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Department of Health and Human Services
Food and Drug Administration
Center for Biologics Evaluation and Research (CBER)
Office of Biostatistics and Pharmacovigilance (OBPV)
Division of Pharmacovigilance (DPV)

POSTMARKETING SAFETY ISSUE MEMORANDUM

From: DPV/OBPV pharmacovigilance review team

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To: STNs 125742/787.0; 125752/341.0; and 125817/50.0

Subject: U.S. VAERS deaths in individuals between the ages of 18 and 24 years following COVID-19 vaccines

Sponsors: Pfizer; Moderna; Novavax

Products: COVID-19 vaccines

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Pfizer-BioNTech COVID-19 Vaccine (Comirnaty); Moderna COVID-19 Vaccine (Spikevax); Novavax COVID-19 Vaccine, Adjuvanted (Nuvaxovid); mRNA COVID-19 vaccine (Mnexspike)

Date: February 10, 2026

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EXECUTIVE SUMMARY

Objective: This memorandum presents findings from an analysis of U.S. VAERS reports of death in individuals aged 18-24 years old following COVID-19 vaccination. This analysis was conducted in response to a request from Dr. Vinay Prasad, Director, CBER, for a structured causality assessment of VAERS reports of deaths of individuals between the ages of 18 and 24 years following vaccination with a COVID-19 vaccine with a formulation currently available in the US. While DPV staff have reviewed such reports previously as part of CBER's routine, ongoing monitoring of incoming VAERS data, typically DPV review of VAERS reports does not include assigning causality at the individual case level due to (a) limitations inherent to passive surveillance databases, including unverified diagnoses, lack of comparator/control group, missing/incomplete data, lack of denominator data, and biases in reporting (underreporting or stimulated reporting), and (b) limitations in causality assessment including inability to eliminate or quantify uncertainty, subjective variability and issues with reproducibility, inability to quantify relationship likelihood or relative contribution of vaccination, oversimplification of complex cases with variable quality information or confounding factors, and inability to definitively prove a connection between a vaccine and an adverse event. A VAERS query was conducted for all domestic reports of a death in patients between the ages of 18 and 24 years who received any COVID-19 vaccine with a formulation currently available in the US, including both monovalent and bivalent formulations. The goal of this analysis is to provide causality assessment at the individual case level based on a systematic review of these reports by using structured causality assessment criteria.

A previous analogous review of US VAERS death reports in pediatric patients was completed in December 2025 (STN 125742/804.0, 125752/343.0, and 125817/64.0). The query for this review yielded 96 unique U.S. pediatric deaths as of data lock point (DLP) 8/14/25, with vaccination dates between 2021 – 2024. Seven of the 96 unique U.S. pediatric deaths identified in this prior review were classified as *possibly* (n = 5) or *probably* (n = 2) related to vaccination. All (7/7) of these cases involved Pfizer-BioNTech COVID-19 Vaccine. Most (5/7) of these cases involved myocarditis. DPV considered that this information concerning myocarditis with fatal outcomes from postmarketing spontaneous adverse event reports to VAERS constituted "new safety information" (NSI) as defined in section 505-1(b)(3) of the Federal Food, Drug, and Cosmetic Act (FDCA). Furthermore, at the time, we considered the NSI of myocarditis with fatal outcomes to be applicable to all mRNA COVID-19 vaccines.

Methods: VAERS was queried for domestic reports of deaths of individuals between the ages of 18 and 24 years following COVID-19 vaccination with formulations currently available in the US, without any restrictions on preferred terms (PTs) for specific adverse events. DPV medical officers reviewed and discussed each individual case, including any available medical records and autopsy reports; overall causality assessment of each case was based on group discussion and consensus, using the World Health Organization-Uppsala Monitoring Centre (WHO-UMC) system for standardized case causality assessment (1). Using this system, each case was classified into one of six categories (certain, probable/likely, possible, unlikely,

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conditional or unassessable) based on the strength of available evidence that the vaccine was causally related to the patient's death.

Results: A cumulative query of VAERS retrieved 88 unique U.S. reports of deaths of individuals between the ages of 18 and 24 years as of data lock point (DLP) 8/14/25, with vaccination dates between 2020 - 2022. There were 52 cases following Comirnaty, 34 cases following Spikevax, and 2 cases where the COVID-19 vaccine was unknown. No cases were retrieved for Nuvaxovid or Mnexspike.

No cases were classified as *certain* or *probable* in relation to COVID-19 vaccination. Three cases were classified as *possibly* related to vaccination. It is important to note that *possible* cases could also be explained by alternative etiology, as the WHO category acknowledges that there "may be another equally likely explanation for the event." *Probable* cases are unlikely to be attributed to alternative etiology though an alternative etiology cannot be ruled out. Both categories of *possible* and *probable* are predicated on a "reasonable time relationship" to vaccine administration (temporality). The remaining 85 cases were classified as *unlikely* (n = 54) or *unassessable/unclassifiable* (n = 31).

The three *possible* cases involved myocarditis, a known risk for mRNA COVID-19 vaccines. Autopsy reports were available for all 3 cases. All cases involved females. Median age of the decedent was 20 years (range 19 – 21 years). Median time to onset of symptoms was 15 days (range 13 – 15 days). Two events occurred following vaccination with Pfizer-BioNTech COVID-19 Vaccine (2020-2021 monovalent formulation), and one occurred following Moderna COVID-19 Vaccine (2020-2021 monovalent formulation). All cases occurred following dose 2. For all cases, vaccination occurred in 2021.

Cumulative US vaccine distribution data are available for COVID-19 vaccines authorized or approved as of 14 August 2025. [redacted]

Conclusions: The findings of this analysis are consistent with those from the previous review of pediatric deaths. Given the small number of deaths in the 18-24 year-old age group that were assessed as *possibly* related, and the absence of any cases in this age group assessed as *probably* or *certainly* related, no new conclusions regarding causal attribution of deaths to COVID-19 vaccine can be made with this analysis. As with the pediatric analysis, the 3 deaths classified as *possibly* related to COVID-19 vaccination occurred after mRNA COVID-19 vaccination, and involved the known serious risk and labeled event of myocarditis.

This is a descriptive review of individual cases, and limitations of VAERS data preclude calculation or estimation of rates of these events. Although distribution data cannot serve as true denominator data with which to assess incidence of reported events, it is

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reasonable to note the number of reports resulting in death and assessed as *possibly* related to vaccination within the context of the distribution data provided above; it is also notable that all of these cases are associated with the known risk of myocarditis.

DPV/OBPV recommendations: The findings of this analysis will be discussed with the Office of Vaccines Research and Review as well as CBER leadership. Consideration of regulatory actions, including safety labeling changes, will take into account the totality of the evidence obtained from this and the previous analysis of pediatric deaths reports. Of note, this review does not constitute a benefit-risk analysis and no changes to *Indications and Usage* or *Contraindications* sections of USPI are recommended based on these data.

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1 BACKGROUND

This memorandum presents findings from an aggregate review of cumulative U.S. VAERS death reports among individuals aged 18-24 years who received any COVID-19 vaccine with a formulation currently available in the US, including both monovalent and bivalent formulations.

During the COVID-19 pandemic, healthcare providers who administered COVID-19 vaccines under Emergency Use Authorization (EUA) were legally required to report to VAERS a range of certain adverse events, including any deaths or cases of myocarditis following vaccination, regardless of causality. Due to heightened public awareness for VAERS reporting during mass vaccination campaigns in the U.S., VAERS reporting for COVID-19 vaccines surged, far surpassing historical rates of reporting for other vaccines. The VAERS program contractor routinely conducts follow-up to further investigate domestic reports of deaths. This follow-up includes contacting reporters and/or the health care provider named in the report to collect vaccination records and clinical records, including death certificates, autopsy reports, hospital admission/discharge records, and, if applicable, clinician visit notes, ED records, etc. As part of their ongoing review of new and incoming VAERS records for their assigned products, FDA medical officers in OBPV individually examine death reports for COVID vaccines on a continuous basis.

This new VAERS-limited analysis was conducted in response to a request from Dr. Vinay Prasad, Director, CBER, for a structured causality assessment of VAERS reports of deaths of individuals aged 18-24 following vaccination with any COVID-19 vaccine with a formulation currently available in the US. While DPV staff have reviewed these cases previously as part of CBER's routine, ongoing monitoring of incoming VAERS data, typically DPV review of VAERS reports does not include assigning causality at the individual case level due to limitations inherent to passive surveillance databases (see section 2.2, Limitations of VAERS data) and lack of a validated, gold standard method for such causality assessments (see section 2.3 Limitations of causality assessments in pharmacovigilance). Causality assessment is a process that can help reviewers characterize the possible causal association between a product and reported events to

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evaluate potential safety issues. By assigning structured categories to a report's clinical history and quality, this process helps identify cases of interest. However, it has limitations and should not be used alone (see section 2.3, Limitations of causality assessments in pharmacovigilance). Causality assessment is most effective when combined with clinical judgment, surveillance experience, knowledge of a condition's epidemiology, and corroboration from additional data sources. The goal of this review is to provide causality assessment based on new analysis of cumulative U.S. VAERS death reports among individuals aged 18-24 years old. There were 88 unique cases of US death reports among individuals aged 18-24 years old as of a query run on 8/14/25.

2 METHODS

To assess postmarketing safety data, we conducted a cumulative VAERS query on 8/14/25 (inclusive of reports up to 8/14/25), for all US death reports for COVID-19 vaccines with formulations currently available in the US (both monovalent and bivalent formulations). For this analysis, per CBER Center Director's request, we then restricted to reports with a known age between 18-24 years.

Of note, although adverse event reporting by patients, caregivers, and healthcare providers is generally voluntary, the terms of the original COVID-19 vaccine emergency use authorizations mandated that vaccine providers report all serious adverse events and deaths following vaccination to VAERS regardless of attribution to vaccination.

The query retrieved 88 unique cases of U.S. death reports in individuals aged 18-24 years old. For each VAERS report, cases were individually reviewed by DPV pharmacovigilance reviewers to:

a) Summarize case narratives (Appendices A and B)

b) Extract and analyze data for:
- vaccine
- vaccination date
- vaccine formulation
- dose number
- patient age and sex
- presence/absence of autopsy report, death certificate, medical records;
- reported cause of death (COD) as per autopsy report and/or death certificate
- adverse event(s)
- time to onset
- alternative etiology/confounder(s)

c) Overall causality assessment was based on group discussion, including input from a pediatric cardiologist for cases with cardiac events. The group classified

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the cases based on the World Health Organization-Uppsala Monitoring Centre (WHO-UMC) case causality assessment categories (1).

Table 1: Causality categories as per WHO-UMC assessment criteria

Causality Term	Assessment criteria*
Certain	• Event or laboratory test abnormality, with plausible time relationship to drug intake • Cannot be explained by disease or other drugs • Response to withdrawal plausible (pharmacologically, pathologically) • Event definitive pharmacologically or phenomenologically (i.e. an objective and specific medical disorder or a recognized pharmacological phenomenon) • Rechallenge satisfactory, if necessary
Probable / Likely	• Event or laboratory test abnormality, with reasonable time relationship to drug intake • Unlikely to be attributed to disease or other drugs • Response to withdrawal clinically reasonable • Rechallenge not required
Possible	• Event or laboratory test abnormality, with reasonable time relationship to drug intake • Could also be explained by disease or other drugs • Information on drug withdrawal may be lacking or unclear
Unlikely	• Event or laboratory test abnormality, with a time to drug intake that makes a relationship improbable (but not impossible) • Disease or other drugs provide plausible explanations
Conditional / Unclassified	• Event or laboratory test abnormality • More data for proper assessment needed, or • Additional data under examination
Unassessable / Unclassifiable	• Report suggesting an adverse reaction • Cannot be judged because information is insufficient or contradictory • Data cannot be supplemented or verified

* All points should be reasonably complied with

2.1 Results

Among the 88 unique cases retrieved by the query, 34 cases (39%) involved vaccination with Moderna COVID-19 vaccine (Spikevax), including 27 cases involving the monovalent formulation, 1 case involving the bivalent formulation, and 6 cases

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where formulation was not reported. Fifty-two cases (59%) involved vaccination with Pfizer COVID-19 vaccine (Comirnaty), including 49 cases involving a monovalent formulation and 3 cases where formulation was not reported. Two cases (2%) involved an unspecified COVID-19 vaccination. Assessment of the 88 unique cases retrieved by the query described above resulted in causality determination of 3 cases as *possibly* related to COVID-19 vaccination, 54 cases as *unlikely* related, and 31 cases as *unassessable*.

With respect to the 3 cases assessed as *possibly* related to vaccination, two occurred following vaccination with Pfizer-BioNTech COVID-19 Vaccine (2020-2021 monovalent formulation), and one occurred following Moderna COVID-19 Vaccine (2020-2021 monovalent formulation). All cases involved females. Median age of the decedent was 20 years (range 19 – 21 years). Median time to onset of symptoms was 15 days (range 13 – 15 days). Autopsy reports were available for all 3 cases. Additional information about these cases is summarized in Table 2 below.

Table 2. Summary of Cases Assessed as *Possible*

VAERS ID	Age	Sex	Date (year)	Dose #	Time to Onset	Days Since Previous Dose	Reported Cause of death	Assessment
[redacted]	19	Female	2021	2	15 days	28	Multi-organ failure following acute heart failure due to idiopathic cardiomyocyte necrosis despite subsequent cardiac transplant; CDC ID Branch Pathology Report indicates cardiac findings of lymphohistiocytic inflammation between areas of infarction, "which may represent a myocarditis or reparative changes after infarct"	Possible
[redacted]	21	Female	2021	2	13 days	21	[Viral] myocarditis	Possible
[redacted]	20	Female	2021	2	15 days	30	Lymphocytic myocarditis with a contributing factor of bronchopneumonia	Possible

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2.2 Limitations of VAERS data

VAERS data has significant inherent limitations that severely restrict its utility for assessing causality, and typically DPV routine safety monitoring practices do not assign causality categories at the individual case level.

Spontaneous surveillance systems such as VAERS are subject to many limitations, including underreporting, variable report quality and accuracy, inadequate data regarding the numbers of doses administered, and lack of direct and unbiased comparison groups. Since the system lacks denominator data, it is impossible to calculate true incidence rates or compare findings to background rates without external data sources (2,3). There is no control group for comparison, and the passive nature of the system leads to both underreporting of common events and stimulated reporting during periods of heightened awareness (such as during a pandemic). FDA does not receive reports for every adverse event or medication error that occurs with a vaccine. Many factors influence whether an event will be reported, such as the time a product has been marketed, or publicity about a particular adverse event. Also, there is no certainty that the reported event was due to the vaccine. Reports often contain missing or incomplete information and are not medically verified, limiting the ability to confirm diagnoses or assess the accuracy of reported details.

2.3 Limitations of causality assessments in pharmacovigilance

Since the early 1980s, causality assessments have been used in pharmacovigilance to make structured assessments of adverse event reports by classifying the likelihood of a causal relationship between a reported adverse event and drug or vaccine (3). Although causality assessments have been used widely in pharmacovigilance centers around the world, none have been universally adopted; because no method has proven to be reliable and reproducible, no gold standard exists (4,5). Despite their widespread use, causality assessments have several significant limitations that should be considered alongside results of a causality assessment:

First, causality assessments cannot eliminate or quantify the uncertainty inherent in passive surveillance adverse event reporting. Because of this uncertainty, causality assessments rarely yield definitive outcomes (i.e., categorizing a causal relationship as "certain"). Instead, outcomes that acknowledge some degree of uncertainty (i.e., causality terms such as "probable/likely," "possible," or "unlikely") are more common (3). Use of causality terms without providing definitions or assessment criteria can lead to misinterpretation. For example, a case categorized as "possible" (for which there may be an equally likely explanation for the event than the drug or vaccine) may be easily misinterpreted as simply "related" (not a WHO-UMC defined term but perceived by lay audiences as more definitive).

Second, causality assessments like the WHO-UMC assessment criteria rely upon subjective judgments by experts (1). When presented with the same data, disagreement between experts can occur, leading to variable outcomes and issues with reproducibility (4,5,6). For example, experts may disagree on the degree to which an alternate

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etiology provides a plausible explanation. Such a disagreement could result in adjudication of cases into very different categories ("possible", "probable", or "unlikely"). Of note, for our analysis, we chose to adjudicate cases as a group to reduce interobserver variability.

Third, causality assessments cannot provide an accurate quantitative assessment of relationship likelihood. Similarly, they cannot quantify the degree to which a drug or vaccine may have contributed to the development of an adverse event (3).

Fourth, causality assessments assign cases in simple categories, which may oversimplify complex and nuanced causal associations that are recognized in clinical practice. While binary responses (yes/no) may be required to proceed through a causality framework, the true answer often lies somewhere in between, especially for cases with limited or incomplete information or confounding factors. For example, the question of whether an event has a reasonable time relationship to vaccination requires a clear yes/no response, but what constitutes a "reasonable time" may exist on a continuum and may be influenced by other factors in the case (3).

Finally, due to the limitations described above, causality assessments cannot definitively prove the connection between a drug or vaccine and a given adverse event.

2.4 Vaccine Availability and Distribution Data

Below is a timeline for authorizations/approvals of COVID-19 vaccines used in adults during the review period for this analysis:

Jan 31, 2020	PHE declared by HHS
Dec 11, 2020	EUA for Pfizer COVID-19 Vaccine monovalent, ≥16 years
Aug 23, 2021	BLA for Pfizer COVID-19 Vaccine monovalent, ≥16 years
Oct 12, 2022	EUA Moderna COVID-19 Vaccine bivalent, > 6 years ; Pfizer COVID-19 Vaccine bivalent, > 5 years
Dec 8, 2022	EUA Moderna and Pfizer COVID-19 Vaccine bivalent, >6 months
Sep 11, 2023	Approved the use of COMIRNATY (2023-2024 Formula) in individuals 12 years of age and older Authorized Pfizer-BioNTech COVID-19 Vaccine (2023-2024 Formula) for use in individuals 6 months of age and older Removed authorization for the use of the Pfizer-BioNTech COVID-19 Vaccine, Bivalent in the United States Approved the use of Spikevax (2023-2024 Formula) in individuals 12 years of age and older Removed authorization for the use of the Moderna COVID-19 Vaccine, Bivalent in the United States
Aug 22, 2024	BLA for Comirnaty (2024-2025 Formula) >12 years / EUA Pfizer BioNTech COVID-19 Vaccine 2024-2025, >12 years
Aug 30 2024	EUA Novavax COVID-19 Vaccine, Adjuvanted (2024-2025 Formula) >12 years

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May 16, 2025	BLA for Nuvaxovid, 12-64 years who have at least one underlying condition that puts them at high risk for severe outcomes from COVID-19
May 30, 2025	BLA for Mnexspike, 65 years of age and older, and 12-64 years who have at least one underlying condition that puts them at high risk for severe outcomes from COVID-19

Information regarding cumulative U.S. and global vaccine distribution of vaccines that had been for all approved or authorized ages prior to August 14, 2025, is summarized in Table 3 below. Vaccines with formulations currently available in the US are included.

Table 3. Summary of U.S. and Global COVID-19 Vaccine Distribution data through 8/14/2025, all ages

Vaccine	U.S. doses distributed	Foreign doses distributed	Total (global) distributed
Comirnaty	[redacted]		
Spikevax			
Nuvaxovid			

Source: Information request responses submitted on 1) 10/28/25 to BLA 125742/787.0 (Comirnaty), 2), 10/31/25 to BLA 125752/341.0 (Spikevax) 3) 10/22/25 to BLA 125817/50.0 (Nuvaxovid).

