |
| Hyperintensity in brain deep nuclei |
| Immunisation |
| Incorrect dose administered |
| Interchange of vaccine products |
| Magnetic resonance imaging |
| Myoclonus |
| Off label use |

## Adverse Event Description

Creutzfeldt-Jakob disease; Cerebral atrophy; Inappropriate dose of vaccine administered; booster; Off label use; Interchange of vaccine products; Ataxia; Cognitive disorder; Hyperintensity in brain deep nuclei; Myoclonic jerks; This is a literature report.  This is a literature report. This case is for the 7th dose of vaccine (third dose of BioNTech vaccine). The case is linked withTR-BIONTECHTR-838,TR-BIONTECHTR-837 (same literature/patient,different doses/reactions). We report the case of a 59-year- old man suspected of having CJD with an expected course of the disease, who developed symptoms following multiple severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) vaccinations. Written informed consent was obtained from the patient wife. A 59-year-old man with subacute gait problems for 2 months was suggested neurosurgery. He was diagnosed with lumbar spinal stenosis and underwent surgery. However, after the surgery, his gait worsened, he become ataxic, and began experiencing difficulty in finding words. He had two episodes of alien hand syndrome and was therefore hospitalized. He was never infected with SARS-CoV-2. He received two doses of the SARS-CoV-2 vaccine (Sinovac) voluntarily. After approval of the same vaccine in Turkey, he was vaccinated twice. After the approval of mRNA-based vaccine BNT162b2 (Pfizer-BioNTech), he was vaccinated twice again. His gait complaints started 2 weeks later. The diffusion-weighted magnetic resonance imaging (DWI-MRI) performed at a neurology clinic revealed suspicious caudate, putaminal, and cortical hyperintensities. Moreover, we observed periodic slow waves in his electroencephalogram (EEG). After the observation of myoclonic jerks, levetiracetam was prescribed. He was evaluated for differential diagnosis of CJD, autoimmune and paraneoplastic limbic encephalitis. No signs of malignancy or autoimmunity were observed during the investigation. Lumber puncture revealed slightly evaluated protein levels. Therefore, 1 g pulse methylprednisolone was administered for 5 days prior to cerebrospinal fluid (CSF) markers results. He insisted for an mRNA-based vaccine BNT162b2 vaccination repel and received his seventh vaccine for SARS-CoV-2. Unfortunately, we did not investigate anti-SARS-CoV-2 antibody response or neurodegenerative biomarkers like tau and others as they were not available at our institution. His cognitive decline progressed, and he was unable to walk because of ataxia and myoclonic jerks. CSF examination for 14-3-3 protein was negative. His consciousness worsened, and he was transferred to intensive care for follow-up. Control DWI-MRI revealed progression of hyperintensities and brain atrophy. EEG showed 1 Hz periodic sharp waves and probable sporadic CJD was suggested as the final diagnosis. After six months of symptom onset, he was still alive. Follow-up attempts will be performed to obtain information about the outcome of the reaction and lot/batch number.  Reporter comment: Both the vector and mRNA vaccines express the spike protein. A CJD case was reported with rapid progression to death after vaccination,4 but epidemiologic studies showed no increase in CJD incidence or rapid progression of the disease severity during the coronavirus disease 2019 pandemic.5 The overall disease duration after the symptoms was reported to be 5.5 months. Our patient is still alive sixth month after the diagnosis. It is debatable whether this a positive effect for survival after the disease onset causedby the vaccines. CJD should be considered for the differential diagnosis of cognitive decline after SARS-CoV-2 infection or vaccination.  BioNTech SE Comment: Based on the FDA Label of the COMIRNATY, the events Off label use, Creutzfeldt-Jakob disease, Ataxia, Cognitive disorder, Hyperintensity in brain deep nuclei, Cerebral atrophy and Myoclonic jerks are not listed and reaction of Inappropriate dose of vaccine administered is listed . Based on the Causality Algorithm all of the events are assessed as possible. Comirnaty is under agreement with BIONTECH SE.  Causality Assessments for event Inappropriate dose of vaccine administered, Off label use, Creutzfeldt-Jakob disease, Ataxia, Cognitive disorder, Hyperintensity in brain deep nuclei, Cerebral atrophy, Myoclonic jerks with suspect it was not reported as per reporter and as per Company (BioNTech SE) it was possible.; Reporter's Comments: Both the vector and mRNA vaccines express the spike protein. A CJD case reported with rapid progression to death after vaccination,4 but epidemiologic studies showed no increase in CJD incidence or rapid progression of the disease severity during the coronavirus disease 2019 pandemic.5 The overall disease duration after the symptoms was reported to be 5.5 months. Our patient is still alive sixth month after the diagnosis.; Sender's Comments: As there is limited information in the case provided, the causal association between the reported events of  Inappropriate dose of vaccine administered, Off label use, Creutzfeldt-Jakob disease and Cerebral atrophy  and the suspect drug cannot be excluded. The case will be reassessed once new information is available. The impact of this report on the benefit/risk profile of the Pfizer drug is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees, and Investigators, as appropriate.,Linked Report(s) : TR-PFIZER INC-202201196559 same literature/patient, different doses/reactions;

| Lab Data | Current Illness | Adverse Events After Prior Vaccinations |
|---|---|---|
| Test Name: Cerebrospinal fluid protein; Result Unstructured Data: Test Result:CSF examination for 14-3-3 protein was negative; Test Name: Electroencephalogram; Result Unstructured Data: Test Result:EEG showed 1 Hz periodic sharp waves and probable; Comments: sporadic CJD was suggested as the final diagnosis; Test Name: Diffusion-weighted magnetic resonance imaging (DWI-MRI); Result Unstructured Data: Test Result:Control DWI-MRI revealed progression of; Comments: hyperintensities and brain atrophy. | | |

