United States Senate

COMMITTEE ON
HOMELAND SECURITY AND GOVERNMENTAL AFFAIRS

WASHINGTON, DC 20510–6250

May 11, 2026

The Honorable Robert F. Kennedy, Jr.
Secretary
Department of Health and Human Services

Dear Secretary Kennedy:

On April 29, 2026 the Senate Permanent Subcommittee on Investigations ("PSI" or "the Subcommittee") held a hearing and released a report titled, "Unmasked: How Biden Health Officials Purposely Turned a Blind Eye Toward COVID-19 Vaccine Safety Signals."[1] Because of your commitment to "radical transparency" and compliance with my January 2025 subpoena, the Subcommittee was able to uncover a major scandal within the Department of Health and Human Services ("HHS") during the Biden administration.[2] Specifically, federal health officials knew their COVID-19 vaccine safety analytic system was insufficient and they refused to implement a superior, updated system that could better detect safety signals for vaccine adverse events.[3]

However, much work remains to fully uncover the extent of federal health officials' willful blindness toward the harms of the COVID-19 vaccines. In particular, the requests connected to my December 15, 2025 letter regarding the Food and Drug Administration's ("FDA") findings of pediatric deaths connected to COVID-19 vaccines still remain outstanding.[4] I write, therefore, to underscore the need for your leadership in ensuring key records and individuals be made available to the Subcommittee to provide the "radical transparency" you have rightly promoted.

As my recent report detailed, on March 1, 2021, the then-Director of the FDA's Center for Biologics Evaluation and Research ("CBER"), Dr. Peter Marks, was informed that the algorithm FDA was using to analyze VAERS data would mask or hide safety signals associated

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[1] *Unmasked: How Biden Officials Purposely Turned a Blind Eye Toward COVID-19 Vaccine Safety Signals*, Hearing before the Permanent Subcomm. on Investigations (119th Cong.); Chairman Ron Johnson, Unmasked: How Biden Health Officials Purposely Turned a Blind Eye Toward COVID-19 Vaccine Safety Signals, April 29, 2026, https://www.ronjohnson.senate.gov/services/files/4DF802C8-DE9B-46C7-B470-37DD85569A76.

[2] Subpoena from Ron Johnson, Chairman, Permanent Subcomm. on Investigations, to Dorothy Fink, Acting Secretary, Dep't of Health and Human Services, Jan. 28, 2025, https://www.ronjohnson.senate.gov/services/files/8FAB9531-F799-4067-BA1C-AB8CA182D100.

[3] Chairman Ron Johnson, Unmasked: How Biden Health Officials Purposely Turned a Blind Eye Toward COVID-19 Vaccine Safety Signals, April 29, 2026, https://www.ronjohnson.senate.gov/services/files/4DF802C8-DE9B-46C7-B470-37DD85569A76.

[4] Letter from Ron Johnson, Chairman, Permanent Subcomm. on Investigations to Robert F. Kennedy, Jr., Secretary, Dep't of Health and Human Services, Dec. 15, 2025, https://www.ronjohnson.senate.gov/services/files/AFDAD3A2-D789-46ED-B895-16341762156A.

with the COVID injections.[5] On March 26, 2021, senior FDA officials were provided a VAERS analysis based on a newer, "state of the art" algorithm that showed "49 cases of extreme masking" and approximately 25 statistically significant safety signals for serious adverse events that were previously undetected, including sudden cardiac death, pulmonary infarction, and Bell's Palsy.[6]

Instead of alerting the public, FDA decided to continue to use the old algorithm that they knew hid safety signals. That algorithm allowed them to insist they weren't seeing safety signals for serious adverse events, and that the adverse events they did observe were generally described as rare and mild.[7] They could be confident they would never find what they weren't looking for. As a result, the American people were not fully informed as they consented or were mandated to get the experimental injection.