3 DISCUSSION

The query yielded 88 unique domestic cases of fatal outcomes in individuals aged 18-24 years who received a Pfizer or Moderna COVID-19 vaccine in the US prior to 8/14/2025. Most cases were associated with a monovalent formulation of either Pfizer or Moderna vaccine; these vaccines comprise most of the COVID-19 vaccines that were distributed over the time period of the query. The 3 deaths assessed as *possible* all involved myocarditis, which is an adverse event that has been described as associated with COVID-19 vaccination and is included in the product labels of mRNA COVID-19 vaccines. It is also noted that the identified risk of myocarditis has been discussed at public meetings, including Advisory Committee on Immunization Practices (ACIP). A presentation at ACIP in November 2021 on mRNA COVID-19 vaccine-associated myocarditis provided a summary of care and outcomes of preliminary myocarditis cases reported to VAERS after mRNA COVID-19 vaccination in persons aged <30 years, including reports of deaths with possible concern for myocarditis (mRNA COVID-19 vaccine-associated myocarditis). Myocarditis was also discussed at the FDA Vaccines and Related Biological Products Advisory Committee (VRBPAC) (Vaccines and Related Biological Products Advisory Committee June 14-15, 2022 Meeting Announcement - 06/14/2022 | FDA).

Assessment of the retrieved cases required review of several clinical considerations relevant to multiple reports; these topics are discussed below.

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Sudden Cardiac Death

Several events of sudden cardiac death (SCD) were reported among reports retrieved by the query. SCD is sudden and unexpected death for which non-cardiac causes have been excluded that occurs within an hour of symptom-onset (or within 24 hours of last being seen alive, if death is unwitnessed). The incidence of SCD in the general population (>35 years of age) is estimated to be 1 in 1000 persons per year. In young persons, SCD is less common; the incidence in persons <35 years of age has been noted in published literature as 0.3–3.6 per 100,000 persons per year (7).

Much of what is known about risk factors for SCD in younger persons has been derived from studies of SCD in young athletes. Risk factors for SCD in young athletes in published literature include hypertrophic cardiomyopathy, congenital coronary anomalies, arrhythmogenic right ventricular dysplasia, dilated cardiomyopathy, aortic rupture due to Marfan syndrome, myocarditis (infectious and noninfectious), valvular disease and electrical disorders (Wolff–Parkinson–White syndrome, long QT syndrome, Brugada syndrome), cardiac sarcoidosis, as well as commotio cordis (7,8).

A relevant anatomical finding, myocardial bridging (MB), was noted in VAERS [redacted]. MB is a congenital coronary artery anomaly involving an overlying myocardium's partial or complete encasement of a coronary artery segment. MB was historically thought to be a benign anatomical variant. However, a significant amount of published literature substantiates the fact that MB can be associated with angina, acute coronary syndromes, and sudden death related to encasement of the coronary artery and resultant alterations of blood flow to the heart; symptomatic patients with MB are often treated with beta-blocker (9,10).

Suicidality in Young Adults

Suicide was one of the more common causes of death in the reviewed reports. Suicide is consistently a leading cause of death in young adults aged 15-24 (11). The 2024 National Survey on Drug Use and Health reported that among adults across all age groups, the prevalence of serious suicidal thoughts was highest among young adults aged 18-25 years (12.6%) (12). Further, multiple studies have demonstrated that the pandemic negatively impacted the mental health of young adults and increased suicidality in this population (13-16). Given the high rate of mental disorders and attempted suicide in young adults, it is not unexpected that several reports of suicide would be retrieved in this query.

COVID-19 Vaccination and Thromboembolic Events

Several reports in the query described thromboembolic events (TEEs). There are a number of risk factors for pulmonary and other venous thromboembolisms, including genetic thrombophilia (factor V Leiden, prothrombin gene mutation, protein C deficiency, and others), prolonged immobility, oral contraceptive pills, obesity, cigarette smoking, major trauma, the postpartum period, and infections (17). The incidence of acute pulmonary embolism ranges from 53 to 162 per 100,000 people in the general

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population, and causes approximately 100,000 deaths annually (18, 19). Several large population-based studies have not found an association between mRNA COVID-19 Vaccines and pulmonary emboli (20-22).

Also relevant to discussion of association of TEEs and COVID-19 vaccination is Thrombosis with thrombocytopenic syndrome (TTS), which was found to be associated with the adenoviral vector COVID-19 vaccine (23). However, it should be noted that current evidence favors rejection of a causal relationship between TTS and mRNA COVID-19 vaccines (24).

Post-Vaccination Autoimmune Disease

Several post vaccination autoimmune events were reported among cases retrieved by this query including diabetes mellitus, Goodpasture syndrome, systemic lupus erythematosus (SLE), and other vasculitides. While there are published case reports in the literature describing possible antigenic and immunogenic effects of mRNA COVID-19 vaccines, conclusive mechanisms have not yet been established and are confounded by multiple interplaying factors including preexisting clinical or subclinical infection and autoimmune disease, and limited information regarding other potential triggers (25). No consistent pattern suggestive of a safety concern has been identified following vaccination with mRNA COVID-19 vaccines. To date, several global multicenter meta-analysis studies have favored minimal induction of disease flares or autoantibodies by vaccination and no significant effect of preexisting antibodies on either vaccine response or breakthrough infections (26, 27). A recent large population-based systematic review and meta-analysis study assessing an association between COVID-19 and new-onset autoimmune diseases found a statistically significant increase in the risk of new-onset autoimmune diseases in association with SARS-CoV-2 infection. This risk was attenuated among vaccinated individuals suggesting a role for immune intensity and vaccination-mediated protection (28). Furthermore, reports of de novo cases remain low and generally follow a benign course responsive to typical treatments (29, 30) though such reports are subject to limitations set by passive safety surveillance.

Sudden Death in Epilepsy

Sudden Death in Epilepsy (SUDEP) is the sudden death of a patient with epilepsy, with or without evidence for a seizure but excluding documented status epilepticus, in which postmortem examination does not reveal a structural or toxicologic cause for death. Pooled case-control studies attempting to assess risk factors for SUDEP have identified younger onset of age of epilepsy, idiopathic etiology of epilepsy, frequency of generalized tonic-clonic seizures, and polytherapy as associated with SUDEP, and history of alcohol abuse and intellectual disability may also increase risk (31). Multiple prospective and retrospective studies have systematically documented adverse events following COVID-19 vaccination in epilepsy populations (32). Most of the serious epilepsy-related events documented were status epilepticus cases (32), which occurred at very low rates; such events are often attributable to other factors (33). Currently, there is no established link between vaccinations and SUDEP.

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4 CONCLUSIONS

The findings of this analysis are consistent with those from the previous review of pediatric deaths. Given the small number of deaths in the 18-24 year old age group that were assessed as possibly related, and the absence of any deaths in this age group assessed as *probably* or *certainly* related, no new conclusions regarding causal attribution of deaths to COVID-19 vaccine can be made with this analysis. As with the pediatric analysis, the 3 deaths classified as *possibly* related to COVID-19 vaccination occurred after mRNA COVID-19 vaccination and involved the known serious risk of myocarditis. Myocarditis is a labeled event for mRNA COVID-19 vaccines, and the safety information yielded by this analysis in young adults is consistent with the current known safety profile of COVID-19 mRNA vaccines.

This is a descriptive review of individual cases, and limitations of VAERS data preclude calculation or estimation of rates of these events. Although distribution data cannot serve as true denominator data with which to assess incidence of reported events, it is reasonable to note the number of reports resulting in death and assessed as *possibly* related to vaccination within the context of the distribution data provided above; it is also notable that these cases are associated with the known risk of myocarditis.

5 DPV RECOMMENDATIONS

The findings of this analysis will be discussed with the Office of Vaccines Research and Review as well as CBER leadership. Potential regulatory actions, including safety labeling changes, will be considered. Consideration of safety labeling changes will take into account the totality of the evidence obtained from this and the previous analysis of pediatric deaths reports. This review does not constitute a benefit-risk analysis and no changes to *Indications and Usage* or *Contraindications* sections of USPI are recommended based on these data.

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Appendix A: Case narratives for COVID-19 vaccine US deaths in individuals aged 18-24 years reported to VAERS – possible cases (n = 3)

1. VAERS [redacted]: 19-year-old female with no significant PMH received her 2nd dose of Moderna vaccine on 5/1/2021 (first dose given 28 days prior on 4/3/2021), presented with fulminant myocarditis 15 days post dose 2, on 5/16/2021, with ensuing orthotopic heart transplant on 524 May 2021, and died of complications of primary graft failure on 11 June 2021 (41 days post dose 2). Family history was notable for a paternal [redacted] who died from HOCM at age 27 and [redacted] with stage 3 HF. Vaccination was complicated by intermittent URI symptoms in the context of sick contacts in her dorm, but multiple negative Covid tests in the interim. Per her mother, she "felt unwell initially in early April following COVID vaccine, did get better for a period of time, but then started to feel congestion again." After her second dose on 1 May 2021, she "visited her parents during 8 and 9 May 2021 and "sounded hoarse and congested." When she returned to campus on 11 May 2021, she began having fevers and cough, had a telehealth visit on 12 May 2021, and was diagnosed with allergies. On 14 May 2021 and 15 May 2021 she presented to her student health clinic, complaining of several days of URI symptoms including fever and sore throat, with new onset nausea and dizziness. Medical records on 14 May 2021 documented "erythema to oropharynx, no ulcerations" with elevated heart rate > 140. Testing for group A Streptococcus, COVID-19, mononucleosis, and influenza A and B was negative. She was advised to go to the ED for further assessment, [redacted]. On 15 May 2021 her exam was notable for "gum inflammation with small ulcers on both upper and lower gums and right tonsil," and she was started on valacyclovir for presumed HSV-1 by exam alone; per visit note no further tests were done and HSV testing was not documented.

   She was brought by EMS to a hospital for care on 16 May 2021, with complaints of 6 days of worsening URI symptoms, 3 days of fever and mouth pain, one day of oral ulcers, and positional vertigo with multiple near syncopal episodes. ED evaluation was notable for "multiple ulcerative lesions to gums, throat," tachycardia (> 120), hypotension, elevated troponin and lactic acid, and cardiomegaly on CXR. Echocardiogram showed EF 37% and mild LVH. Drug testing and comprehensive respiratory viral panel including COVID-19, along with CMV, Coxsackie, HIV, and MRSA tests were negative; HSV testing was not documented.

   While in the ED, she developed bradycardic arrest, requiring CPR, with return of spontaneous circulation (ROSC) obtained within 5 minutes. She subsequently developed EKG abnormalities including wide complex VT (~ 150) with pulse, followed by diffuse ST elevation. Follow up echo showed LV function of 35% with global hypokinesis and she was admitted to the cardiac catheterization lab for an emergent intra-aortic balloon pump. Coronary arteries were noted to be normal. She was admitted to the ICU with presumed viral myocarditis. Subsequent

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inpatient history was complicated by multiple episodes of cardiac arrest requiring CPR, and pericardial effusion requiring window (effusion fluid negative for adenovirus, CMV, EBV, Enterovirus, and bacterial growth). Subsequent echocardiograms revealed minimal RV/LV function, so she was transferred to another hospital on 20 May 2021 for heart transplantation on 24 May 2021. However, course was complicated by low pulmonary compliance, RV dilation, LV dysfunction (EF of 5%), and cardiogenic shock; the patient also sustained numerous other complications. Repeat respiratory viral testing panel including COVID-19, as well as HIV, CMV, MRSA, and blood cultures was negative. On 11 June 2021 her continuous veno-venous hemofiltration clotted, doppler tones were lost in the left popliteal artery, her condition deteriorated, and she was [redacted] and pronounced dead, 41 days after her 2nd Moderna dose.

Autopsy of the explanted heart on 12 June 2021 was notable for idiopathic cardiomyocyte necrosis. Microscopic examination showed acute and subacute multifocal geographic transmural myocardial infarction of the left and right ventricles. Per the report, “histologic examination revealed no evidence of myocarditis…however the possibility of myocarditis as the underlying etiology cannot be excluded” and “vaccine-related etiology cannot be ruled out.” There was no immunohistochemical (IHC) or molecular evidence of SARS-CoV-2, human enterovirus RNA, parechovirus RNA, parvovirus DNA, or Borrelia burgdorferi. Lung and spleen tissue bacterial and fungal cultures were also negative. There was no testing performed for HSV or other organisms. The cause of death on the autopsy report on 12 June 2021 is "multiorgan failure including primary graft failure, necrotizing pneumonia and diffuse alveolar damage due to acute heart failure due to idiopathic cardiomyocyte necrosis [of the explanted heart]." There is no available death certificate.

CDC’s infectious disease pathology branch (IDPB) also did not find an infectious etiology on tissue-based testing. CDC pathology’s postmortem examination of the explanted heart tissue on 21 July 2021 noted acute and subacute multifocal transmural myocardial infarction as well as lymphohistiocytic inflammation between areas of infarction, “which may represent a myocarditis or reparative changes after infarct.” The available postmortem infectious disease workup of the heart tissue noted negative gram stain and negative IHC for SARS-CoV-2 COVID-19 nucleocapsid and spirochetes, but immunoreactive IHC for unspecified select gram-negative bacteria and Human C4d (suggesting immune-mediated injury). Additional infectious disease testing included negative SARS-CoV-2 (N gene) RT-PCR, negative Enterovirus group RT-PCR, negative Human parvovirus B19 PCR, and negative Human parechovirus PCR (although the report notes that for the PCR tests for Human parvovirus B19 and Human parechovirus “performance characteristics have NOT been fully established by IDPB”). There was no documentation of testing for HSV or other organisms.

Reviewer comment: This case was assessed as possibly related to COVID-19 vaccination. The patient’s clinical presentation and course were consistent with

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myocarditis. Although the explanted heart autopsy did not show active inflammation and infiltrates, there was extensive necrosis. Medical literature suggests that myocardial necrosis can be caused by an immunologic process that targets the myocardium in cases of vaccine-induced myocarditis[1] (34). It has also been shown that the late Gadolinium enhancement (LGE) on MRI noted in some COVID-19 vaccine-induced myocarditis cases is a marker of significant myocardial injury, necrosis, scarring, or fibrosis (34-36). Per cardiology SME reviewer, the necrosis seen in the native heart may be a late indicator of severe precipitatory myocarditis. The original explanted heart autopsy also reported that myocarditis cannot be excluded due to the clinical presentation. Additionally, the CDC pathology report did note the presence of focal lymphohistiocytic inflammation between areas of infarction, which, in the setting of positive C4d staining, may represent myocarditis apart from post-infarct reparative changes.

The CDC pathology report, however, did not include documentation of extensive testing for all potential causative organisms of myocarditis, including HSV; such infections could represent alternative etiologies for presentation. She was clinically diagnosed with HSV based on gum and throat ulcers and started on empiric treatment with Valacyclovir on day 1, one day prior to presentation to the ED. HSV is a rare but known cause of myocarditis, with an estimated prevalence of less than 1% of acute myocarditis cases (37). Further, the empiric treatment of HSV with antivirals could have led to systemic clearance of antigen of the other viruses that were tested for, resulting in the negative tests. Other viruses not tested for such as varicella-zoster could be alternative culprits for oral ulcerations with myocarditis (38,39). Finally, oral ulcers could also be a presentation of Behcet's Disease, a systemic inflammatory process that can include myocarditis and has been associated with genetic factors (40).

2. VAERS [redacted]: 21-year-old female with PMH of hypothyroidism and obesity received 2nd dose of the Pfizer-BioNTech COVID-19 vaccine and died 13 days later with a diagnosis of myocarditis. Per the VAERS report, she experienced 3-days of fever (101.6F) post-vaccination which then resolved. She then felt "fine" until 12-days post-vaccination when she reportedly became confused and complained of feeling lightheaded; she subsequently experienced seizure-like activity and became unresponsive. EMS was called and she was transported to the ED. En route to the ED, EMS was unable to intubate; she was shocked multiple times and went in and out of asystole with eventual ROSC. Bedside echo showed 35-40% ejection fraction and trace pericardial effusion with no valve abnormality. CT angiogram (CTA) was negative for pulmonary embolus (PE). Labs were significant for leukocytosis (WBC 43.4, 6% bands), troponin 4.89, TSH 7.112, glucose 500, HGB A1C 5.5, creatinine 1.89, ALT 239, AST 262, and IgE 319.7 (reference range=0-160.0 IU/mL). Despite multiple defibrillations, ultimately, she was in V-tach "with thready pulse not sustainable with life." She was declared deceased 13-days post-vaccination.
The autopsy cause of death was viral myocarditis. Heart autopsy findings included histologic lymphohistiocytic infiltrate diffusely through the myocardium

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with occasional eosinophils and areas of myocyte necrosis. Other autopsy findings included a nodule in the right thyroid gland with papillary thyroid carcinoma. The autopsy report noted that "consultation with the CDC revealed PCR detection of parvovirus B19 in heart tissues and no evidence of SARS-CoV-2 or other etiologic agents. The direct association of parvovirus with myocarditis is somewhat unclear. Postmortem studies reveal no elevated tryptase…support[ing] a non-anaphylactic reaction."

This case was reviewed by the CDC IDPB. Heart findings included severe lymphohistiocytic myocarditis with rare eosinophils, no molecular evidence of SARS-CoV-2 or enteroviruses; immunohistochemistry was negative for Neisseria meningitidis and spirochetes, including Borrelia burgdorferi. There was PCR evidence of parvovirus B19 in the heart and thyroid. The heart also showed immunohistochemical evidence of C4d. Per the report, this finding is consistent with myocardial injury associated with myocarditis. The autopsy report comments indicate that the significance of detecting parvovirus B19 in the heart tissue was "unclear as parvovirus B19 likely has long-term persistence in heart tissues and is frequently detected in heart tissues from autopsies of patients with no clinical or histopathologic evidence of myocarditis." The lungs showed severe leukocytosis and intraalveolar hemorrhage with no molecular evidence of SARS-CoV-2. Additionally, there was no immunohistochemical evidence of Neisseria meningitidis (lung, kidney, liver).

*Reviewer comment: This case was assessed as **possibly** related to COVID-19 vaccination. This individual experienced a high fever post-vaccination and then reportedly felt well until 12-days post-vaccination when she experienced cardiac arrest with subsequent death. Autopsy revealed severe lymphohistiocytic myocarditis, and the death occurred in temporal association with vaccination. However, parvovirus B19 was detected in heart tissue. Parvovirus B19 (B19V) is a common infection, with seropositivity up to 50% in adolescents (11). It is a known cause of myocarditis, involving infection of cardiac endothelial cells (12). B19V has also been suggested as a cause of dilated cardiomyopathy, but studies of this association have yielded mixed results, as B19V DNA can also be found in cardiac tissue of individuals without myocarditis or cardiomyopathy (13). Diagnosis of active infection can be accomplished by detection of specific antibodies against B19V by enzyme-linked immunofluorescence assays, or by detection of viral DNA with the use of PCR (14). Additional testing can include in situ hybridization testing in erythroblasts (15). However, in cases where such testing is not performed or when results are not available, discerning causes of autopsy-reported cardiac disease where B19V is detected is challenging. The clinical significance of the finding in this case is unclear. However, as the autopsy reported cause of death is viral myocarditis, B19V is a plausible alternate etiology for this death.*

3. VAERS [redacted]**:** 20-year-old female with PMH of acid reflux, recurrent nausea and vomiting bile (indeterminate workup), received the 2nd dose of Pfizer-

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BioNTech COVID-19 vaccine and died 15 days post-vaccination. Per medical records, twelve-days post-vaccination her roommate observed her exhibiting seizure-like activity ("shaking") for approximately 5-seconds; she was subsequently able to talk. About 45 minutes later, she laid down on the floor and again exhibited "significant shaking." EMS was called and they noted "heavy secretions or vomitus and there was some aspiration," and she was taken to the ER.
The decedent continued to exhibit seizure activity/status epilepticus despite multiple seizure medications and propofol. She was placed on pressors, intubated, and transferred to a tertiary care facility. MRI of the brain showed no acute intracranial abnormality. EEG showed "generalized slowing of the background of moderate to severe in nature, indicative of moderate to severe diffuse encephalopathy, non-specific etiology." Urine drug screen was positive for benzodiazepine and cannabinoids. Despite aggressive medical intervention, she coded in the ICU and died 15-days post-vaccination.