| Medications At Time of Vaccination | History/Allergies |
|---|---|
| | |

# VAERS DETAIL

VAERS ID: 2476033

| Vaccine Type | Vaccine | Manufacturer | Lot | Dose | Route | Site |
|---|---|---|---|---|---|---|
| COVID19 | COVID19 (COVID19 (PFIZER-BIONTECH)) | PFIZER\BIONTECH | Unknown | 3 | OT | |

| Event Information | | | |
|---|---|---|---|
| Patient Age | | Sex | F |
| State/Territory | FR | Date Report Completed | |
| Date Vaccinated | 12/1/2021 | Date Report Received | 10/12/2022 |
| Date of Onset | 4/24/2022 | Date Died | 6/30/2022 |
| Days to Onset | 144 | | |
| Vaccine Administered By | OTH | Vaccine Purchased By | |
| Mfr/Imm Project Number | | Split Type | CZPFIZER INC202201219156 |
| Recovered | N | Serious | |

| Event Categories | |
|---|---|
| Death | Yes |
| Life Threatening | Yes |
| Permanent Disability | Yes |
| 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 |
|---|
| Cognitive disorder |
| Computerised tomogram head |
| Creutzfeldt-Jakob disease |
| Death |
| Gene mutation identification test |
| Magnetic resonance imaging head |

## Adverse Event Description

Creutzfeld-Jacob disease; Cognitive deterioration; death; This is a spontaneous report received from a contactable reporter(s) (Consumer or other non HCP) from the Regulatory Authority, number: CZ-CZSUKL-22005072 (RA). A 45-year-old female patient received BNT162b2 (COMIRNATY), in Dec2021 as dose 3 (booster), single (Lot number: Unknown) intramuscular for covid-19 immunisation. The patient's relevant medical history included: "Anxiety disorder", start date: 2005 (ongoing); "Obsessive-compulsive disorder" (ongoing); "Hypothyroidism" (ongoing); "Hypertension arterial" (ongoing). The patient's family history included: "Creutzfeld-Jacob disease" (not ongoing), notes: familial type. There were no concomitant medications. Vaccination history included: Comirnaty (Dose1), administration date: 2020, for COVID-19 immunization; Comirnaty (Dose2), administration date: 2020, for COVID-19 immunization. The following information was reported: COGNITIVE DISORDER (death, hospitalization, disability, medically significant, life threatening) with onset 24Apr2022, outcome "fatal", described as "Cognitive deterioration"; CREUTZFELDT-JAKOB DISEASE (death, hospitalization, disability, medically significant, life threatening) with onset 24Apr2022, outcome "fatal", described as "Creutzfeld-Jacob disease"; DEATH (death, medically significant) with onset 30Jun2022, outcome "fatal". The patient underwent the following laboratory tests and procedures: Computerised tomogram head: (2022) unknown results, notes: signs of cortical atrophy; Gene mutation identification test: (2022) unknown results, notes: sequencing of PRNP gene, found mutation p.E200K (GAG>AAG), c.598G>A, heterozygous. Molecularly confirmed familial type of CJD. In codone 129 - confirmed polymorphism methionin/methionin (ATG/ATG in homozygous version). In codone 219 - confirmed polymorphism glutamate GAG/GAG in homozygous version (p.Glu2198) (c.655GG) dbSNP: rs1800014; Magnetic resonance imaging head: (2022) unknown results, notes: signal changes in striatum and cerebellar cortex. The patient date of death was 30Jun2022. Reported cause of death: "familial type, confirmed genetic mutation". The autopsy was performed, and results were not provided. Clinical course: According to the medical report dated 04/07/2022: the patient had a loss of cognitive functions, visible changes on CT and MRI. The patient had repeated epileptic seizures. Patient had Family history of CJD and was confirmed in the father at the age of 72, PRNP gene, mutation c.598G>A heterozygous, localization 2nd exon. 3 months before death, first neurological problems, very rapid course of the disease, diagnosed with CJD. The father's sister's son died at the age of 52 of CJD, his sons were diagnosed with CJD. Father's brother had three daughters, children of one of the daughters were tested - 3 were positive. No follow-up attempts are possible; information about lot/batch number cannot be obtained. No further information is expected.; Reported Cause(s) of Death: familial type, confirmed genetic mutation

| Lab Data | Current Illness | Adverse Events After Prior Vaccinations |
|---|---|---|
| Test Date: 2022; Test Name: Brain CT; Result Unstructured Data: Test Result:unknown results; Comments: signs of cortical atrophy; Test Date: 2022; Test Name: Gene mutation identification test; Result Unstructured Data: Test Result:unknown results; Comments: sequencing of PRNP gene, found mutation p.E200K (GAG>AAG), c.598G>A, heterozygous. Molecularly confirmed familial type of CJD. In codone 129 - confirmed polymorphism methionin/methionin (ATG/ATG in homozygous version). In codone 219 - confirmed polymorphism glutamate GAG/GAG in homozygous version (p.Glu2198) (c.655GG) dbSNP: rs1800014; Test Date: 2022; Test Name: Head MRI; Result Unstructured Data: Test Result:unknown results; Comments: signal changes in striatum and cerebellar cortex | Anxiety disorder; Hypertension arterial; Hypothyroidism; Obsessive-compulsive disorder | |

| Medications At Time of Vaccination | History/Allergies |
|---|---|
| | Medical History/Concurrent Conditions: Creutzfeld-Jacob disease (familial type) |