Although federal officials deliberately used a system incapable of truly identifying safety signals, the raw number of reports to VAERS should have been cause enough to raise the alarm. As of March 27, 2026, VAERS is reporting worldwide 1,675,590 adverse events and 39,077 deaths, with 9,329 (23.9%) of those deaths occurring within 2 days of vaccination.[8] As you know, the HHS-commissioned Harvard University Pilgrim Health Care study found that less than 1% of vaccine adverse events were reported to VAERS.[9] As a result of underreporting in VAERS, it is unknown how many people were actually injured or died.

In addition to the data masking and underreporting in VAERS that diminished the detection of COVID-19 vaccine adverse events, federal health officials also muzzled individuals who were suffering from vaccine injuries. In March 2021, just as FDA officials were informed of masked safety signals, doctors within the National Institutes of Health reportedly began diagnosing and treating patients injured by the COVID injections. Dr. Avindra Nath led the team that eventually treated 23 patients.[10] Federal health officials, however, allegedly did not want their acknowledgement of the vaccine injured to be widely known. The vaccine injured were reportedly asked to stay silent regarding their treatment, with the promise that once enough information was gathered, their injuries would be acknowledged and a study would be published

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[5] Chairman Ron Johnson, Unmasked: How Biden Health Officials Purposely Turned a Blind Eye Toward COVID-19 Vaccine Safety Signals, April 29, 2026, https://www.ronjohnson.senate.gov/services/files/4DF802C8-DE9B-46C7-B470-37DD85569A76 at 16-17.
[6] *Id.* at 18-19.
[7] Chairman Ron Johnson, Failure to Warn: How Federal Health Agencies Downplayed the Risk of Myocarditis and Other Adverse Events Following COVID-19 Vaccination, Permanent Subcomm. on Investigations, May 21, 2025, https://www.hsgac.senate.gov/wp-content/uploads/2025.05.21-PSI-Majority-Staff-Interim-Report-Failure-to-Warn.pdf at 47-48.
[8] *Unmasked: How Biden Officials Purposely Turned a Blind Eye Toward COVID-19 Vaccine Safety Signals*, Hearing before the Permanent Subcomm. on Investigations (119th Cong.).
[9] Ross Lazarus, et al., Electronic Support for Public Health-Vaccine Adverse Event Reporting System (ESP: VAERS), 2010, available at https://digital.ahrq.gov/ahrq-funded-projects/electronic-support-public-health-vaccine-adverse-event-reporting-system#nav-publications.
[10] *See* Jennifer Couzin-Frankel and Gretchen Vogel, In rare cases, coronavirus vaccines may cause Long COVID-like symptoms, Science, Jan. 20, 2022, available at https://www.science.org/content/article/rare-cases-coronavirus-vaccines-may-cause-long-covid-symptoms.

so others could be treated.[11] The promised study does not appear to have been published. The fact that a study was never published and their injuries were never acknowledged serves to underscore the despicable behavior of those responsible for safety surveillance and warning the public.

On December 15, 2025, I wrote to HHS requesting records connected to a November 28, 2025 memorandum written by the then-CBER director, Dr. Vinay Prasad, revealing that "at least 10 children have died after and because of receiving COVID-19 vaccination."[12] To date I have received only a partial and totally inadequate response from FDA Commissioner Marty Makary. On May 4, 2026, HHS provided the Subcommittee a December 5, 2025 memorandum detailing 96 pediatric deaths following COVID-19 vaccination, some of which were labeled as "possibly" or "probably" related to the vaccine.[13] The analysis described in this memorandum and conducted under your leadership provides even more evidence of the Biden administration's coverup of the safety risks associated with the COVID-19 injections.[14] I suspect there are many additional records that are responsive to my December 15, 2025 request about pediatric deaths following COVID-19 vaccination and I respectfully ask for HHS to immediately provide my office with those documents.

I appreciate your commitment to make current HHS employees that were involved in or had knowledge of the department's scandalous handling of COVID-19 vaccine safety oversight available for interviews with the Subcommittee. I am concerned, however, that federal documents may have been destroyed or are being withheld as part of the coverup. On April 9, 2025, based on information provided by your agency, I referred allegations that Dr. Tom Shimabukuro deleted or destroyed federal records to the Department of Justice and HHS Inspector General.[15] To date, however, I have been unable to ascertain whether or not the HHS Inspector General is conducting an investigation of the matter. I ask for your commitment to inform the Subcommittee whether or not an investigation is underway. In light of the recent indictment of Dr. David Morens on conspiracy and destruction of federal documents charges, it is important for the public to know whether additional investigations are occurring based on similarly strong evidence.