Cardiac findings at autopsy were significant for "scattered band-like myxoid appearing regions divide up the myocardium and surround the vessels. Patchy foci of lymphocytes are within the myocardium and infiltrate the myocardium. There is rare myocyte necrosis, and no acute inflammatory infiltrates are observed. Rare contraction bands are present. Special staining with Masson's Trichrome reveals the myxoid appearing regions to be fibrosis." Lung findings included microscopic findings suggestive of early viral pneumonia with large peribronchial lymphocytic infiltrates and alveolar infiltrates within the lungs, and congestion of lungs with mucous plugging of the small caliber airways. The documented cause of death was lymphocytic myocarditis with a contributing factor of bronchopneumonia. The autopsy report commented that the "origin of the myocarditis is likely viral, as evidence of an evolving viral pneumonia was observed within the lungs." The report further noted that "inflammation of the heart muscle may disrupt the normal electrical conduction pathways resulting in arrhythmias. Arrhythmias may negatively impact the ability of the heart to function properly and can result in loss of consciousness, multiorgan failure, or sudden death." SARS-CoV-2 was negative.

*Reviewer comment: This case was assessed as **possibly** related to COVID-19 vaccination. The individual experienced new onset of seizures of unclear etiology with status epilepticus 12-days post-vaccination and was noted to exhibit heavy secretions and aspiration; hospital records indicated she had a pulmonary infiltrate with suspected aspiration into the airways and suspected pneumonia. The cause of death per autopsy was lymphocytic myocarditis with a contributing factor of bronchopneumonia. The autopsy report commented that the origin of myocarditis was likely viral due to autopsy findings of an evolving viral pneumonia. However, a specific virus was not identified to support a viral etiology. The records in VAERS indicate that SARS-CoV-2 testing was negative and there is no available documentation that a viral respiratory panel was performed. While viral myocarditis in the setting of an evolving viral pneumonia is*

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a potential alternate etiology for this death, in the absence of positive viral testing, it is also possible the COVID-19 vaccination contributed to the myocarditis.

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Appendix B: Case narratives for COVID-19 vaccine adult US deaths in individuals aged 18-24 years reported to VAERS – cases assessed as unlikely (n = 54) or unassessable (n = 31)

VAERS [redacted]**:** 22-year-old female with Rett syndrome (nonverbal and bedbound at baseline) and history of seizures died 23 days after receiving the 2nd dose of Pfizer BioNTech COVID-19 vaccine on 29 January 2021. The decedent was status-post total colectomy with end ileostomy and tracheostomy. Date of 1st dose is unknown. Per her mother, she had been having colostomy blockages, 1 day of vomiting, and had not had her seizure medications on the day of presentation. She presented to the ED with "gurgling" and unresponsiveness. Upon arrival to the ED, she went into ventricular tachycardia and then asystole and PEA arrest. ROSC was achieved after which she was directly admitted to the ICU. Laboratory study findings were significant for lactic acid of 17.7, troponin of 0.19, and procalcitonin of 80. ECG reportedly noted QTc prolongation but there is no available report. CT chest findings included mild perihilar consolidation, likely cardiogenic pulmonary edema, and a linear 2.5cm metallic density projecting at the thoracic inlet to left trachea representative of a foreign body vs external overlapping shadow. The decedent arrested while undergoing imaging in the CT suite and expired approximately 5 hours from initial ED presentation.

The immediate cause of death reported on death certificate was cardiac arrest due to Rett syndrome, cardiomyopathy, seizure, and possible small bowel obstruction. Autopsy was marked as not performed.

*Reviewer comment: This case was assessed as **unlikely** related to COVID-19 vaccination due to multiple identified risk factors associated with the individual's underlying condition of Rett syndrome (RS) that likely predisposed the fatal outcome, including complications of colostomy blockage from small bowel obstruction, aspiration, and arrhythmic cardiac arrest. QTc interval and T-wave abnormalities are known cardiac risks in MECP2 disorders, leading to an annual mortality rate in Rett syndrome of 1.2%; a high proportion (26%) of which were sudden and unexplained (41). Historically, it has been suggested that loss of physiologic heart rate variability associated with an increase of adrenergic tone represented the electrophysiologic basis of cardiac instability and sudden death in children with RS (42). However, lack of an autopsy precludes conclusive determination of cause of death.*

VAERS [redacted]**:** 18-year-old obese male with no significant medical history died 3 days after receiving the 1st dose of Moderna COVID-19 vaccine on 2 March 2021. The decedent reportedly developed fatigue, body aches, and a headache 1 day after vaccination. On the morning of his death, he complained of chest pain for which he took Tylenol and went back to bed. He was found a few hours later by his family who called EMS and was declared deceased on-site. Cause of death reported on death certificate at the time was listed as "pending investigation."

Other than source documents from previous primary care well visits and telehealth sick visit notes since the age of 9, there is no other available information regarding

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semiology leading up to death. The most recent note on [redacted] (approximately 2.5 months prior to death) documented normal exam and no significant medical concerns; routine labs were generally within normal limits other than high triglycerides to 229 mg/dL (reference range 0-89 mg/dL).

Separate reports for ancillary evaluations associated with the autopsy report, including neuropathology and cardiac pathology consultations, histology sections, toxicology, and viral testing by nasopharyngeal swab, were originally attached to the autopsy report, but were not available for review in the record. Autopsy findings in the record were significant for pulmonary edema with a combined lung weight of 1248g, though it was noted that this was a non-specific finding that can be seen in cardiac deaths. Cardiac pathology consultation identified a recent acute myocardial infarction of the left lateral ventricle likely due to narrowing of the coronary arteries and "the fact that one of the vessels travels through the heart muscle during part of its course". Neuropathology consultation identified severe cerebral edema and cerebellar tonsillar herniation, and hyponatremia of the vitreous "which could have contributed to death." Immunoglobulin E was noted as elevated (504 kU/L) but could have been due to recent vaccination. Overall, the cause of death reported on autopsy was acute myocardial infarction due to coronary artery hypoplasia and tunneling.

*Reviewer comment: This case was assessed as **unlikely** related to COVID-19 vaccination due to an alternate etiology of acute myocardial infarction secondary to coronary artery hypoplasia and tunneling (please see Discussion, section on Sudden Cardiac Death), and possible risk factors of hypertriglyceridemia and obesity.*

VAERS [redacted]: An 18-year-old female with a history of asthma died 8 days following a second dose of Pfizer BioNTech COVID-19 vaccine. She reportedly exhibited seizure-like activity shortly after her first dose, including staring and jerking motions in her upper extremities. Concerned about an allergic reaction and unable to palpate a pulse, the pharmacist administered epinephrine resulting in resolution of the patient's jerking movements. She was transported to the ED, where vital signs and evaluation, including urinalysis, blood serum assessment, toxicology screen, EKG, and CT of the head were generally unremarkable. Chest x-ray demonstrated central peribronchial opacities suggesting age-indeterminate bronchitis. The patient was assessed as having post vaccination syncope and was discharged from the ER with a recommendation for outpatient primary care follow-up.

The case report form states that the patient died 8 days after her second dose of the Pfizer COVID-19 vaccine. However, there are no medical records describing the events immediately surrounding her death. Furthermore, the date of death is listed as 27 February 2021, but the patient's ER evaluation for the post-vaccination syncopal episode was on 12 March 2021 (after her first dose). There is, additionally, no autopsy report or death certificate available in VAERS.

*Reviewer Comment: This case is classified as **unassessable** given the missing autopsy report, missing death certificate, and lack of medical records describing the events*

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immediately surrounding this patient's death which precludes a causality assessment. Furthermore, there is conflicting information between the VAERS records and the medical records regarding the temporal association between vaccination and death.

VAERS [redacted]: An 18-year-old male living in a skilled nursing facility with a history of portal hypertension secondary to portal vein thrombosis, esophageal varices, pancytopenia, epilepsy, splenomegaly, asthma, and severe cognitive impairment died 14 days after his second dose of the Moderna COVID-19 vaccine. Per the report, following his first dose, the patient developed abscesses of the arm, groin, thigh and knees. At an unspecified interval after the first dose, he received a second vaccine dose, after which he was noted to be hypoactive. Fourteen days after his second vaccination dose, he was found unresponsive in bed with his head wrapped in the sheet and secretions coming from his mouth and nose. EMS was called and he was pronounced deceased upon their arrival. There were limited additional details regarding the clinical course of this case and no VAERS source documents available for review, including medical records, vaccination records, autopsy report, and death certificate.

*Reviewer Comment: This patient had multiple underlying medical issues that may have contributed to his death. However, this case is **unassessable** due to the missing autopsy report and death certificate and insufficient information regarding this patient's diagnostic evaluation and cause of death.*

VAERS [redacted]: A 23-year-old bedridden, male with cerebral palsy, spastic quadriplegia, epilepsy, hydrocephalus, and multiple sclerosis died 4 days following his first dose of the Moderna COVID-19 vaccine. The decedent's medical history is significant for gastrostomy-dependence. Eleven days prior to vaccination, he was hospitalized for vomiting; no records from this hospitalization are available in the report. He received his first dose of the Moderna COVID-19 vaccine on the day of discharge back to the nursing home facility where he resided. On the day of vaccination, the reporter stated that the decedent experienced weakness and lack of appetite. Four days post vaccination, he began coughing up foul-smelling secretions. EMS was called; during the EMS intake evaluation, he was noted to be hypoxic with oxygen saturation of 44%. Presumably he became unresponsive, CPR was initiated, and he was transported to the hospital. There are very limited records associated with this report and limited details regarding the circumstances surrounding this patient's death. Notably, there are no available diagnostic testing records, and some sections of the records are in Spanish. Available medical records translated from Spanish to English using an automated AI translator state that patient arrived at the hospital in a comatose state. Documented temperature on arrival was 36.2°C (97.2F) with no pulse, blood pressure, or respirations. He was pronounced deceased upon arrival to the ER after an EKG confirmed asystole.

No autopsy report is available in the record and it is unclear whether one was performed. The death certificate cause of death is cardiorespiratory arrest (translated from Spanish). The response in the death certificate section entitled "Brief narrative of

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the circumstances of death" is "patient with liver cirrhosis bedridden in bed had convulsions/seizures."

*Reviewer Comment: This event is assessed as **unlikely** to be related to vaccination. While there is a temporal association with vaccination, the description of the decedent's foul-smelling secretions as well as his rapid respiratory failure suggests a likely infectious etiology for his demise. Furthermore, he has multiple risk factors for aspiration and/or pneumonia including cerebral palsy with spastic quadriplegia, multiple sclerosis, epilepsy, and recent hospitalization. Given this and despite limited clinical details available in the report, infection is the most likely etiology of death, with other chronic medical issues possibly contributing to his demise.*

VAERS [redacted]: A 21-year-old Asian male with no known medical history died 12 days after receiving the first dose of the Pfizer-BioNTech COVID-19 vaccine. The decedent had a family history significant for diabetes. Following vaccination, he developed a headache, back pain, and lightheadedness that improved over the course of a week. Seven days after vaccination, he experienced severe vomiting. He collapsed while attempting to go to the bathroom and appeared to be gasping for air. His friends initiated CPR and called EMS. When EMS arrived, he was unresponsive and breathing 3 times per minute; blood glucose fingerstick registered as "high." Pulse and breathing improved with bag valve mask ventilation, but upon arrival to the ER, he had altered mental status and was noted to be intermittently tachycardic and hypertensive. Initial EKG showed normal sinus rhythm, moderate intraventricular conduction delay, no STEMI. Troponin was mildly elevated at 0.23. Serum chemistry was significant for hyponatremia, hyperkalemia, elevated creatinine (3.1), and grossly elevated serum glucose (1041). His lipase, lactate, and procalcitonin levels were also elevated. He was given insulin, but became progressively more tachypneic, tachycardic, and hypoxic and he was subsequently intubated. Arterial blood gas demonstrated severe metabolic acidosis. Chest x-ray demonstrated possible right sided upper and paratracheal infiltrate and CT of chest showed bilateral consolidative lung opacities with debris in the trachea and mainstem bronchi concerning for aspiration pneumonia. CT of the head showed no bleed but evidence of sinus thickening that was concerning for fungal sinusitis. He was admitted to the intensive care unit with a diagnosis of diabetic ketoacidosis, acute hypoxemic respiratory failure, dehydration, septic shock in the setting of possible aspiration pneumonia, acute kidney injury, and hyperkalemia.

The patient was started on empiric antibiotics, acyclovir, and amphotericin. Anti insulin antibodies, islet cell IgG antibodies, antinuclear antibodies, and glutamic acid decarboxylase antibodies were all negative or within the reference range, and hemoglobin A1C was 5.7. MRI of the brain showed temporal and posterior gyral inflammation consistent with encephalitis. Lumbar puncture was performed with high opening pressure noted but cerebrospinal fluid examination showed no evidence of infection. A broad infectious work up, including blood cultures, COVID, influenza, RSV, and CSF gram stain and culture was also negative. Nasal endoscopy demonstrated purulent drainage from the bilateral sphenoid ostia consistent with sinusitis; sinus culture grew few Staphylococcus aureus, few Proteus mirabilis, but was also

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"overgrown with Proteus species." EEG showed no evidence of seizure activity. By hospital day 4, the patient's DKA had been successfully managed via DKA drip/protocol, but he remained intubated and unresponsive. Later that day, he was noted to have bilateral, nonreactive pupils which was an acute change from his prior status. An urgent head CT showed diffuse loss of gray-white matter differentiation consistent with edema and global loss of perfusion. Per neurosurgery, he was not a candidate for mannitol or external ventricular drain. The next day, CT of the head revealed partial herniation of the brain stem. After a failed apnea test, he was pronounced deceased on hospital day 5. The cause of death documented in his medical records was massive aspiration resulting in irreversible hypoxic brain injury, cerebral edema, and herniation.

The death certificate stated cause of death was aspiration pneumonia and sepsis complicating vomiting, severe hyperglycemia with ketoacidosis and hyperosmolality, and T-cell lymphocytic pancreatitis following first dose of Pfizer COVID-19 vaccination. An autopsy was performed but there was no autopsy report among the VAERS source documents.

*Reviewer Comment: This case is assessed as **unlikely** related to vaccination. This patient's clinical presentation appears consistent with fulminant diabetes mellitus (FDM). While there is no autopsy report available for review, his death certificate diagnosis of T-cell lymphocytic pancreatitis presumably came from the autopsy report. This pathological diagnosis in the setting of profound hyperglycemia suggests an autoimmune insult to the beta islet cells and surrounding pancreatic tissue. Type I diabetes typically has an indolent course that begins with the appearance of islet autoantibodies and progresses through distinct stages of autoimmunity with progressive loss of functional beta islet cell mass until a clinical diagnosis is made. Conversely, FDM is characterized by rapid progression from hyperglycemia to diabetic ketosis or ketoacidosis within days or weeks. In these patients, pancreatic destruction most often occurs as a result of a direct attack by cytotoxic T cells. As a result, pancreatic autoantibodies are often absent and hemoglobin A1C levels are normal which is consistent with a rapid onset of disease (43).*

FDM is most common in patients of East Asian descent accounting for 7.1% of all type I diabetes and 30.4% of adult-onset type 1 diabetes in Korea with a similar incidence in Japan and China. Studies have suggested an association between FDM and certain HLA haplotypes that are unique from those typically associated with the development of type I DM (44). While the etiology of FDM has not been elucidated, flu-like symptoms are frequently observed as a prodrome to FDM and viral infection is the most common environmental trigger implicated in its development. Evidence has also suggested associations with pregnancy, immune checkpoint therapy, and higher incidences in individuals with drug-induced hypersensitivity syndrome have also been noted (44).

There is currently no well-established relationship between the development of FDM and COVID-19 vaccination. While there are several case reports describing new-onset FDM following COVID-19 vaccination, some of these cases fail to indicate whether the

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patient underwent an infectious work up (45, 46) and other cases describe FDM following COVID-19 vaccination in the setting of preexisting viral illness (47).

This patient's aspiration and resultant pneumonia presumably occurred after the onset of FDM, as a result of his altered mental status and metabolic encephalopathy. However, the presence of sinusitis suggests a preceding infection since most cases of rhinosinusitis are viral and even instances of bacterial sinusitis often begin with viral induced inflammation of the sinuses with secondary bacterial infection. He did undergo a respiratory pathogen work up consisting of COVID-19, influenza, and RSV. However, viral testing was not comprehensive, and he did not undergo serological testing for coxsackieviruses, cytomegalovirus, Epstein-Barr virus, or human herpes viruses which are commonly associated with FDM. Furthermore, current evidence does not support an association between COVID-19 vaccination and autoimmune disease (please see Discussion section, subsection on Autoimmune Diseases). With respect to DM, while there are case reports and smaller meta-analyses based on these case reports that describe a possible association between COVID-19 vaccination and the onset of DM (48), there is stronger evidence in the form of observational studies and larger meta analyses that do not support a causative relationship (49-51). Thus, in this case, preceding infection serves as a more likely inciting event.

VAERS [redacted]: 21-year-old female with morbid obesity (BMI 61.9 kg/m^2) and a history of migraines, depression, and anxiety, and previous overdose, died one day after her first dose of Pfizer COVID vaccine. She developed sudden dyspnea immediately after taking a shower on the day after her first dose of Pfizer Covid vaccine. She called EMS and was found to be hypoxic with severe respiratory distress; blood glucose was 266. She then had witnessed cardiac arrest in front of EMS. She arrived at the ED in asystole with telemetry report documenting "CPR was stopped several times, asystole with episodes of VF/VT 30s-20s noted." Death was pronounced after one additional hour of CPR. A respiratory panel including Covid test was done but results are not available.

Postmortem tox screen was positive for prescribed psychiatric medications (citalopram [therapeutic range], trazodone, topiramate) and marijuana. Autopsy report noted marked hepatic steatosis and cardiac hypertrophy with concentric LVH, but no microscopic evidence of acute myocarditis. Histologic exam of the heart showed "slight to moderate parenchymal fibrosis and enlarged and adjacent myofibers with enlarged hyperchromatic nuclei consistent with hypertrophy... a vessel with neutrophilic marginalization…no neutrophilic or lymphocytic myocyte infiltrations or myocardial necrosis." Autopsy attributed death to "probable cardiac arrhythmia in the setting of obesity and cardiac hypertrophy, with possible contribution to death by vaccination one day prior, per medical examiner." Death certificate is not available.

*Reviewer comment: Role of vaccine is **unlikely** based on more likely etiology of cardiac hypertrophy and no evidence of acute myocarditis on autopsy (see Discussion, subsection on Sudden Cardiac Death). Of note, both marijuana and trazadone can*

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prolong QT interval, especially when used synergistically, and predispose to fatal arrhythmia (52).

VAERS [redacted]: 19-year-old female with unknown PMH was found dead at her boyfriend's residence on 13 March 2021, 7 days after first dose of Pfizer vaccine was administered on 6 March 2021. The initial report was completed by a local health district representative who "didn't know the exact events but was asked to fill in the information…and to contact the medical examiner's office for more information." The autopsy report was mostly normal with the heart weighing at 300 grams and normal anatomy and patent vessels, and the only histologic finding of note was "very focal mild/moderate hypertrophy in the heart." The tox screen noted a positive finding of Delta-9 THC at 0.52 ng/ml (reporting limit 0.50). The manner of death is noted as "natural," and cause of death is listed as cardiac arrhythmia. Death certificate also notes cause of death as cardiac arrhythmia. There are no other source documents other than vaccine records.

*Reviewer comment: Role of vaccine is **unassessable** due to no interim information between vaccination or death or other source documents.*

VAERS [redacted]: 21-year-old male with history of antiphospholipid syndrome treated with Xarelto and unspecified hospitalization at age 16 was found dead at home 2 days after his first dose of the Moderna vaccine. The only available source document apart from VAERS report is the death certificate, listing COD as Coronary atherosclerosis and thrombosis; there is no autopsy report.

*Reviewer comment: Role of vaccine is **unlikely** due to alternate etiology of CAD and thrombosis listed on death certificate and in the context of history of antiphospholipid syndrome.*

VAERS [redacted]: This consumer report, submitted in May 2021, documents a person of unknown sex, age (listed as "in their 20s"), and medical history, who received the Pfizer vaccine (unknown dose number) on an unknown date "in the morning, and dropped dead in the afternoon for no reason." The cause of death documented in the report is "dropped dead." It is unknown if an autopsy was performed, and there is no death certificate or any other source documents available. The reporter is identified only by a first name with unknown relation to the patient and lists 2 similar deaths without any further information.

*Reviewer comment: Role of vaccine is **unassessable** due to no source documents or further information.*

VAERS [redacted]: 23-year-old male with prior history of COVID-19 infection in December 2020 was found dead in his girlfriend's car one day after receiving the first dose of Pfizer vaccine on 30 April 2021. He was previously in good health with no known illness in the preceding month of receiving the vaccine and occasionally only took Tylenol for migraines and melatonin for sleep.

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The autopsy report is in Spanish and was translated to English using an automated AI translator. Per the translated report, the heart anatomy was completely normal, with no microscopic "evidence of inflammation, fibrosis, or necrosis." The only positive finding was "moderately congestive lung parenchyma" with "a moderate amount of fluid that flows under pressure" and "moderate diffuse congestion" under microscopy. The toxicology report was negative. The report documents a positive nasopharyngeal swab for Molecular SARS-CoV-2 (COVID-19). The manner of death is listed as natural and cause of death documented as "probable complication of COVID-19: a. Negative toxicology and microscopic examination. b. Pulmonary congestion. c. SARS-CoV-2 PCR positive." There is no death certificate in the source documents.

The report documents include a 2023 email from the decedent's stepmother; she reported that after a day of shopping and going to [redacted], he "went to church with his girlfriend and died there, like he fell asleep." She also reported that she requested the [redacted] forensic department to test him 2 more times after the first positive result and was told that both came out negative.

*Reviewer comment: Role of vaccine is **unlikely** due to the autopsy-documented COD of COVID-19 representing a more likely etiology; pulmonary congestion on autopsy is consistent with this etiology. Of note, there are no documented test results consistent with the negative COVID-19 test results reported by the decedent's stepmother. There is no additional clinical information pointing to a vaccine-related etiology.*

VAERS [redacted]: A 19-year-old male with history of autism and ADHD (on Clonidine, Vyvanse, Vraylor), was found deceased in bed 12 hours after his first dose of Moderna vaccine. He had a family history notable for paternal death from enlarged heart at age 35. Per initial primary care provider's VAERS report, there were no notable preceding symptoms.

Postmortem COVID-19 PCR was negative. The autopsy was only notable for pulmonary edema and congestion. The heart had a normal anatomy and normal microscopic examination, with no gross or microscopic e/o acute or subacute inflammation or fibrosis in heart or other organs, and no gross seizure focus found in the brain. The coroner's toxicology report was positive for clonidine below the reporting limit, amphetamine barely above therapeutic level, and a normal tryptase level. Autopsy report lists cause and manner of death as undetermined. There is no death certificate. However, the initial report by the primary care reports that postmortem IgE level was elevated, and there was "suspected heart arrhythmia (family history, history of chest pain, and medications) or seizure"; these findings are not documented in the autopsy or toxicology report.

*Reviewer comment: Role of vaccine is **unlikely.** There were no autopsy findings suggestive of a possible relationship between the patient's demise and COVID-19 vaccination. However, notable in the clinical history is use of Vyvanse stimulant*

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medication and Clonidine (possibly contributing to abnormalities in cardiac rhythm (53), and documented family history of early paternal cardiac death from enlarged heart.

VAERS [redacted]: 20-year-old male with PMH of beta thalassemia and anxiety received his 1st dose of the Pfizer-BioNTech COVID-19 vaccine and died of suicide 6 days later. One day after vaccination, he reportedly had a headache and was feeling unwell. He spoke to his mother at 7:30 pm on the day of death and was found [redacted] in his college dorm room several hours later. EMS was called and found him in cardiac arrest; he was resuscitated and admitted to the hospital. SARS-CoV-2 test was positive (nucleic acid amplification); mother reported he had tested negative for COVID-19 prior to vaccination. He was in a coma and suffered complications related to his time without oxygen, including anoxic encephalopathy, cerebral edema, and ventilator dependent respiratory failure. He died in hospice 6-days post-vaccination. Medical records indicate his parents denied any known history of depression or prior suicide attempts. The autopsy indicated the individual died of complications [redacted]; the manner of death was suicide.

*Reviewer comment: This case was assessed an **unlikely** related to COVID-19 vaccination. Complications [redacted] (suicide) provides an alternative explanation for this death. Please see Discussion, subsection on Suicidality in Young Adults.*

VAERS [redacted]: 22-year-old female with history of traumatic brain injury at 11 months of age, movement disorder, seizures, and speech loss, who received her first Moderna vaccine on 3/19/2021, and was found dead 16 days later. Per reporter, patient had had a yearly exam with her physician on an unknown date after vaccination, and no new health issues were noted at the time of the exam. An autopsy was not performed, and cause of death was reported as due to natural causes on the death certificate per reporter. The death certificate is not available.

*Reviewer comment: This case was assessed an **unassessable** due to limited information/ no available source documents, including autopsy or death certificate.*

VAERS [redacted]: 20-year-old male with PMH of seizures and depression (per ER records) received the 2nd dose of the Pfizer-BioNTech COVID-19 vaccine and died 5 days later. Per the report, the decedent had reported to his family that he had been feeling unwell since vaccination. Three days post-vaccine, he began having nausea and black, dark coffee-ground emesis. He was found unresponsive at home 5 days post-vaccination. EMS responded and he was noted to be in asystole which did not respond to cardioversion. The ER medical records indicate the clinical history raised the suspicion of a GI bleed and blood loss anemia. He was transported to the ED, but ROSC was never achieved and and the individual was pronounced dead after arrival. The autopsy report noted an approximate weight of 209 pounds and approximate height of 64 inches (BMI approximately 36). The autopsy revealed hepatomegaly (3900 grams) and a section of liver showed extensive macrovesicular steatosis involving approximately 95% of hepatocytes. The autopsy noted the stomach contained approximately 280 mL of dark green-black fluid with a granular suspension. Toxicology

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was positive for acetone (38 mg/dL), caffeine, and naloxone (which had been given by EMS). Both the autopsy report and death certificate concluded that the individual died of fatty liver disease, and the autopsy "opinion" section noted that the fatty liver natural disease process disrupts the function of the liver and may result in abnormal electrolytes in the blood and abnormal heart rhythms. The opinion also noted that liver malfunction may also result in the liver not making proteins to help the blood clot normally and may result in bleeding into the gastrointestinal tract. Of note, the autopsy report indicated that the family did not endorse prior drug or alcohol abuse by the decedent.

*Reviewer comment: This case was assessed as **unlikely** related to COVID-19 vaccination. While there was temporal association with vaccination, the death certificate and autopsy reported cause of death was complications of hepatic steatosis, which can include gastrointestinal bleeding, and this diagnosis provides a more likely explanation for this individual's death. This etiology is consistent with the individual's elevated BMI of 35.9.*

VAERS [redacted]: 23-year-old male with PMH of cerebral palsy with severe developmental delays, epileptic seizures, deteriorating bones in hips, and hydrocephalus with a VP shunt received the 1st dose of the Pfizer-BioNTech COVID-19 vaccine, experienced vomiting that began 2-days post-vaccination, and died nine days post-vaccination. The individual was seen in the ER 6-days post-vaccination and was given medications to stop vomiting. CT scan of the abdomen/pelvis demonstrated findings that might "represent adynamic ileus related to enteritis/colitis, however early or partial mechanical small bowel obstruction cannot be excluded." His symptoms improved in the ER, and he was discharged home with Zofran. However, he continued to experience daily vomiting. There is no death certificate or autopsy report in VAERS nor additional records describing the days between the ER visit and his demise.

*Reviewer comment: This case was **unassessable** in relation to COVID-19 vaccination. The individual had chronic medical conditions and died 9-days post-vaccination after experiencing vomiting, but cause of death was not reported and there was no death certificate or autopsy report available for review.*

VAERS [redacted]: 21-year-old male with no reported PMH received the 1st dose of the Pfizer-BioNTech COVID-19 vaccine and died 57 days post-vaccination. The report lists an adverse event starting 1-day post-vaccination, but the only description of the event is "he died" with a listed date of death 57 days post-vaccination. It is unknown if an autopsy was performed. A death certificate was requested and the public health department response indicated that a death certificate could not be located for this individual.
*Reviewer comment: This case is **unassessable** in relation to COVID-19 vaccination due to insufficient clinical information and inability of the public health department to locate a death certificate for this individual.*

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VAERS [redacted]: 22-year-old male with muscular dystrophy received his first dose of the Moderna vaccine on 4/21/2021 and died 25 days after vaccination from myocardial infarction. Per the report, he experienced flu-like illness on 1 May 2021, consisting of fever 101.4, chills, headache, and abdominal discomfort; there is no further clinical information. It is unknown if autopsy was done. There is no death certificate or any other source documents in VAERS.

*Reviewer comment: This case is **unassessable** in relation to COVID-19 vaccination due to limited information/no source documents, including autopsy or death certificate.*

VAERS [redacted]: 18-year-old female with obesity (263 lb), no other medical conditions, but on oral contraceptive as well as multiple medications for presumed psychiatric conditions, died in a car accident 23 days after she received her 2nd Moderna dose.

First dose of Moderna COVID-19 vaccine was given 30 days prior to 2nd dose. Autopsy after the accident/death demonstrated "left pulmonary artery completely occluded by a pulmonary thromboembolus, which is nonadherent to the vessel wall, no pulmonary infarcts, and no residual thrombus in the legs." On microscopy, "the thromboembolus mostly consists of fibrin. At one edge there is a newer layer with intact RBC's and WBC debris. This demonstrates the clot has been propagating." The rest of the autopsy was significant for "internal decapitation, multiple skeletal fractures, transection of aorta at the isthmus, bilateral hemothoraces, liver and posterior spleen laceration, and fracture of hyoid bone." Toxicology screen was negative. Per medical examiner the deceased "most likely threw clot while driving, passed out, and lost control of the vehicle."

Cause of death on the death certificate was listed as "internal decapitation due to automobile vs concrete barrier, preceded by pulmonary thromboembolus (minutes)."

*Reviewer comment: Role of vaccine is assessed as **unlikely** due to alternate etiology of thromboembolism leading to a car accident that was the proximate cause of death. Cause of thromboembolism is unclear, but obesity and OCP use are possible risk factors.*

VAERS [redacted]: 21-year-old male with PMH of asthma and obesity received his 2nd dose of the Pfizer-BioNTech COVID-19 vaccine and died 24 days post-vaccination. He reportedly experienced flu-like symptoms with vomiting and nausea for 2 weeks after vaccination, but there was no information in the report regarding the immediate circumstances of his death. Per the autopsy, cause of death was diabetic ketoacidosis (DKA) with findings of vitreous glucose >500 mg/dl, vitreous urea nitrogen >100 mg/dl, acetone in blood, and severe fatty liver. A urine dipstick demonstrated moderate ketones and glucose at least 500.

*Reviewer comment: This case was assessed as **unlikely** related to COVID-19 vaccination. Diabetic ketoacidosis, a serious and potentially fatal condition, provides an alternative explanation for this death. It appears from the information available in VAERS that diabetes was not diagnosed prior to his death. DKA most commonly occurs in individuals with type 1 diabetes and can be the initial presentation in 25-40% of these individuals (54). Studies have shown that the incidence and prevalence of DKA varies more widely in individuals with type 2 diabetes, with a prevalence range of 0.0%-50.0%*

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and an incidence range of 0.0-24.5 events per 1000 person-years (55). High prevalence rates of DKA in type 2 diabetes have been reported in the U.S. in patients newly diagnosed with type 2 diabetes during the COVID-19 pandemic (2020, 47.1%) and in patients <21 years of age with type 2 diabetes who were hospitalized with COVID-19 (46%) (55). Delays in accessing medical care during the COVID-19 pandemic and presence of infection may have contributed to the high prevalence of DKA during this time (55). While triggers for DKA can be unclear (55), infection is a common precipitating factor for DKA and this individual experienced flu-like symptoms with nausea and vomiting for 2-weeks. Information on infectious disease testing was not found in VAERS records.

VAERS [redacted]: 20-year-old male with PMH of asthma presented to the ED 9 days after second dose of Moderna vaccine with nausea, vomiting, fatigue, poor PO intake, headache, dizziness, inability to walk, and fever of 103 and died two days later. He reportedly began having fevers and chills on the same day as vaccination, which gradually improved until post-vaccination day 5 when he again experienced fever, with nausea and vomiting. Review of systems was negative for diarrhea, chest or abdominal pain, blurred vision or neck stiffness. He was seen at [redacted] ED 5 days post vaccination and had a negative workup, including unremarkable echocardiogram and discharged after 24 hours of IV fluids.

Upon arrival in the ED, he had a normal exam except orthostasis, negative COVID-19 PCR, and an unremarkable abdominal XR and US. His EKG was read as normal sinus rhythm at 67 bpm with PACs. He was started on metronidazole for suspected enteritis. He continued to have dizziness the next day and had a negative head CT. He subsequently sustained a seizure, which subsided with Ativan. However, due a recurrent seizure longer than 10 minutes he was intubated, transferred to ICU and diagnosed with status epilepticus. His CBC showed lymphocytosis and mild neutropenia, and he was started on antibiotics and acyclovir for possible meningitis. Blood cultures, viral hepatitis markers, MRSA screen, and drug screen were all negative. He had elevated ammonia and lactic acid levels and transaminitis (without hyperbilirubinemia) of unclear etiology. EEG showed encephalopathy consistent with the patient's clinical condition but did not detect any active seizures during the recording; it was noted that drug-induced changes were the most likely explanation for the EEG abnormalities as patient was heavily sedated. LP was ordered but was not able to be performed prior to patient's demise; he died of multiorgan failure the day after admission to the ICU.

It is unknown if an autopsy was done. Multiple requests were made to obtain the death certificate from the [redacted] Department of Public Health, but no death records were found in the [redacted] vital records system.

*Reviewer comment: This case is **unassessable** due to lack of autopsy or death certificate and no information on decedent's final course of demise. Additional key missing information includes lumbar puncture to investigate possible infectious diseases that could serve as inciting factors for the patient's acute presentation.*

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VAERS [redacted]: 22-year-old male with colon cancer received Pfizer-BioNTech COVID-19 vaccine (unknown dose number), and then felt unwell, developing vomiting and chills 5 days later; he died 8 days post-vaccination. He had been receiving Irinotecan and Avastin for colon cancer and his last visit for chemotherapy was 2-days prior to vaccination. Per the report, his parent indicated that "blood counts indicated no imminent organ failure and he was not jaundice[d]." He was found unresponsive in his room 8 days post-vaccination and was pronounced dead on that day. The death certificate cause of death is complications of colonic adenocarcinoma due to Li-Fraumeni syndrome. The death certificate indicates that an autopsy was performed, and that autopsy findings were used to determine the cause of death. The autopsy report is not available in the record, although it appears it was requested.

*Reviewer comment: This case was assessed as **unlikely** related to COVID-19 vaccination. The death occurred in an individual who was receiving chemotherapy for colon cancer. The cause of death was listed as complications of colonic adenocarcinoma due to Li-Fraumeni syndrome which provides a likely alternative explanation for this death. It is noted that the individual was experiencing vomiting, chills, and feeling unwell, which are common adverse events after receiving Irinotecan, per the US product insert (USPI). In addition, the USPI for Avastin (56) includes Warnings and Precautions for various potentially fatal adverse reactions including gastrointestinal (GI) perforations and fistula (including serious and sometimes fatal GI perforations), severe or fatal hemorrhage (including severe or fatal hemorrhage, including GI bleeding and hematemesis), arterial and venous thromboembolic events (including serious and sometimes fatal events), and hypertension. Of note the Avastin USPI Patient Counseling Information also lists "Gastrointestinal Perforations and Fistulae" and indicates that patients should be advised to immediately contact their healthcare provider for high fever, rigors, persistent or severe abdominal pain, severe constipation, or vomiting, which could be symptoms of perforation.*

VAERS [redacted]: 20-year-old female with PMH of morbid obesity (BMI=50.0-59.9), chronic back pain, GERD, asthma, and obstructive sleep apnea on CPAP received 2nd dose of the Pfizer-BioNTech COVID-19 vaccine and died 36 days later. Per the report, she began experiencing symptoms including tightness of muscles and chest and herpes simplex mouth sores 1-day post-vaccination. She saw her primary care doctor and received a muscle relaxer and antibiotic cream. She subsequently began experiencing chills, hot flashes, and shortness of breath, among other symptoms. Approximately 33-days post-vaccination she went to sleep with dyspeptic symptoms and woke up later that night choking and gagging on her own secretions. She then experienced persistent chest tightness and respiratory distress that led her to seek care in the ER 2 days later. She was found to be afebrile. Laboratory findings included hemoglobin of 4.3 g/dL. Chest x-ray showed bilateral patchy infiltrates that opacifies most of the airspace with interpretation of pneumonia. The medical records indicate she likely had an aspiration incident resulting in pneumonitis and then pneumonia with bronchospasm. Medical records noted there was also concern for a PE (respirations were documented at 22 per minute, oxygen saturation 93%) but the individual was too heavy for the CT scanner

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and nuclear medicine VQ scanner. Duplex ultrasounds of the lower extremities were negative. The morning following admission she experienced recurrent respiratory distress, went into cardiac arrest, and died.

The death certificate and autopsy listed cause of death as consequences of morbid obesity. Autopsy findings included cardiomegaly and biventricular hypertrophy which were noted as a sign of hypertension, which is a complication of morbid obesity. The autopsy also noted that severe anemia and history of asthma were both contributing conditions to death. In addition, the autopsy documented "heavy congested lungs" with pulmonary edema. There were no pulmonary emboli.

*Reviewer comment: This case was assessed as **unlikely** related to COVID-19 vaccination. While the initial onset of symptoms was temporally associated with vaccination, the progression of symptoms over the next month are consistent with the more likely etiology of aspiration pneumonia and acute respiratory failure, complicated by severe anemia and possible heart failure from a possible high output state. Cardiomegaly with biventricular dilatation as a complication of morbid obesity likely also contributed to the patient's demise.*

VAERS [redacted]: 18-year-old male with PMH of hypertrophic obstructive cardiomyopathy (diagnosed 1 year prior per his family) and sickle cell trait received the 1st dose of the Pfizer-BioNTech COVID-19 vaccine and died two days later. Per the report, on the day prior to vaccination, he reported no complaints at a cardiology appointment. Two days post-vaccination, he was playing football when he became unresponsive and fell back, striking his head. CPR was started immediately, followed by advanced cardiac life support en route to the ED. In the ED, he was in asystole with cardiac standstill on bedside ultrasound, his pupils were fixed and dilated. Resuscitation was unsuccessful and death was pronounced.

The death certificate lists the immediate cause of death as "Pfizer COVID vaccine #1" with underlying causes of myocarditis and hypertrophic cardiomyopathy. The death certificate indicates an autopsy was performed and that autopsy findings were available to confirm the cause of death. However, correspondence responding to attempts by VAERS contractors to obtain the autopsy indicates "the Medical Examiner Department declined jurisdiction and no autopsy was performed." A VAERS report submitted by the supervising ER physician indicated the individual "had been recently diagnosed with hypertrophic obstructive cardiomyopathy, and I suspect this was the cause of death and that the vaccine was unrelated."