While I appreciate your efforts to ensure transparency, including producing the December 5, 2025 memorandum, there is far more to discover regarding federal health officials' response to the coronavirus pandemic. Five years have already passed since Dr. Marks decided to ignore VAERS safety signals, and we are only now just learning about that appalling decision and the

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[11] *Unmasked: How Biden Officials Purposely Turned a Blind Eye Toward COVID-19 Vaccine Safety Signals*, Hearing before the Permanent Subcomm. on Investigations (119th Cong.).

[12] Letter from Ron Johnson, Chairman, Permanent Subcomm. on Investigations to Robert F. Kennedy, Jr., Secretary, Dep't of Health and Human Services, Dec. 15, 2025, https://www.ronjohnson.senate.gov/services/files/AFDAD3A2-D789-46ED-B895-16341762156A.

[13] PSI_COVID-19_VACCINE_000006-73 (enclosed). HHS applied the majority of the redactions in the memorandum. The Subcommittee applied minimal additional redactions for personally identifiable information.

[14] *Id.*

[15] Letter from Sen. Ron Johnson, Chairman, Permanent Subcomm. on Investigations, to Pamela Bondi, Attorney General, Department of Justice, Kash Patel, Director, Federal Bureau of Investigation, and Juliet Hodgkins, Principal Deputy Inspector General, Office of Inspector General, Department of Health and Human Services, Apr. 9, 2025, available at https://www.ronjohnson.senate.gov/services/files/7EC8AB4F-A151-4ADD-8603-7AA906295FC9.

actions that followed. We must speed up the discovery process. As a result, I am requesting, at your earliest convenience, a meeting with you and the officials within HHS that can discuss how to make that happen.

The public deserves complete transparency about the safety of the COVID-19 vaccines. HHS must ensure that there is no delay in achieving that objective. Thank you for your attention to this matter.

Sincerely,

Ron Johnson
Chairman
Permanent Subcommittee on Investigations

Enclosure

cc: The Honorable Richard Blumenthal
Ranking Member
Permanent Subcommittee on Investigations

The Honorable Marty Makary
Commissioner
Food and Drug Administration

The Honorable Jay Bhattacharya
Acting Director
Centers for Disease Control and Prevention

The Honorable T. March Bell
Inspector General
Department of Health and Human Services

Enclosure

Department of Health and Human Services
Food and Drug Administration
Center for Biologics Evaluation and Research (CBER)

[redacted]

POSTMARKETING SAFETY ISSUE MEMORANDUM

From: [redacted]

[redacted]

To: STNs 125742/804.0; 125752/343.0; and 125817/64.0

Subject: U.S. VAERS pediatric deaths following COVID-19 vaccines

Sponsors: Pfizer; Moderna; Novavax

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

Date: December 5, 2025

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EXECUTIVE SUMMARY

Objective: This memorandum presents findings from an analysis of U.S. VAERS pediatric death reports following COVID-19 vaccines. This analysis was conducted in response to a request from the Office of Vaccines Research and Review (OVRR) for a structured causality assessment of VAERS reports of pediatric deaths following COVID-19 vaccination. While [redacted] staff have reviewed such reports previously as part of CBER's routine, ongoing monitoring of incoming VAERS data, typically [redacted] 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 a patient under 18 years old who received any COVID-19 vaccine, 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.

Methods: VAERS was queried for domestic reports of pediatric (patient age <18 years old) deaths following COVID-19 vaccines, without any restrictions on preferred terms (PTs) for specific adverse events. [redacted] 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, 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 96 unique U.S. pediatric deaths as of data lock point (DLP) 8/14/25, with vaccination dates between 2021 - 2024. There were 79 cases following Comirnaty and 17 cases following Spikevax. No cases were retrieved for Nuvaxovid or Mnexspike.