*Reviewer comment: This case was **unassessable** in relation to COVID-19 vaccination. There appears to be conflicting information on whether an autopsy was performed and the role of the vaccine in the death. If an autopsy was performed, the autopsy report is not available in VAERS for review. Thus, myocarditis as a cause of death cannot be verified. However, this individual had a history of hypertrophic obstructive cardiomyopathy and died while playing football. Sudden death from hypertrophy*

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obstructive cardiomyopathy is a likely alternate etiology for this death (see Discussion, subsection on Sudden Cardiac Death).

VAERS [redacted]: 22-year-old obese female died at home 3 days after her first dose of Moderna vaccine administered on 5/11/2021. Per parent report, she "got very sick, and was already not feeling well before vaccine." The death certificate listed manner of death as "natural" and cause of death as "complications of active Covid-19 infection with superimposed obesity," in addition to noting the decedent as "disabled" under the occupation field. The death certificate also noted that an autopsy was not performed. There are no other source documents.

*Reviewer comment: This case was assessed as **unlikely** related to COVID-19 vaccination. The decedent was documented as "feeling sick before the vaccine," suggesting a process/alternate etiology that preceded vaccination. The death certificate lists complications of active Covid-19 infection with superimposed obesity.*

VAERS [redacted]: 23-year-old obese female received her 2nd Pfizer-BioNTech COVID-19 vaccine and died of COVID-19 on an unspecified date. Her BMI was >40. It was not reported if an autopsy was performed.

*Reviewer comment: This case was **unlikely** in relation to COVID-19 vaccination. This was a manufacturer report that indicated the physician who reported the case did not wish to be contacted for follow-up. The individual reportedly died of COVID-19, but the report contains limited clinical details and no medical records, death certificate, or autopsy report are available for review.*

VAERS [redacted]: A 22-year-old male with Becker muscular dystrophy, immobility, dilated cardiomyopathy, congestive biventricular heart failure, history of thromboembolism, iron deficiency anemia, intellectual disability and obesity received a first dose of Moderna monovalent COVID-19 vaccine on 18 August 2021 at 1:30 pm, developed unresponsiveness and shallow breathing 7.5 hours post-vaccination and died at 11:10 pm, approximately 10 hours after vaccination.

Family history included heart disease in his paternal [redacted], and early death in his paternal [redacted]. The patient was a resident in a long-term care facility at the time of his death. He had been hospitalized one month prior to vaccination for management of acute on chronic heart failure. He was last seen well at 3:15pm, when he was alert and watching TV. Upon discovery of his unresponsiveness at 8:50 pm, staff attempted to treat him with supplemental oxygen and notified 911. His eyes were open but he was non verbal at that time. They could not measure his blood pressure. There are no further records describing the circumstances leading to death.

Death certificate indicates that the immediate cause of death was congestive heart failure, with underlying conditions of hypertension and Becker muscular dystrophy. The manner of death was determined to be natural. An autopsy was not performed. No further information is available.

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*Reviewer comment: The relationship between death to vaccination was determined to be **unlikely** based on the more likely alternate etiology of congestive heart failure/cardiomyopathy as a result of Becker muscular dystrophy. Cardiomyopathy is the leading cause of death in Becker muscular dystrophy patients (57). Although the onset and course of cardiomyopathy is variable, this patient's development of dilated cardiomyopathy, biventricular heart failure, and immobility by age 22 suggests an accelerated course (58). Sudden death in Beckers muscular dystrophy can be due to heart failure, skeletal muscle failure, or arrhythmia.*

VAERS [redacted]: A 19-year-old female with no reported past medical history received a second dose of Comirnaty monovalent COVID-19 vaccine on an unknown date and died on an unknown date (unknown date of first dose as well). Events leading to death are not described in the original report. It is unknown if autopsy was performed. There are no medical records, death certificate, or autopsy available for review.

*Reviewer comment: The causal relationship to vaccination was determined to be **unassessable** based on missing time-to-onset, missing events leading to death, and missing supporting medical records.*

VAERS [redacted]**:** 21-year-old male with PMH of alcohol abuse received the 1st dose of the Pfizer-BioNTech COVID-19 vaccine, experienced severe vomiting 18-days post-vaccination, and was found expired on the floor of his hotel room 19-days post-vaccination. Per the report, on the day prior to death, the decedent expressed concern "about throwing up so much that he'd lose his stomach lining." The next day he was found unresponsive. EMS responded, and he was pronounced dead at the scene.

The death certificate and autopsy cause of death was complications of chronic alcohol abuse. The autopsy findings included dilated cardiomyopathy and steatohepatitis "that can be the result of chronic alcohol abuse." Autopsy heart findings included a 370-gram heart with a globular configuration with unremarkable epicardial surface and a moderate amount of epicardial fat. All four chambers were markedly dilated with thinning of the ventricular walls. No focal endomyocardial lesions were present. Microscopic heart findings showed scattered foci of mildly hypertrophic cardiomyocytes with enlarged nuclei and scattered binucleated cardiomyocytes. Liver findings included a 1990-gram liver with a smooth serosal surface and parenchyma that was yellowish-tan and greasy in texture from fatty change. Microscopic liver findings included steatosis with a mixed periportal and lobular infiltrate and scattered ballooning hepatocytes. The autopsy report noted the individual was normally developed and normally nourished with a height of 66 inches and weight of 182 pounds (calculated BMI=29). Testing was negative for COVID-19. Toxicology was positive for delta-9-THC and THC-COOH.

*Reviewer comment: This case was assessed as **unlikely** related to COVID-19 vaccination. The cause of death in both the death certificate and autopsy was complications of chronic alcohol abuse; dilated cardiomyopathy and steatohepatitis can*

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be the result of chronic alcohol abuse (59-61). Complications of chronic alcohol abuse provides a plausible alternate etiology for this death.

VAERS [redacted]**:** 19-year-old female with PMH of depression and anxiety, known history of fentanyl abuse, and history of suicide attempts [redacted], received the 1st dose of Pfizer-BioNTech COVID-19 vaccine and was found deceased at home 15 days post-vaccination. The VAERS report submitted by the coroner listed medications as "none" and indicated that "the pathologist found blood clots in her lungs during autopsy, and she was concerned the blood clots may be related to the vaccine she received on 8 May 2021." The autopsy cause of death was acute fentanyl toxicity. Toxicology was positive for fentanyl (19 ng/mL, which was noted in the autopsy to be a lethal amount) and its metabolites and cotinine. The autopsy also revealed small pulmonary thromboemboli in the lower lobes of unclear source; deep venous thromboses were not identified. The autopsy report noted scarring on arm consistent with self-harm, history of suicide attempts [redacted] and history of her recent COVID-19 vaccination. The autopsy noted the extremities did not show non-therapeutic punctures or needle tracks. She was noted as being "slender" with a height of 66 inches and a weight of 135 pounds.

*Reviewer comment: This is case was assessed as **unlikely** in relation to COVID-19 vaccination. The autopsy cause of death was acute fentanyl toxicity in an individual with known history of fentanyl use, a history of prior suicide attempts [redacted], and a lethal amount of fentanyl found on toxicology exam. Pulmonary thromboemboli of unclear source were detected on autopsy, although thromboemboli were not listed in the autopsy as a cause of death. Despite the unknown etiology and source of pulmonary thromboemboli, acute fentanyl toxicity is the most likely explanation for this death.*

VAERS [redacted]: An 18-year-old male with recent diagnosis of systemic lupus erythematosus (SLE), drug hypersensitivity, vitiligo, and [redacted] was vaccinated with a second dose of Moderna monovalent COVID-19 vaccine on 23 July 23, 2021, developed fever and shortness of breath 38 days post-vaccination and died 54 days post-vaccination after a complicated hospital course involving multi-organ failure.

The patient had been hospitalized twice for symptoms including weight loss, proteinuria, and anemia in the two months prior to death; during these hospitalizations, he was diagnosed with SLE based on renal biopsy showing class III and class IV lupus nephritis. He was vaccinated with dose 2 Moderna monovalent COVID-19 vaccine on the day of discharge from the second hospitalization, 23 July 23 2023 (first dose received one month prior).
He was again hospitalized 11 August 2021 to 22 August 22, 2021 for febrile neutropenia. He then presented to the hospital for the final time on 30 August 2025 with several days of fatigue, abdominal pain, nausea/vomiting, and one day of fever and shortness of breath. He was treated per sepsis protocol with multiple antibiotics and received solumedrol. Within 48 hours he developed respiratory failure and was

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intubated. Bronchoscopy revealed diffuse alveolar hemorrhage, which was attributed to profound hypoalbuminemia. Undetectable C4, low C3, and high ESR, CRP were considered to be consistent with SLE flare. Superimposed infectious disease was considered but all workup was negative, including blood and tracheal cultures. He was treated with broad-spectrum antibiotics, anti-fungals, steroids, cyclophosphamide and 3 days of plasmapheresis, but his condition worsened, with progression to ARDS and multi-organ failure. He ultimately developed acute myocardial infarction with total occlusion of the LAD and circumflex arteries. The decision to [redacted] on 15 September 2021 resulting in death. Death certificate was not available for review and autopsy was not mentioned in available records.

*Reviewer comment: In this medically complex case, the causal relationship to vaccination was determined to be **unlikely** based on the presence of multiple severe manifestations of pre-existing SLE and complications that provide plausible explanations for death. In addition, the temporal relationship of events with vaccination (pre-existing SLE, exacerbation 38 days after vaccination), does not support a relationship.*

VAERS [redacted]: A 21-year-old female with non-ischemic dilated cardiomyopathy and congestive heart failure (NYHA II, followed by a cardiologist on Carvedilol, Entresto and sprinolactone) received a second dose of Moderna monovalent COVID-19 vaccine, became unresponsive, and died 7 days after vaccination on 30 June 2021. The first dose was given 26 May 2021, 35 days prior to death.

As of a recent cardiology tele-health visit on [redacted], the decedent's condition was noted to be stable. An echocardiogram from [redacted] showed an ejection fraction of 20%, a severely dilated LV, and mild to moderate mitral regurgitation. The decedent was last known alive at 11 pm on 29 June 2021 and had no known symptoms that day. She was found unresponsive by her boyfriend at 12:45 pm the following day and was unable to be resuscitated.

Autopsy report indicates that dilated cardiomyopathy was the cause of death, with final pathological diagnosis of dilated cardiomyopathy. Findings included cardiomegaly (450 grams, 95th percentile for body weight), mitral valve circumference of 7 cm, tricuspid valve circumference of 10 cm, and extensive histologic evidence of ischemic injury in the myocardium. According to the pathologist in the autopsy report, diffuse bands of fibrosis predominantly along the inner surface of the left ventricle are significant risk factor for developing arrythmias. Toxicology was negative.
*Reviewer comment: The relationship between death and vaccination was determined to be **unlikely** based on the alternate more likely etiology of severe dilated cardiomyopathy and ischemic changes seen on autopsy.*

VAERS [redacted]: A 23-year-old male with no significant past medical history received a second dose of monovalent Moderna vaccine COVID-19 vaccine on 1 September 2021 and died the following day. Per the report, at 3 pm on the day of vaccination (4 hours

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later), he developed nausea and vomiting. The following day he was weak but "feeling better" around 6 am but later was found unresponsive by his mother at lunch time. Resuscitative efforts by EMS were not successful. Paramedics stated that he had a heart attack. No further information, supporting medical records, death certificate, or autopsy were available for review.

*Reviewer comment: The causal relationship to vaccination was determined to be **unassessable** based on missing key information and missing supporting records.*

VAERS [redacted]**:** 22-year-old female with PMH of morbid obesity (BMI=59.9), obstructive sleep apnea with CPAP use, hyperglycemia, elevated blood pressure, and history of COVID-19 in July 2020 with a 2-week ICU admission received the 1st dose of the Pfizer-BioNTech COVID-19 vaccine in April 2021 and was found unresponsive on her bedroom floor 18 days post-vaccination; she was subsequently unable to be resuscitated and died. She reportedly consumed two beers the night prior to death and "did not voice any complaints."

The decedent had been diagnosed with obstructive sleep apnea and a sleep study in [redacted] showed baseline oxygen saturation of 81.4% with a nadir of 50.0%; the mean oxygen saturation during the study was 67.7% and the cumulative time under 88% oxygen saturation was 91.1 minutes. EKG demonstrated PVCs, and the "interpretation" of the study was severe obstructive sleep apnea.

The death certificate and autopsy cause of death was probable cardiac arrhythmia with other significant conditions of cardiomegaly, obesity, and obstructive sleep apnea. The autopsy revealed a heart weight of 710 grams and all heart chambers were moderately dilated. The myocardium did not show areas of necrosis or fibrosis. Microscopic review of the heart showed focal myocyte hypertrophy and "abundant bacterial organisms within vessels and scattered throughout myocardium, without vital reaction." Toxicology was positive for alcohol and caffeine. Postmortem blood cultures were positive for *Clostridium sordellii*. Testing for novel coronavirus was negative.

*Reviewer comment: This case was assessed as **unlikely** related to COVID-19 vaccination. The cause of death was probable cardiac arrhythmia with cardiomegaly, obesity, and obstructive sleep apnea as significant other conditions that contributed to death. Cardiac arrhythmia related to chronic conditions in this individual provides a more likely explanation for the death. Severe obstructive sleep apnea increases the risk of sudden death from cardiac causes, including cardiac arrhythmias, particularly during sleeping hours (62-64). In addition, there are various shared risk factors (e.g., obesity, prolonged QT, diabetes mellitus, hypertension) and complex pathophysiologic connections between obstructive sleep apnea and sudden cardiac death, including increased intrathoracic pressure, hypoxia, increased myocardial demand, myocardial hypertrophy, increased sympathetic tone, and increased arrhythmogenicity (65).*

VAERS [redacted]: 18-year-old male with PMH of congenital perimembranous ventricular septal defect, severe aortic valve insufficiency, aortic valve stenosis, aortic root dilation,

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PVCs, multiple cardiac surgeries (heart valve surgery in [redacted], ventricular septal defect and ventricular repair in [redacted], and aortic valvuloplasty in [redacted] and repeat in [redacted]), hypertension, and elevated BMI, experienced acute shortness of breath, cough, nausea and vomiting 1 week prior to vaccination, and died 3 days after vaccination in the setting of multiorgan failure.

Per the report, cardiac function had been deteriorating in the month prior to vaccination. A cardiologist had suggested corrective surgery to treat worsening aortic valve dysfunction, and a cardiac MRI in [redacted] showed worsening aortic insufficiency, increased LV dilation, and reduced LVEF of 60%, and reduced RVEF of 66%. Per the report, in [redacted], approximately 1-week prior to his 2nd dose of Pfizer-BioNTech COVID-19 vaccination, he was not feeling well with shortness of breath, cough, nausea and vomiting. He went to urgent care and was told he likely had a viral infection. He received the 2nd dose of the Pfizer-BioNTech COVID-19 vaccine on June 10, 2021 (date of 1st COVID-19 vaccine dose was not reported). Two-days post-2nd dose of vaccination he presented to the ED with fatigue, worsening cough and shortness of breath, and pain in his chest when coughing, and vomiting and diarrhea. ED records noted an elevated white count (17.9 10^3/uL) and lactate. CXR showed an enlarged cardiac silhouette and focal consolidation of the right lung base with patchy areas of opacification in the more superior right lung; he was placed on Rocephin and Zithromax. PCR testing for SARS-CoV-2 was negative. EKG showed normal sinus rhythm with anterior lateral and inferior ST changes. Troponin was 480 ng/L and ED records commented on "likely myocarditis." D-dimer was 2.2 mg/L and CT angiogram was negative for PE. He went into a PEA arrest, was resuscitated, intubated and placed on venoarterial ECMO.

He was transferred to the tertiary care facility where he experienced worsening pulmonary edema. Bedside TEE showed severely reduced LVEF of approximately 10%, "wide open AI, a flail aortic leaflet with poor coaptation of the aortic valve leaflets, and a small RV." Despite Impella placement and VA-ECMO circuit, the patient experienced worsening clinical status and progressive multi-organ system failure. The [redacted], and he died 3-days post-vaccination. It is unknown if an autopsy was performed. There was no autopsy or death certificate available for review.

*Reviewer comment: This case was assessed as **unlikely** related to COVID-19 vaccination. While this death was temporally associated with vaccination, this individual had significant underlying cardiac conditions that were worsening in the months prior to vaccination and the need for additional corrective surgery of the aortic valve had been previously discussed. He also experienced acute symptoms of shortness of breath, cough, nausea and vomiting that began about a week prior to his 2nd vaccine dose, suggesting a possible infection. While available medical records from the ED commented on an elevated troponin and "likely myocarditis," the available medical records from the cardiac team at the tertiary medical center, including the discharge summary, do not discuss myocarditis. The individual died after [redacted] due to his worsening clinical status and poor prognosis. It is unknown if an autopsy was performed, and no autopsy report or death certificate were available for review.*

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However, the death appears most likely due to worsening of his underlying significant cardiac condition.

VAERS [redacted]: A 21-year-old female with atrial septal defect status-post closure (12 years prior, at age 9), pulmonary hypertension, and prolonged QT received a second dose of monovalent Moderna COVID-19 vaccine on 10 September 2021 and developed cardiac arrest and death the next morning. EMS found her with a pulse of 26, which quickly progressed to asystole. Resuscitation efforts were not successful. She pronounced dead at 8:58 AM, approximately 24 hours after vaccination. The circumstances and clinical course between vaccination and the onset of sudden death are not provided. Death certificate indicates that the cause of death was 'coronary artery disease – patient had history of pulmonary hypertension, prolonged QT interval.' According to the death certificate, an autopsy was not performed.

*Reviewer Comment: The relationship between death and vaccination was determined to be **unassessable** based on missing key information about the severity of the patient's pre-existing conditions, the circumstances leading to death, as well as autopsy.*

VAERS [redacted]: A 20-year-old male with no reported past medical history received a second dose of monovalent Moderna COVID-19 vaccine on 13 October 2021, developed 'heart attack, blood clots, [and] stroke 5 days after vaccination and died 3 November 2021, 21 days post-vaccination. No further information, supporting medical records, death certificate, or autopsy were available for review.

Reviewer comment: The causal relationship to vaccination was determined to be **unassessable** based on missing key information and missing supporting records.

VAERS [redacted]: A 22-year-old male with no reported past medical history or concurrent conditions received monovalent Pfizer-BioNTech COVID-19 vaccine (dose number not reported) on 6 November 2021, developed dizziness and lethargy the same day and went to bed at 8pm. According to the original report, he was found dead the next morning of 7 November 2021, one day post vaccination. No further information, supporting medical records, death certificate, or autopsy were available for review.

*Reviewer comment: The causal relationship to vaccination was determined to be **unassessable** based on missing key information and missing supporting medical records.*

VAERS [redacted]: A 22-year-old female, with no reported past medical history or concurrent conditions received a second dose of monovalent Pfizer-BioNTech COVID-19 vaccine on 1 July 2021 and died 4 months post-vaccination. She was pregnant at the time of vaccination. She developed 'severe illness' followed by death on 14 November 2021,136 days post-vaccination. No further information, supporting medical records, death certificate, or autopsy were available for review.

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Reviewer comment: The causal relationship of events to vaccination was determined to be unlikely based on a latency of 136 days that makes a relationship improbable.

VAERS [redacted]: A 22-year-old female with seizures since age 13 and "cardiac vessel disease not otherwise specified" received a third dose of monovalent Moderna COVID-19 vaccine on 16 December 2021 at 3:00 pm and was found deceased the next day. She developed symptoms of chills, body ache, and headache six hours post-vaccination. She was last seen alive at 9:00 am on the day of death and was found unresponsive in bed at 2:15 pm. Emergency services were called, but no further information about clinical course was available for review.

Vaccine records indicate that prior doses of monovalent moderna vaccine were administered on 9 April 2021 and 7 May 2021. Public health records indicate an autopsy was performed but autopsy was not available for review. Cause of death was determined to be Sudden Unexpected Death in Epilepsy (SUDEP) secondary to idiopathic seizure disorder. A field for "other cause" of death states "recent COVID-19 vaccination." No further information or records were available for review.

*Reviewer Comment: The causal relationship of events to vaccination was determined to be **unlikely** based on the strength of available evidence that fails to find an association between COVID-19 vaccination and sudden unexpected death in epilepsy (Please see Discussion, subsection on Sudden Death in Epilepsy).*

VAERS [redacted]: A 23-year-old female with history of opioid abuse received a second dose of monovalent Moderna COVID-19 vaccine on 11 March 2021 (first dose 11 February 2021), was hospitalized for respiratory failure starting on 2 August 2021 (144 days post-vaccination) and died on 7 August 2021,149 days post-vaccination. At the time of vaccination she was pregnant, and at the time of adverse events she had recently given birth (2-4 weeks prior) with "no reported complications."

According to hospital records, on the day of symptom onset, the patient was observed by her family to be "not acting right," appearing sleepy and confused, and slurring words; this progressed to cardiopulmonary arrest, she was transported to the hospital. Upon arrival to the hospital she was pulseless and cyanotic. After stabilization, diagnostic testing revealed seizure activity and anoxic brain injury. A urine drug screen was negative for amphetamine, barbiturates, cocaine and opiates but lab results were only partially available for review. Despite targeted temperature management and other interventions, the patient did not regain brain function [redacted] the patient was tested for COVID-19 on 6 August 2021; she was found to be COVID-19 positive. She died five days after initial hospitalization.

Death certificate indicates that the cause of death was respiratory failure as a consequence of anoxic global brain injury, as a consequence of "unknown cardiac or respiratory arrest." No autopsy or pathology results were available for review.

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*Reviewer comment: The causal relationship of events to vaccination was determined to be **unlikely** based on latency of 144 days that makes a relationship improbable. The exact cause of death is uncertain in this case due to lack of information – for instance, the role of COVID-19 positivity cannot be determined, and urine drug screen results were not completely available for review. Autopsy is mentioned but is not available for review.*

VAERS 2017855: A male in his 20s with no reported past medical history received a dose of monovalent Moderna COVID-19 vaccine (number in series not provided) on an unknown date, developed a heart attack on an unknown date post-vaccination and died at an unknown date. No further information, supporting medical records, death certificate, or autopsy were available for review.

*Reviewer comment: The causal relationship to vaccination was determined to be **unassessable** based on missing key information and missing supporting records.*

VAERS [redacted]: A 23-year-old male with class II obesity received 2 doses of the Moderna COVID-19 vaccine, on 24 March 2021 and 29 April 2021 and died of complications of COVID-19 disease 8 months after dose 2.

Approximately 8 months (254 days) after his second vaccine dose, he was diagnosed with a SARS-CoV-2 infection after experiencing cough and nasal congestion which was managed conservatively at home. Eighteen days later and 272 days after vaccination, he developed fever, cough, shortness of breath, fatigue, non-bloody diarrhea, myalgias, and a painful rash all over his body. He was started on cefdinir and steroids by his primary care physician. Five days later, he presented to the ER and was admitted for acute kidney injury and rash; he was also found to have multiple laboratory derangements, including thrombocytopenia, elevated D-dimer, and troponin-I of 1359 pg/mL. Infectious work up was negative. He was diagnosed with multisystem inflammatory syndrome in adult (MIS-A) following COVID-19 disease. Despite treatment with steroids, antibiotics, and intravenous immunoglobulin, his rash progressed to bullae on his legs and thighs with sloughing of skin over his trunk, back, and extremities, and he developed non-purulent conjunctivitis. On hospital day 3, he went into cardiac arrest secondary to ventricular fibrillation and was resuscitated and intubated, and on hospital day 7, he succumbed to refractory shock.

The death certificate listed cause of death as multisystem inflammatory syndrome in an adult (MIS-A) associated with COVID-19, Stevens-Johnson syndrome with toxic epidermal necrolysis overlap. Other contributing conditions included COVID-19 infection, class 2 obesity, acute liver failure, DIC, acute kidney failure with acute interstitial nephritis, cardiac arrest, and acute pulmonary edema. The death certificate also stated that an autopsy was not performed.

*Reviewer Comment: This case is assessed as **unlikely** related to COVID-19 vaccination. Of note, the VAERS records for this case include both medical record source documents as well as a published literature report (66).*

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The authors of the literature report state that the patient described in this case report met criteria for MIS-A based on the following CDC criteria: age ≥ 21 years, primary clinical criteria (fever, rash, and nonpurulent conjunctivitis), secondary clinical criteria (hypotension and thrombocytopenia), several laboratory criteria, and negative infectious work-up with a history of recent COVID-19 disease. MIS-A is a rare, Kawasaki-like complication of SARS-CoV-2 infection characterized by an exaggerated inflammatory response resulting in multiorgan dysfunction. It has been well described in children but can also occur in young to middle-aged adults (67). MIS-A occurs as a delayed reaction to infection typically occurring 2 to 6 weeks after infection, commonly in patients with a reportedly mild acute SARS-CoV-2 infection (68). The authors of this case report state that the relationship between MIS-A and COVID-19 vaccination in this patient is unknown. However, recent evidence suggests that vaccination for COVID-19 is rarely associated with MIS and may protect against it (69-71). In this case, COVID-19 vaccination preceded his development of MIS-A by 8 months and fell outside the biologically plausible MIS-A risk window, unlike SARS-CoV-2 infection which preceded disease onset by only 3 weeks. Therefore, this case is assessed as unlikely related to COVID-19 vaccination given that SARS-CoV-2 infection was a proximal and more likely inciting event.

VAERS [redacted]: A 20-year-old of unknown sex and unknown medical history received the Pfizer COVID-19 vaccine on an unknown date and died an unknown duration after vaccination. The cause of death was not stated and there is no autopsy report, death certificate, or medical records. Narrative case summary states that "20-year-old professional athlete died." There is no lot information or specific patient-related information throughout the report.

*Reviewer Comment: This case is **unassessable** due to missing medical records, autopsy report, and death certificate.*

VAERS [redacted]: A 19-year-old of unknown sex and unknown medical history received the Moderna COVID-19 vaccine on an unknown date and died an unknown duration after vaccination. No information regarding the suspected cause of death or symptoms following vaccination was provided. There is no autopsy report, death certificate, or medical records in VAERS.

*Reviewer Comment: This case is **unassessable** due to insufficient information including lack of detail regarding post vaccination events, lack of latency information, and lack of autopsy and death certificate.*

VAERS [redacted]: A 22-year-old of male with unknown medical history received the Pfizer COVID-19 vaccine on an unknown date and died an unknown duration after vaccination. No information regarding the suspected cause of death or symptoms following vaccination was provided. The report narrative states, [redacted] There is no autopsy report, death certificate, or medical records in VAERS.

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*Reviewer Comment: This case is **unassessable** due to insufficient information including lack of detail regarding post vaccination events, lack of latency information, and lack of autopsy and death certificate.*

VAERS [redacted]: 19-year-old of unspecified sex with unknown medical history reportedly deceased 6 hours after receiving an unspecified dose number of Pfizer BioNTech COVID-19 vaccine on an unknown date. The cause of death is unknown. It is unknown if an autopsy was performed. No other clinical information or records are available.

*Reviewer comment: This case was assessed as **unassessable**/unclassifiable due to lack of adequate clinical information for meaningful causative analysis including baseline characteristics, temporality, diagnostic elements, and clinical course.*

VAERS [redacted]: 18-year-old female with history of anorexia nervosa (lost more than 80lbs in the last 1 year) and reported cardiac murmur as a child, family history of [redacted] with congenital heart disease, presented to the ED in sudden cardiac arrest 12 days after receiving the 2nd dose of Pfizer BioNTech COVID-19 vaccine on 28 October 2022. The decedent was vaccinated with the 1st dose of Pfizer on 20 July 2022 (14-week interval between doses). The decedent was at a friend's house the preceding night and reportedly consumed alcohol as well as "medical marijuana," but her friends denied any other drug use. She was observed by friends to be slightly unstable when going to the bathroom the following morning, but her friends assumed she was hung over. She went back to sleep and was found unresponsive and cyanotic presumably a few hours thereafter after which EMS was called. Upon EMS arrival it was noted that no CPR had been initiated for approximately 20 minutes and the decedent was found to be in and out of ventricular tachycardia and ventricular fibrillation, blood glucose was greater than 200.

She was transported to the ED. ECG in the ED with written impression of sinus rhythm and second-degree block at a rate of 51 bpm and QRS 126; no acute STEMI criteria noted. Labs showed severe metabolic derangements suggesting multiorgan failure due to prolonged cardiac arrest. The decedent was directly admitted from the ED to the ICU, and within approximately 4 hours of admission it was communicated to her family that there were a variety of multiorgan failure complications potentially contributing to her rapid decline, including progressive neurological injury, "additional intra-abdominal organ injury/death," and poor oxygenation leading to severe hypoxemia and/or hemorrhage. [redacted] and the decedent expired approximately an hour later. At the time of death, the source of her initial cardiac arrest was still of unclear etiology.

Document labeled as death certificate in the report marked death certificate availability and autopsy report as "Yes", but certificate and autopsy reports are not available in the record. Final disease or underlying condition resulting in death was listed as unknown.

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*Reviewer comment: This case was assessed as **unlikely** related to COVID-19 vaccination due to an existing history of anorexia nervosa with recent significant weight loss suggesting a more likely etiology of arrhythmic cardiac arrest due to metabolic derangement (72, 73) and fluid and electrolyte shifting from refeeding syndrome (74).*

VAERS [redacted]**:** 25-year-old female with history of Shone complex, status-post aortic and mitral valve replacements, heart block status-post permanent pacemaker implantation, end-stage renal disease on hemodialysis, chronic respiratory failure status-post tracheostomy, restrictive pericarditis status-post ECMO in [redacted], and spontaneous bilateral subdural hematomas presented to the ED in PEA arrest 606 days after receiving the 2nd dose of Moderna COVID-19 vaccine at the age of 23 (date of 1st dose is unknown); she died on post-vaccination day 607. Her mother reported several days of general malaise, cough, headache and observed seizure-like activity during home hemodialysis. Initial work-up was positive for SARS-CoV-2 by PCR and multiple organisms from bronchial fluid with imaging concerns of pneumonia, and labs consistent with septic shock including leukocytosis to 33,000 (85% neutrophils). She was transferred to a higher-level care center in profound septic shock likely secondary to COVID-19 pneumonia with superimposed ventilator associated pneumonia leading to MSSA bacteremia. She was deemed a poor candidate for ECMO and CRRT and died [redacted]. The case was reportedly discussed and declined by the office of the medical examiner.

*Reviewer comment: This case was assessed as **unlikely** related to COVID-19 vaccination due to an implausible temporal relationship and alternate etiology of COVID pneumonia in the context of existing conditions possibly predisposing a fatal outcome.*

VAERS [redacted]: This is a 21-year-old male with end stage renal disease (ESRD), on dialysis, gastroesophageal reflux disease (GERD), hypertension (HTN), dysphagia, obstructive sleep apnea, on a continuous positive airway pressure (CPAP) machine at night, who received three doses of the COVID-19 Pfizer-BioNTech vaccine and died nine months post-dose three. Nine days before his death, he developed weakness, body aches, shortness of breath, fevers, upper back pain, and tested positive for COVID-19. His primary care physician prescribed him Azithromycin and Oxycodone. He was found dead at home nine days after his initial diagnosis of acute Covid-19 infection. No autopsy was performed per the death certificate, which lists the causes of death as ESRD and COVID-19 illness.

*Reviewer Comment: This case was assessed as **unlikely** due to the COVID-19 vaccine, given the implausible temporal relationship, and the death certificate indicating an alternative cause of death (COVID-19 infection in the context of ESRD). Patients on chronic hemodialysis are at high risk for COVID-19 infection and have a worse prognosis than patients with normal renal function (75, 76).*

VAERS [redacted]: 22-year-old female with a complex PMH including a traumatic brain injury at 1-year-old, spastic quadriplegia (wheelchair bound), O2 dependent with a tracheostomy, tracheal stenosis, tube feeding with a G-tube, developmental delay,

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intrathecal baclofen pump, encephalitis [NOS], seizure disorder, and chronic respiratory failure. On [redacted], the patient reportedly experienced increased coughing and sputum/secretion production, increased heart rate (103), and seborrhea. She received treatment that included fluoroquinolone antibiotic ear drops and glycopyrrolate. She received Dose 1 of Moderna COVID-19 vaccine on 19 March 2021. The mother stated in the days following vaccination, the patient may have had some facial twitching and shallow breathing but was unsure as shallow breathing was normal for the patient. The patient died 16 days after vaccination on 4 April 2021, with the death certificate indicating cause of death as encephalitis with approximate interval between onset and death listed as "year(s)" and manner of death as natural. No autopsy was performed.

*Reviewer comment: This case was assessed as **unlikely** related to COVID-19 vaccination. Complications of multiple serious chronic medical conditions including encephalitis (the reported cause of death) is a more likely etiology for this death.*

VAERS [redacted]: 23-year-old male with no relevant PMH or concomitant medications received dose 3 of Pfizer COVID-19 vaccine on 2 December 2021 and died approximately 11 months later. He was in his usual state of health until 28 October 2022, when he was observed to be breathing fast and expressed feeling panic; he did not report other symptoms at this time. He was alert and communicating clearly until he became unresponsive 15 minutes later. Emergency services arrived approximately 04:15 AM. He reportedly died at approximately 05:15 AM.

The cause of death listed in the autopsy report was bilateral pulmonary "thromboembolic" due to deep vein thrombosis of lower extremity of undetermined etiology. There was no history of recent immobilization, trauma, or surgery noted in the report, no histopathologic evidence of malignancy, and no genetic markers of thrombophilia or sickle cell disease. Family medical history included a 25-year-old [redacted] who "developed TIA [transient ischemic attack]" secondary to "embolism, a few weeks post COVID vaccination." The report also noted dilated cardiac hypertrophy (500 gm); microscopic tissue examination of the heart revealed unremarkable parenchyma without fibrosis, acute ischemic changes, myocardial inflammation, disarray, or inclusions. Toxicology screening was negative for ethanol and drugs of abuse except cannabinoids (test result was "Presumptive Positive"). No death certificate was provided.

*Reviewer comment: This case was assessed as **unlikely** related to COVID-19 vaccination. The time to onset (>10 months) was not consistent with a causal relationship. Bilateral pulmonary thromboemboli due to deep vein thrombosis of lower extremity (as noted in the autopsy report) is the likely etiology for death.*

VAERS [redacted]: An adult female in her twenties (or 3-decade-old female) received Moderna COVID-19 vaccine (dose number unknown) on an unknown date. On an unknown date, the patient experienced a fatal adverse event of Deep Vein Thrombosis. It is unknown if an autopsy was performed. No autopsy report, medical history, or further clinical information was provided. No death certificate was submitted.

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*Reviewer comment: This case was assessed as **unassessable** related to COVID-19 vaccination. With no timeline, autopsy report, or death certificate, there is insufficient information to assess causality.*

VAERS [redacted]: 18-year-old female with no reported past medical or psychiatric history received Dose 1 of the COVID19 (Pfizer-BioNTech) vaccine on 17 April 2021, dose 2 on 8 May 2021, and an additional dose (unknown brand or date) and died of suicide, approximately 1.5 years after dose 1. Per the report, she began experiencing adverse events including brain fog, heart arrhythmia (unspecified), skin rashes and psychological symptoms such as insomnia, anxiety, panic, and depression two days after receiving dose 1, and the symptoms increased in severity after dose 2. After receiving the third COVID-19 vaccine dose she reportedly experienced psychosis (visual and auditory hallucinations), mood and energy swings, general delusions, and increased suicidal ideation. Despite being hospitalized in a psychiatric ward twice, the last admission in the month prior to death, she committed suicide on 28 November 2022. The death certificate indicated the cause of death was [redacted]. No autopsy report was available in the record.

*Reviewer comment: This case (death) was assessed as **unlikely** related to COVID-19 vaccination. The peak age of onset for a first-time episode of psychosis for females tends to be teens to late-20's, with earlier onset corresponding to poorer outcomes (77-79). Primary psychotic disorders typically begin in the late teens to early 30's, may have subtle prodromal symptoms resembling another psychiatric disorder (schizophrenia presenting with symptoms of depression), initially present during significant life stressors, and are "generally synonymous with auditory hallucinations" (77). Medical or neurological psychosis more often presents after age 40, acutely, and without auditory hallucinations (77). Complications of a primary psychotic disorder provides an alternate explanation for this death.*

VAERS [redacted]: 22-year-old male with past medical history of Down Syndrome received Dose 2 of COVID19 (Pfizer-BioNTech) vaccine on 9 April 2021 and died approximately 2.5 years later of septic shock. He presented on 16 August 2023 with 3 weeks of nausea/vomiting and a cough after two reported prior admissions at another facility. Urinalysis was abnormal (suggestive of urinary tract infection) and he was tachycardic, he was hospitalized for sepsis. However, subsequent blood and urine cultures were resulted as no growth. He was subsequently diagnosed with COVID-19 and suspected cholecystitis. In the hospital, his condition rapidly deteriorated and he died on 20 August 2023. The death certificate indicated he died from septic shock and COVID-19, with acute kidney injury, probable bilateral pulmonary emboli, and down syndrome listed as other significant conditions contributing to death, and manner was listed as natural. No autopsy performed.

*Reviewer comment: This case was assessed as **unlikely** related to COVID-19 vaccination. With the last reported COVID-19 vaccine occurring over 2 years prior to the*

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events, the time to onset is inconsistent with vaccine related causality. Complications of sepsis and COVID-19 provide a more likely alternate explanation for death.

VAERS [redacted]: 20-year-old male with history of febrile seizures in childhood received dose 2 of the Pfizer-BioNTech COVID-19 vaccine on 1 October 2021 and died of sudden cardiac death approximately 11 months later. He reportedly had abused prescription drugs including alprazolam and Percocet to manage anxiety [redacted] He was in his usual state of health until the day of his death. Per the report, his mother heard him snoring in his bed and about an hour later found him unresponsive outside the shed in which he lived with "foam from his mouth." The patient had urinated in his bed. He was never resuscitated.

Per the autopsy report, the medical examiner indicated the decedent "most likely had a sudden arrhythmia with a collapse and death." Autopsy findings of significance included minor abrasions to the face, right shoulder, and right hand, hypertensive cardiovascular disease, cardiomegaly (455 grams) but otherwise unremarkable heart, and capillary telangiectasia in the right temporal lobe. Postmortem toxicology was significant for presence of THC. Genetic testing was negative for any reported genetic disorders associated with abnormal heart rhythms or sudden death. The medical examiner postulated the decedent may have had a seizure resulting in incontinence followed by sudden collapse or a second seizure; benzodiazepine withdrawal seizure vs seizure associated with the small brain lesion were postulated as possible triggers. The medical examiner also noted that the enlarged heart (due to hypertension or extensive physical activity), recent marijuana use, or a combination of both could have predisposed to an arrhythmia. The death certificate lists the cause and manner of death as undetermined. The decedent's mother submitted the report and indicated the outcome was "Sudden Cardiac Death by Myocarditis on 9/19/22."

Reviewer comment: This case was assessed as ***unlikely*** *related to COVID-19 vaccination. With the last reported COVID-19 vaccine occurring almost 1 year prior to the events, the time to onset is inconsistent with vaccine-related causality. The autopsy report provided no information to support the mother's reported diagnosis of myocarditis. A sudden arrhythmia secondary to hypertensive heart disease in the context of these other factors and possibly benzodiazepine withdrawal provides an alternate explanation for this death.*

VAERS [redacted]: 23-year-old male with PMH of chronic asthma since childhood described as well managed received an unknown dose of an unknown COVID-19 vaccine on 1 November 2021 and died approximately 3 weeks later. Concomitant medications were not reported. On the afternoon of 25 November 2025, he presented to the emergency room with "chest pain and shortness of breath" and was evaluated and discharged. Several hours later the patient returned to the emergency room "in great distress and having trouble breathing." Patient received treatment but passed away in the emergency room. No death certificate or autopsy report was included.

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*Reviewer comment: This case was assessed as **unassessable** related to COVID-19 vaccination. The individual had chronic asthma and died 24 days post-vaccination after experiencing chest pain and shortness of breath. The cause of death was not reported and there was no death certificate or autopsy report available for review. The specific vaccination and dose received is also unclear.*

VAERS [redacted] 23-year-old male received COVID19 (Pfizer-BioNTech) vaccine on 02/10/2022 and died of cancer more than two years later. He had reportedly experienced back pain through December 2022 followed by foot drop, mobility limitation and inability to urinate or defecate in January 2023. He was subsequently diagnosed with [redacted] glioma spinal tumor, and despite treatment, died from metastasis to the brain on 15 October 2024. No autopsy or death certificate was available in the record to review.

*Reviewer comment: This case was assessed as **unlikely** related to COVID-19 vaccination. Complications of metastatic glioma is the likely etiology for death.*

VAERS [redacted]: 19-year-old male with history of hypertension and morbid obesity received dose 3 of Moderna COVID-19 vaccine in January 2022 and died approximately 2 years later of hypertensive heart disease. On 26 December 2023, the patient was moving into a new home and was noted to be gasping for air while sitting on the couch; he subsequently became unresponsive. Resuscitation efforts were unsuccessful, and he was pronounced dead at the hospital on the same day. Autopsy findings were significant for listed cause of death of hypertensive heart disease, cardiomegaly (heart weight: 650 grams with left ventricular hypertrophy and four chamber enlargement), and presence of myocardial bridge of the mid left anterior descending coronary artery. No death certificate was available in the record.

*Reviewer comment: This case was assessed as **unlikely** related to COVID-19 vaccination. With the last reported COVID-19 vaccine occurring almost 2 years prior to the events, the time to onset is inconsistent with vaccine-related causality. Complications of hypertensive heart disease and morbid obesity are the likely explanation for death.*

VAERS [redacted]: 22-year-old female with a complex medical history including achondroplasia, restrictive lung disease, rheumatic mitral stenosis, severe persistent asthma, cervical myelopathy, obstructive sleep apnea, and chronic respiratory failure requiring ventilator dependence and tracheostomy received her third dose of the COVID-19 Pfizer-BioNTech vaccine on 14 December 2021 and died five days later.

On the day of death, 5 days post-COVID vaccination, the patient experienced a witnessed cardiac arrest. Emergency Medical Services arrived within five minutes, initiated CPR, and achieved ROSC. She was transported to the ED. A respiratory pathogen panel including COVID-19 PCR, adenovirus, coronavirus 229E, HKU1, NL63 and OC43, metapneumovirus, rhinovirus/enterovirus, influenza A and B, parainfluenza 1,2,3 and 4, RSV, Bordetella pertussis and parapertussis, Chlamydophila pneumoniae

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and mycoplasma pneumoniae returned negative results. Initial chest radiographs revealed complete bilateral lung opacification, obscuring the cardiomediastinal silhouette. The patient's condition rapidly deteriorated despite aggressive interventions. She ultimately became bradycardic and arrested. After approximately 15 minutes of CPR without return of pulses, the patient was pronounced dead.

The death certificate lists the immediate cause of death as "undetermined causes" related to chronic respiratory failure with hypoxia and rheumatic mitral stenosis. Dwarfism was noted as a significant contributing condition but not as part of the underlying cause of death. No autopsy was performed.

*Reviewer Comments: This case is **unlikely** related to COVID-19 vaccination given the patient's multiple severe underlying respiratory conditions. The clinical presentation of complete lung opacification, suspected mucus plugging, and progressive respiratory failure is consistent with the patient's known history of restrictive lung disease, severe asthma, and chronic respiratory failure, providing a plausible alternative explanation for the cause of death.*

VAERS [redacted]: 19-year-old female student received two doses of the Moderna COVID-19 Vaccine (mRNA-1273) and died approximately 6 weeks after the second dose. The vaccination dates and date of death are unknown**,** and it is unknown if an autopsy was performed.No medical history, concomitant medications, treatment details, autopsy findings**,** or death certificate were provided with this report.

*Reviewer Comments: This case is **unassessable** due to limited clinical data reported in this case, including the absence of vaccination dates, death date, medical history, circumstances of death, autopsy reports, and death certificate.*

VAERS [redacted]: 22-year-old male with a history of substance abuse, was discovered unresponsive in his bedroom, and died on May 25, 2021, 35 days following his second Pfizer-BioNTech COVID-19 vaccination. Per the report, he was observed alive approximately 12 hours prior to being found unresponsive. Clinical records were not available for review within the report.

Toxicological analysis from autopsy the following day detected ethanol in femoral blood and vitreous samples (0.122 g/dL and 0.148 g/dL respectively), amphetamines (0.23 mg/L), and diphenhydramine below the limit of quantification. The toxicology findings were deemed non-significant. Gross autopsy findings revealed dilated cardiomyopathy moderate left ventricular dilatation but no significant histopathologic abnormalities in the heart, brain, thyroid, kidneys, adrenal glands, liver, or spleen. Cause of death was undetermined. The death certificate also listed the cause of death as undetermined.

*Reviewer Comments: This case is **unlikely** related to COVID-19 vaccination. The 34 day time to onset is outside the risk window for known vaccine-related cardiac adverse events. Autopsy did not note inflammatory changes characteristic of vaccine-associated myocarditis on microscopic examination but did document cardiomyopathy,*

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which can be a sequela of methamphetamine use (80). This event is consistent with Sudden Cardiac Death (please see Discussion, subsection on Sudden Cardiac Death).

VAERS [redacted]: 20-year-old male received his second dose of Moderna COVID-19 vaccine on 13 May 2021 and died 7 months later. On 15 June 2021, approximately one month post-second vaccination, he began to develop progressive joint pain for which he was prescribed steroids. Over the next three months, he also experienced worsening bilateral foot swelling and increased pain and developed painless, non-raised lesions on his hands and feet. On 17 September 2021, he presented to the emergency department after 3-4 days of shortness of breath and cough, with difficulty breathing and coughing up blood. He was noted to be hypoxic, tachycardic, and febrile. Laboratory studies revealed leukocytosis (30.0k with left shift), anemia (Hgb=10.5, HCT=31.5%), and thrombocytosis (621). Urinalysis showed hematuria, proteinuria, and granular casts with normal creatinine. CT chest ruled out pulmonary embolism but showed extensive bilateral alveolar infiltrates with elevated right heart pressures, consistent with pneumonia or ARDS. His hypoxia worsened, requiring intubation for progressive respiratory failure and ICU transfer. PCR testing for COVID-19, RSV, influenza, and rapid Group A strep were negative. He was evaluated by the Rheumatology team; comprehensive panel identified positive anti-GBM antibody and proteinase 3 antibodies, confirming Goodpasture's and ANCA vasculitis overlap syndrome with low C4. Skin biopsy of petechial rash showed thrombotic vasculopathy, and renal biopsy on showed crescentic glomerulonephritis. Despite aggressive supportive care in the ICU, his condition deteriorated with multi-organ failure. He died on 28 October 2021 from complications related to the vasculitis process [redacted]. The death certificate listed right ventricular failure as the immediate cause of death due to pulmonary embolism, with contributing conditions including ARDS, diffuse alveolar hemorrhage, CNS vasculitis, Goodpasture syndrome, pneumonia, acute renal failure, pneumothorax, and upper gastrointestinal bleeding.

*Reviewer Comments: This case is **unlikely** related to COVID-19 vaccination given the alternative etiology provided by the Goodpasture's diagnosis*.

VAERS [redacted]: 23-year-old male with a medical history of cystic fibrosis, bipolar disorder with prior suicidal ideation, substance abuse, and migraines received two doses of the Pfizer-BioNTech COVID-19 vaccine on February 25, 2021 and March 18, 2021; he died approximately 3 weeks after dose 2. Following dose 1, he experienced low-grade fever and body aches but completely recovered within 24 hours per the reporter. After the second dose, he experienced two days of fever and body aches and was feeling "very weak and washed out," and according to the reporter "was near death in his bed 3 weeks later."

On April 9, 2021, the patient sustained cardiac arrest at home; EMS intubated him and transported him to the ED. He was pulseless, pale with blue discoloration, stiff, with no end tidal CO2 on monitor. SARS-CoV-2 PCR test result was negative. CPR was performed for approximately 45 minutes without achieving ROSC. Resuscitation efforts were discontinued, and the patient was pronounced deceased at 16:32. The medical

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examiner's report identified the cause of death as complications of cystic fibrosis with manner of death listed as natural. An internal examination was not performed due to "[redacted]

Post-mortem toxicology testing of femoral blood showed the presence of ranitidine (trace amounts), naloxone, lidocaine, and lamotrigine. Blood volatiles were negative, and drugs of abuse were negative in both blood and urine testing (20 April 2021). However, a rapid urine drug screen was positive for opioids. No death certificate was available.

*Reviewer Comment: This case is **unassessable** due to the lack of internal examination on autopsy and missing death certificate.*

VAERS [redacted]**:** 23-year-old male with history of Type 1 diabetes and coccidioidomycosis with subsequent chronic oxygen use received his third dose of Moderna COVID-19 vaccine on 5 February 2022 and died 10 days later. He was brought to the ED by his mother on the day of death for altered mental status and worsening shortness of breath. Hospital staff found him in cardiac arrest and initiated CPR and he was emergently intubated; a large amount of blood was seen in his airway. COVID-19 test was negative; no other labs/imaging were included in the records. Advanced cardiac life support protocol was continued for 30 minutes with no ROSC and the patient passed away.

The medical examiner declined the case and no death certificate was provided.

*Reviewer Comments: This case is **unassessable** due to insufficient medical records, absence of autopsy examination, and lack of death certificate information.*

VAERS [redacted]: 21-year-old male with no reported medical history received the 2nd dose of the Pfizer COVID-19 vaccine on 2/18/2021. The reporter states that her son died one week later. Per the report, he had tested negative for COVID-19. No autopsy report or death certificate was provided; however, per the report, no cause of death was found by autopsy.

*Reviewer Comments: This case is **unassessable** due to the lack of comprehensive medical records, autopsy report, and death certificate.*

VAERS [redacted]**:** 21-year-old female with end-stage renal disease (on peritoneal dialysis), hypertension, chronic anemia, hyperparathyroidism, GERD, and hyperlipidemia received her second dose of Moderna COVID-19 vaccine on 5/18/2021 and died approximately 5 months later. Per the report, she had experienced two weeks of productive cough with white sputum, chills, nausea, and vomiting, along with bilateral numbness in hands and feet. On the day she presented to the ED, she had experienced multiple near-syncopal episodes. In the ED, she was noted to be hypotensive. Chest X-ray was unremarkable; EKG was notable for prolonged QTc of 500 milliseconds. Laboratory evaluations were significant for pancytopenia (WBC 2.6,

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hemoglobin 11.4, platelets 125) and elevated troponin (0.048). Urinalysis was consistent with urinary tract infection, showing positive nitrite, 3+ leukocyte esterase, 4+ bacteria, and 51-100 WBCs. Urine culture ultimately grew 70,000 CFU/ml of gram-positive mixed bacterial flora with >100,000 CFU/ml of Streptococcus agalactiae (Group B) as the predominant organism. Peritoneal dialysis fluid culture and blood cultures were negative. The patient tested positive for COVID-19 via PCR.

The patient was hospitalized for approximately 3 days. Treatment included IV fluids, antibiotics, monoclonal antibodies and inpatient peritoneal dialysis. She was discharged in stable condition as she felt “back to normal.” Discharge instructions included completing antibiotics for UTI and self-isolation for 21 days due to COVID infection.

The VAERS report indicates the patient died on 10 September 2021 (the same day as discharge), but follow-up investigation by the State Department of Health's Center for Health Statistics was unable to locate a death record. A February 19, 2025, communication confirmed "the death record for this person can't be located," and a February 25, 2025, follow-up stated "information provided was insufficient to identify a matching death certificate." No autopsy information was provided.

*Reviewer Comment: This case is **unassessable** due to the inability to identify and verify death records, despite the reported death date of 10 September 2021, which coincides with the patient's hospital discharge date when she was documented as being in stable condition.*

VAERS [redacted]: 19-year-old male with no medical history received dose 1 of Moderna COVID-19 vaccine on September 9, 2021 and dose 2 on October 7, 2021. He died two months later.

Per the record, the decedent’s parents reported that after the first vaccination, he began complaining of gastric discomfort and lower back pain, and after dose 2, he was more tired than usual, always sleepy, with progressive gastric discomfort. However, he passed his [redacted] physical exam within a few days of death, and notes for a well visit on December 3, 2021 (9 days before his death) documented normal physical examination findings. On the day of his death, December 12, 2021, he was brought to the emergency department via EMS after he collapsed in front of his parents when he attempted to get up from the couch. The family performed CPR for approximately 15 minutes after the witnessed arrest before EMS arrived. Initial cardiac rhythm showed ventricular tachycardia. Physical exam revealed a Glasgow Coma Score of 3. The patient was unresponsive with fixed dilated pupils, asystole, bilateral lower extremity edema and cold clammy mottled skin. He was pronounced dead in the Emergency Department.

The autopsy report identified the cause of death as cardiac dysrhythmia of unclear etiology in a 19-year-old male with sudden witnessed collapse. The heart pathology report showed heart weight of 391 grams, mild right ventricular dilatation with a 4 mm thickness, posterior left ventricular with epicardial fibrosis, left ventricular thickness of

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12mm, interventricular thickness of 11 mm with mild interstitial fibrosis, significant cardiac myocyte hypertrophy, no gross or histologic evidence of acute infarction, and no inflammation identified Gastroenterology evaluation was significant for finding of inflammatory bowel disease. Toxicology screen was negative.

No death certificate was available for review.

*Reviewer Comment: This case is assessed as **unlikely** to have been related to vaccination. The cardiac findings of cardiomyocyte hypertrophy and interstitial fibrosis on autopsy are non-specific pathologic changes that occur in numerous cardiac conditions and do not meet established diagnostic criteria for myocarditis which requires histologic evidence of myocardial inflammatory infiltrate, necrosis, or degeneration of adjacent myocytes (81). Additionally, while fibrosis can be a late marker of previous myocarditis, in this patient, there was no documented evidence of prodromal cardiac symptoms consistent with myocarditis.*

The patient's progressive abdominal discomfort was likely due to undiagnosed inflammatory bowel disease (IBD). Active IBD has been associated with myocardial involvement characterized by diffuse left ventricular fibrosis as well as focal fibrosis in a non-ischemic pattern, with approximately 16% of all IBD patients demonstrating such fibrosis (82). Furthermore, IBD has been shown to increase risk of cardiac arrhythmias (83), suggesting that IBD as a more likely etiology of this event of death.

VAERS [redacted]**:** 19-year-old female with no significant medical history or concomitant medications who received dose 3 of the Pfizer monovalent COVID-19 vaccine (BNT162B2) on an unknown date, and died in her sleep on June 9, 2022. Per the limited report, prior symptoms included fatigue. She was taken to the coroner the same day. According to the reporter (mother) the autopsy confirmed a "myocardial event and fluid around her heart and lungs." The 15 day follow up report states "the autopsy revealed "myocardial event" (cardiomyopathy); [and] "fluid around her heart and lungs" (hypervolemia)." However, no autopsy report or death certificate was submitted.

*Reviewer Comment: This case is classified as **unassessable** due to limited clinical information including medical history, death certificate and autopsy report.*

VAERS [redacted]**:** 19-year-old male with no significant medical history received 2 doses of the Pfizer COVID-19 vaccine (vaccination date for one dose 8/1/21; date for the other dose unreported); he collapsed while running in his neighborhood on July 30, 2022 and died eleven months later on August 2, 2022.

Per the report, the patient was described by his family as a runner who exercised most mornings and had previously participated in high school track without complications although he would occasionally report lightheadedness. There was no reported history of substance use. Family history was negative for sudden cardiac death, hypertrophic cardiomyopathy, prolonged QT syndrome, arrhythmias, or coronary artery disease.

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On 30 July 2022, he was discovered unresponsive by a bystander. EMS found him pulseless/apneic with PEA on cardiac monitoring. ACLS was initiated, including naloxone administration, with point-of-care glucose measuring approximately 240 mg/dL. ROSC was achieved after 4 minutes, and he was transported to the ED intubated.

Physical examination showed intermittent myoclonic movements. Chest x-ray and CT of the head and cervical spine were negative. EKG showed sinus tachycardia with deep ST depressions and T-wave inversions in multiple leads, with normal QT/QTc intervals. Laboratory studies showed acute kidney injury (creatinine 2.07 mg/dL), elevated liver enzymes (AST 292, ALT 280), lactic acidosis (5.9 mmol/L), and elevated trops (initial 175.9 pg/mL, rising to 7,623.5 pg/mL). Toxicology screening was negative for all substances tested. PCR testing was negative for influenza A/B and COVID-19. Echocardiography showed moderate asymmetric left ventricular hypertrophy but was otherwise unremarkable with ejection fraction of 50-55%.

Neurological evaluation in the ICU revealed unresponsive state with absent brainstem reflexes, and EEG performed on 1 August 2022 was consistent with severe anoxic brain injury. Two physicians declared the patient brain dead [redacted] on August 2, 2022. No autopsy was performed, and the death certificate listed cause of death as “undetermined” and the manner of death as "undetermined circumstance.”

*Reviewer Comments: This case is **unlikely** related to COVID-19 vaccination given the extended time interval between vaccination and death (approximately 11 months) as well as the echocardiographic findings of moderate left ventricular hypertrophy with an ejection fraction of 50-55%, which are consistent with hypertrophic cardiomyopathy (HCM), the most frequent cause of sudden cardiac death in athletes. Please see Discussion, subsection on Sudden Cardiac Death.*

VAERS [redacted]: 19-year-old male with an unknown past medical history received the Pfizer vaccine on May 16, 2021; per the report, within four days of vaccine receipt, the patient developed respiratory distress and anxiety and died the next day. However, the VAERS report also lists the date of death as May 17, 2022, which would be 1 year and 1 day after vaccination. No medical records are available. No autopsy or death certificate is available for review.
*Reviewer Comment: This case is classified as **unassessable** due to limited clinical information including medical history, death certificate and autopsy report, and due to conflicting/erroneous information regarding interval between vaccination and event.*

VAERS [redacted]: 22-year-old male with a past medical history of multiple sclerosis, anxiety, depression, bipolar disorder, suicidal ideation, seizures, and illegal substance abuse received the Moderna vaccine on 21 June 2022; he was found dead at home four days later. Per the report, he felt sick after vaccination, with chills, and cough. Four days later, he was found dead, with white foam coming from his nose and blood on his face. The autopsy states that the cause of death was anoxia due to pulmonary edema

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and that the pulmonary edema was the result of toxic levels of fentanyl and moderate levels of alcohol found during the toxicology screen. No death certificate was available.

*Reviewer Comment: This case is classified as **unlikely** related to vaccination, as drug overdose is a more likely alternative cause of death.*

VAERS [redacted]: 18-year-old male with a past medical history of cerebral palsy, seizure disorder, spasticity, and congenital postural scoliosis received dose 2 of the Moderna vaccine on June 8, 2021 and died 7 months later. On January 14, 2022, EMS was called to his home after he was found unresponsive and pulseless. Resuscitation was initiated; initial cardiac rhythm was ventricular tachycardia but was asystole by the time of hospital arrival. Additional resuscitation efforts failed, and he was pronounced dead. In the medical records, the cause of death was listed as cardiac arrest, cause unspecified. The death certificate states the cause of death as cerebral palsy and epilepsy. It also states that COVID-19 infection was a significant contributing condition to death. No autopsy was performed.

*Reviewer Comment: This case is **unlikely** related to COVID-19 vaccination given the alternative etiology of cerebral palsy and epilepsy in the context of COVID-19 infection, as well as the seven-month interval between vaccination and event that is inconsistent with a temporal relationship.*

VAERS [redacted]: 18-year-old female with a past medical history of anxiety, depression, PTSD, and ADHD received the Moderna COVID-19 vaccine on 21 May 2021 and died in a motor vehicle accident two months later. On 19 July 2021, she was witnessed exhibiting seizure-like activity while driving a car before the car accident. She died at the scene of the accident. The autopsy report demonstrated mild cardiomegaly as well as moderate degeneration of the mitral heart valve with mild prolapse, and acute pulmonary edema. Toxicology tests were negative. The medical examiner concluded that the patient died because of complications from cardiomegaly and mitral valve prolapse and noted that both conditions can precipitate sudden lethal cardiac arrhythmias. The death certificate states the cause of death was complications of cardiomegaly and mitral valve prolapse. The death certificate also states that COVID-19 infection was a significant contributing condition to death. No hospital records are available for review.
*Reviewer Comment: This case is **unlikely** related to COVID-19 vaccination given the alternative etiology of cardiomegaly and mitral valve prolapse in the context of COVID-19 infection, as well as the two-month interval between vaccination and event that is inconsistent with a temporal relationship.*

VAERS [redacted]: 23-year-old male with a recent past medical history of ventilator dependence, anoxic encephalopathy, seizure disorder, chronic respiratory failure, and history of previous cardiac arrest, received the Pfizer COVID vaccine on 17 January 2021 and died four days later. Two days post-vaccination, he developed a fever of 104; chest X-ray was remarkable for a previous persistent infiltrate and a new perihilar infiltrate. He was treated with IV antibiotics and IV fluids, but 4 days after vaccination,

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he went into cardiac arrest and could not be resuscitated and died. His death certificate states the immediate cause of death was sepsis due to pneumonia which was due to chronic respiratory failure and COVID-19 infection. No autopsy was done.

*Reviewer Comment: This case is **unlikely** related to COVID-19 vaccination given the alternative etiology of pneumonia (and sepsis, per the death certificate) in the context of COVID-19 infection.*

VAERS [redacted]**:** 18-year-old male college student with a history of autism, ADHD, anxiety, on quetiapine, clonidine, Adderall XR, and sertraline, and elevated BMI (BMI of 27.7 on [redacted] and 25.3 on [redacted]) received dose 2 of Pfizer-BioNTech COVID-19 vaccine in May 2021 and died on 7 Jul 2021. The decedent had visited his doctor for ADHD follow-up the week prior to death. Records from that visit noted a BMI of 24.7, HR 85, and O2Sat 99%. At the visit, the patient complained of not being able to fully bend his right toe, but he denied medication side effects, including chest pain, shortness of breath, and syncope. No medical records detailing events immediately preceding the death were available for review.

Autopsy was performed, however, no corresponding report is available for review. Per death certificate, cause of death is listed as Pulmonary Thromboembolism.

*Reviewer comment: This death is considered **unlikely** related to COVID-19 vaccination due to the more likely etiology of pulmonary thromboembolism (the listed cause of death) in a person with previous BMIs consistent with overweight. Please see Discussion, subsection on COVID-19 Vaccination and Thromboembolic Events.*

VAERS [redacted]**:** 18-year-old male with a history of asthma and obesity received Pfizer-BioNTech on 26 Aug 2021 and died approximately one month later. Three weeks prior to death, he was treated with a course of amoxicillin for tonsillitis. Although symptoms had been reportedly subsiding, he presented to the ED on 23 Sep 2021 with severe odynophagia associated with dysphagia. The decedent underwent nasotracheal intubation due to concern for impending airway collapse with a diagnosis of acute bacterial epiglottitis noted. After admission to the PICU, he became hypotensive and increasingly hypoxic, and experienced bradycardia followed by cardiac arrest; resuscitation efforts were not successful, and he died on 24 Sep 2021.

Per the autopsy, cause of death was pulmonary thromboembolism; additional findings included epiglottitis (+S. viridans, P. aeruginosa), bacteremia (+S. hominis) and obesity (BMI 39.1). Per death certificate, the immediate cause of death was “cardiopulmonary arrest due to or as a consequence of pulmonary embolism due to or as a consequence of complications due to Epiglottitis.”

*Reviewer omment: This death is considered **unlikely** related to COVID-19 vaccination due to more likely etiology of pulmonary thromboembolism (the listed cause of death) in the context of bacterial epiglottitis. Please see Discussion, subsection on COVID-19 Vaccination and Thromboembolic Events.*

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VAERS [redacted]: 18-year-old female with a history of syncope, peanut allergy, on oral contraceptive received dose 1 of Pfizer-BioNTech on 23 Sep 2021 and suddenly expired approximately one week later on 1 Oct 2021. Per the report, the decedent had presented to her doctor's office on [redacted], reporting nasal congestion, postnasal drip, chest congestion, and wheezing. COVID-19 testing was planned, however, no results were included in the visit note. She was reported to have died suddenly at work [redacted] on 1 Oct 2021. Per records in the report, an autopsy was performed, with cause of death and manner of death listed as Undetermined, but an autopsy report was not available for review.

*Reviewer comment: This case is classified as **unassessable** due to limited clinical information including death certificate and autopsy report.*

VAERS [redacted]: 19-year-old female received dose 1 of Pfizer-BioNTech COVID-19 vaccine on 1 Sep 2021 and dose 2 of on 28 Sep 2021 and died of suicide approximately one month later. Information in the record regarding past medical history includes a primary care note from [redacted] documenting "no psychotic or suicidal thoughts." The initial VAERS report includes depression as a "chronic or long-standing health condition" and states that the decedent's "diaries turned increasingly dark immediately after the first [COVID-19] injection." Prior to suicide, "depression increased and degraded at a rapid rate which included a 72 hour hold at a psychiatric hospital." By Oct 2021, primary care outpatient notes indicated that the decedent was experiencing suicidal ideation, anxiety, auditory hallucinations, and delusions, as well as new persistent headache suspected by her provider to be due to stress in the setting of recent life events [redacted] She had also admitted to using illicit drugs (unspecified substance[s] and duration). Available laboratory testing was notable for low vitamin D (24.5 ng/mL, RR: 30–100 ng/mL). She was admitted to a behavioral health center for management and referred to Neurology to rule out autoimmune encephalitis (given the acute nature of symptoms), but she completed suicide by [redacted] on 30 Oct 2021.

Death certificate cause of death was listed as [redacted]. No autopsy was performed.

*Reviewer comment: This death is considered **unlikely** related to COVID-19 vaccination. Though onset is unclear, the decedent's history was notable for depression, as well as illicit drug use and apparent life stressors, consistent with etiology of death. Please see Discussion subsection on Suicidality in Young Adults.*

VAERS [redacted]: 21-year-old female with a history of epilepsy on lamotrigine, substance abuse, ocular migraine headaches received Pfizer-BioNTech COVID-19 vaccine (unspecified dose) on 30 Dec 2021 and expired approximately two weeks later. On the night prior to death, she had reportedly been huffing nitrous oxide (N_2O) and ingesting "acid." On the morning of her death on 17 Jan 2022, the decedent appeared "to be in good health," but she was later found deceased in bed. Per autopsy report, multiple empty cartridges from N_2O canisters were noted at the death scene. Postmortem toxicology

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testing was negative for alcohol/drugs (including N_2O and lysergic acid diethylamide [LSD]).

The autopsy cause of death was listed as hepatic steatosis of unclear etiology in an individual with seizure disorder (Epilepsy) and hyponatremia. The manner of death was natural.

*Reviewer comment: This death is considered **unlikely** related to COVID-19 vaccination. Although Sudden Unexpected Death in Epilepsy (SUDEP) is not specifically noted in the autopsy report as a cause of death, multiple analyses have indicated an increased risk of SUDEP among persons with a history of substance abuse (84). Please see Discussion, subsection on Sudden Unexpected Death in Epilepsy*

VAERS [redacted]: 23-year-old male with a history of perforated peptic ulcer, exploratory laparotomy and gastronomy tube placement (both in [redacted] and anabolic steroid use received dose 1 of Pfizer-BioNTech COVID-19 vaccine on 18 Oct 2021 and dose 2 on 8 Nov 2021; he died on 24 Nov 2021. Within 15 minutes of vaccination, he reportedly experienced chest pain; he continued to have intermittent chest pain and shortness of breath for two weeks. On 24 Nov 2021, the decedent was on the side of the road and did not return after leaving to urinate. EMS was called and found the decedent in cardiac arrest, with emesis in his airway and right-sided gurgling noted on exam. Total down time was noted as greater than one hour. He was intubated and transported to the ED and was subsequently pronounced deceased after resuscitation efforts failed. No autopsy report or death certificate was available for review.

*Reviewer comment: This case is classified as **unassessable** given the absence of autopsy report/death certificate findings, including cause of death.*

VAERS [redacted]: 19-year-old female with a history of neurodegenerative disease (GM1 gangliosidosis Type 2 inborn error of metabolism), chronic lung disease, g-tube dependence, global developmental delay, failure to thrive, acute kidney injury [redacted] and hospital visits for presumed aspiration pneumonia and sepsis in the two months preceding death received dose 1 of Pfizer-BioNTech on 26-Dec-2021 and dose 2 on 7 Feb 2022 and expired approximately one week later on 15 Feb 2022. She was found unresponsive by her family on the morning of death and EMS was called. On EMS arrival, she was pulseless and was transported to the ED; she was pronounced deceased following failed resuscitation attempts. She tested positive for SARS-CoV-2 (PCR) on 15 Feb 2022.

The death certificate cause of death was listed as sudden cardiac death, due to or as a consequence of COVID-19. No autopsy was performed.

*Reviewer comment: This case is considered **unlikely** related to COVID-19 vaccination given the alternate etiology of COVID-19 infection, superimposed upon the decedent's complex medical conditions, including chronic lung disease.*

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VAERS [redacted]: 19-year-old female with a history of seasonal and animal allergies, bipolar disorder, received Pfizer-BioNTech on 16 Feb 2021 and expired approximately eight months later on 12 Oct 2021. Per the initial VAERS report, the decedent experienced increased nasal congestion and sinus pain in the spring following vaccination. On 9 Oct 2021, she was referred to the ED after presenting to urgent care with tachypnea and tachycardia; chest x-ray findings consisted of a right upper lobe cavitary lesion as well as lower lobe findings consistent with pneumonia. She was subsequently admitted to the hospital. Hospital record notes that she had experienced intermittent cough, hemoptysis, and a 10-pound weight loss within the month preceding presentation. CT chest after admission demonstrated multiple cavitary lesions. Laboratory examinations were significant for negative COVID-19 and QuantiFERON-TB gold testing.

Per the record, the decedent experienced hypoxic respiratory failure during bronchoscopy and required intubation. She decompensated suddenly on 12 Oct 2021, becoming bradycardic and pulseless; after 3 hours, resuscitative attempts were discontinued. The hospital record notes the cause of death to be fungal pneumonia and sepsis. Posthumously, her anti-proteinase-3 antibody (C-ANCA) result was elevated, and autopsy cause of death was complications of granulomatosis with polyangiitis.

Reviewer comment: This death was assessed as ***unlikely*** *related to COVID-19 vaccination. Although cases of anti-neutrophil cytoplasmic antibody (ANCA)-associated vasculitis, including granulomatosis with polyangiitis (GPA), have been reported following COVID-19 vaccination (85, 86), data from a national cohort did not indicate a statistically meaningful increase in ANCA-associated vasculitis risk following COVID-19 vaccination (87). Please see Discussion, Subsection on Autoimmune Disease.*

VAERS [redacted]: 18-year-old male with a history of paroxysmal tachycardia NOS as of age five, as well as ADHD, disruptive mood disorder, and other specified neurodevelopmental disorder received tetanus/diphtheria/pertussis vaccine, inactivated polio vaccine, and meningococcal vaccine on 14 Oct 2021 and one dose of Pfizer-BioNTech on 15 Oct 2021 and expired on 24 Oct 2021. Preceding death, [redacted]. Per the autopsy report, interviews with [redacted] indicated that the decedent did not have infectious symptoms while in [redacted] leading up to the date of his death. Testing on 13 Oct 2021 was negative for COVID. He experienced a witnessed collapse associated with reported convulsions on 24 Oct 2021 after running a lap around a training area track and was found unresponsive and pulseless (either in PEA or asystole) by EMS. The decedent was brought to the ED with CPR ongoing. ROSC was not achieved after continued resuscitative efforts and he was pronounced deceased in ED.

The death certificate dated [redacted] cited "Myocarditis following Administration of the BNT162B2 COVID-19 Vaccine" as the immediate cause of death. Autopsy had been performed on 26 Oct 2021, however, the first available autopsy report was dated 12 Jun

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2022. This report noted “mild, acute and chronic, myocardial inflammatory infiltrate without myocyte necrosis.” Toxicology screening and COVID testing was negative. A variant of uncertain significance pertaining to the FLNC gene was noted on a cardiac genetic panel. The autopsy report also included a cardiac autopsy performed by the [redacted] that was notable for finding of a left main coronary artery of anomalous origin from the right sinus of Valsalva. The consultation report noted that immunostaining ruled out lymphocytic myocarditis (per “essentially negative” CD3). CD68 immunostaining revealed “a borderline increase in interstitial macrophages,” suggesting possible hypersensitivity myocarditis, however, given the absence of necrosis this finding was considered incidental. The “sparse inflammation” noted immunohistochemically was ultimately considered in this consultation report as noncontributory to the death. However, the medical examiner who prepared the final autopsy report concluded that "Myocarditis following Administration of the BNT162b2 (Pfizer-BioNTech) COVID-19 Vaccine” was the cause of death with “Anomalous Left Coronary Artery from the Right Sinus of Valsalva” as a contributing factor, citing, “By convention, when a possible congenital cause of death and an acute cause of death are both identified during the course of an autopsy, the acute issue is assigned as the primary cause of death, as is being done in this report.”

Of note, the autopsy report also provided additional context on the decedent’s pediatric cardiac history, noting “the decedent would experience episodes of palpitations that would sometimes be accompanied with chest pain or tightness, would most commonly occur upon awakening, would last up to several minutes in length, and would be relieved with resting, including laying down…there was concern from the parents regarding decreased exercise tolerance/activity levels surrounding these episodes. The decedent was referred to pediatric cardiology…and underwent cardiac event monitoring as part of the workup, but no abnormality was identified at the time…and there were no activity restrictions recommended…similar episodes [occurred] around age 10 with no further evaluation at that time.”

On 01 Nov 2022, consultation on this case was provided by the U.S. Centers for Disease Control and Prevention’s (CDC’s) Infectious Diseases Pathology Branch (IDPB); their evaluation noted Streptococcus spp in several specimens and concluded that the cause of death was bacterial sepsis. An additional IDPB report from 30 Apr 2023 noted molecular testing of cardiac tissue samples for enterovirus and human parvovirus B19 was negative. The medical’s examiner’s amended autopsy report on 10 Jul 2023 included this evaluation and continued to cite "Myocarditis following Administration of the BNT162b2 (Pfizer-BioNTech) COVID-19 Vaccine” as the cause of death with “Anomalous Left Coronary Artery from the Right Sinus of Valsalva” as a contributing factor.

*Reviewer comment: This case was considered **unlikely** related to COVID-19 vaccination. The deputy medical examiner concluded that myocarditis following administration of the BNT162b2 (Pfizer-BioNTech) COVID-19 vaccine was the cause of death in this case, citing histological findings, negative SARS-CoV-2 PCR on relevant histology specimens, and a convention to assign the "acute issue" as the cause of death in cases where there is also evidence of a congenitally-acquired condition. However, consultants from the CDC and the [redacted] suggested that the decedent's cardiac histological findings did not indicate*

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myocarditis as the cause of death. CDC reported the cause of death as bacterial sepsis, but per the autopsy report, interviews [redacted] indicated that the decedent did not have infectious symptoms while [redacted] leading up to the date of his death; thus, sepsis appears to be a less plausible diagnosis in this case. [redacted] reported a diagnosis of "Anomalous origin, left main coronary artery from right sinus of Valsalva," and noted that this anomaly is "a cause of sudden exertional death, usually in adolescence or young adulthood." The decedent's childhood symptoms (e.g., palpitations, chest pain, parents' concern for reduced exercise tolerance) are consistent with the presence of this anomaly. The anomaly is thought to be highly lethal; in a published summary of 38 necropsies where the anomaly was noted, 23 (61%) died suddenly during the first two decades of life (88). Further, published literature suggests that "the first clinical symptom [of an anomalous aortic origin of a coronary artery]…may be sudden death, particularly in young athletes and military recruits" (89), and findings from a retrospective study based on [redacted] data noted that [redacted] (90). In contrast, the risk of death due to vaccine-induced myocarditis is likely much lower. A cohort study that enrolled 558 subjects who had received an mRNA COVID-19 vaccine and were diagnosed with post-COVID-19 vaccination myocarditis noted one death (0.18%) in the 18 months of follow up (91). The preponderance of the evidence in this case suggests that the decedent's congenital cardiac anomaly, and not the histologically "mild" myocarditis, was the primary etiology of SCD.

VAERS [redacted]: 20-year-old male with a history of allergic reaction (rash) to Augmentin, on citalopram (no indication noted) received Pfizer-BioNTech in Apr 2021 and May 2021 and expired on 11 Oct 2021. Per the report, the decedent was diagnosed with COVID-19 in Dec 2020 and again on 30 Aug 2021. Per the reports, on 2 Sep 2021, he presented "at [a] local [redacted]" with symptoms including arthralgias and painful rash involving hands, feet, and mouth. The record indicates that he was hospitalized on 4 Sep 2021 and that treatment included remdesivir, Z-Pak, Lovenox, and steroids, but hospital records were not included in the report. He was discharged 7 Sep 2021.

The decedent again presented to ED on 15 Sep 2021 with dyspnea and tachycardia; he had been referred from a post-hospitalization follow-up visit with his PCP. In ED, vital signs included oxygen saturation of 91% on room air and heart rate in 150s. Chest X-ray indicated extensive multilobular pneumonia bilaterally, with increased infiltrate compared to 4 Sep 2021 study [presumably from previous hospitalization]. He was treated in ED with ceftriaxone, azithromycin, and dexamethasone for pneumonia due to COVID-19 virus, hypoxemia and leukocytosis. Condition was noted as "critical." CT of the neck was notable for findings consistent with acute on chronic sinusitis and dental abscess. He was treated with antibiotics, stabilized, and discharged on 23 Sep 2021; per the note, the discharge plan included placement of midline [catheter] to continue IV antibiotics, follow-up in infectious disease clinic, and oral surgery as outpatient.

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He was subsequently evaluated as an outpatient (date not provided) with purpuric body rash and angioedema involving lips. He was noted to be hypotensive and anemic and was again referred to "hospital due to his septic appearance." He was hospitalized, but after a clinical course that included "multiple transfusions, antibiotics and steroids," as well as multiple cardiac arrests, he expired on 11 Oct 2021.

No autopsy was performed. Death certificate cause of death was noted as "Cardiac Arrest due to, or as a consequence of Acute Respiratory Failure due to, or as a consequence of Purpuric Skin Lesions due to, or as a consequence of COVID-19 Pneumonia; significant contributing conditions not related to cardiac arrest included Vasculitis of Undetermined Etiology, Splenic Infarcts, Hyperkalemia with Acute Renal Failure, and History of Dental Abscess."

Reviewer comment: This case was assessed as ***unlikely*** *related to COVID-19 vaccination. Although risk factors for this complicated course following COVID-19 infection are unclear from available clinical records in the report, given the protracted time to onset from vaccination, the death certificate-listed cause of death of COVID-19 pneumonia is the likely etiology.*

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