No cases were classified as *certain* in relation to COVID-19 vaccination. Seven cases were classified as *possibly* (n = 5) or *probably* (n = 2) 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 89 cases were classified as *unlikely* (n = 62) or *unassessable/unclassifiable* (n = 27).

The *possible/probable* cases involved cardiac events, with most cases involving myocarditis (n = 4) or myocarditis with stress cardiomyopathy (1); myocarditis is a known risk for mRNA COVID-19 vaccines. Other cases described cardiomyopathy without myocarditis (n = 1) and cardiac arrhythmia (n = 1), neither of which is an established risk for mRNA COVID-19 vaccines. Autopsy reports were available for all 7 cases. There were 5 males and 2 females. Median age of the decedent was 13 years (range 7 – 16 years). Median time to onset of symptoms was 3 days (range 1 – 15 days). All events occurred following vaccination with Pfizer-BioNTech COVID-19 Vaccine. Six cases were following Pfizer-BioNTech COVID-19 Vaccine original monovalent and one case was following Pfizer-BioNTech COVID-19 Vaccine bivalent. Of the cases following Pfizer-BioNTech COVID-19 Vaccine original monovalent, 3 cases were reported following dose #1 and 3 cases followed dose #2 (records for two of the cases documented that dose 2 was administered 3 weeks following dose 1). The event following the bivalent formulation occurred after dose #3. For all cases, the vaccination dates were between 2021 – 2022.

Cumulative vaccine distribution data in pediatric individuals is available for products specifically labeled for individuals less than 12 years of age, as the same products/doses are used in adolescents 12-17 years of age and adults. As of 8/14/2025, an estimated total of 95,571,750 doses of Comirnaty and 42,570,884 doses of Spikevax had been distributed in the U.S. for individuals less than 12 years of age. Age-restricted distribution data for Nuvaxovid is not available as there is one product approved for ages 12 years and older; as of 8/14/2025, an estimated total of 9,059,330 doses of Nuvaxovid had been distributed in the U.S. for all approved age groups.

Conclusions: While myocarditis is a known serious risk and labeled event for mRNA COVID-19 vaccines, the 5 deaths involving myocarditis that are classified as *probably/possibly* related to Comirnaty represent greater severity of the known risk of myocarditis, and the reporting of fatal outcomes is not currently described in the prescribing information for mRNA COVID-19 vaccines. Therefore, based on this new cumulative case-level review of all reported death cases in patients <18 years in the over 4 years of vaccine use, we consider this information from postmarketing spontaneous adverse event reports to VAERS to be “new safety information” (NSI) as defined in section 505-1(b)(3) of the Federal Food, Drug, and Cosmetic Act (FDCA). Furthermore, we consider the NSI of myocarditis with fatal outcomes to be applicable to all mRNA COVID-19 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/probably* related to vaccination within the context of the distribution data

provided above; it is also notable that most of these cases are associated with the known risk of myocarditis.

There is insufficient data from this review to draw further conclusions on other cardiac events like cardiomyopathy or arrhythmia, and additional active surveillance data may provide information on these outcomes.

[redacted] **recommendations:**

1. Discuss NSI with OVRR during [redacted]-OVRR review team meetings.
2. Discuss potential safety labeling changes (SLC) with OVRR in [redacted]-OVRR review team meetings.
   - Section 505(o)(4) of FDCA authorizes FDA to require holders of approved drug and licensed biological product applications to make safety-related labeling changes based upon NSI that becomes available after approval of the drug or biological product. [redacted] *preliminary* recommendation, pending OVRR input: class SLC for mRNA COVID-19 vaccines to include the NSI for myocarditis with fatal outcomes in the labeling for Comirnaty, Spikevax, and Mnexspike, in the following sections of the USPI: Addition of a *Boxed Warning*; Updates to *Warnings and Precautions – Myocarditis and Pericarditis*; Updates to *Adverse Reactions – Postmarketing Experience*; Updates to *Patient Package Insert*.
   - 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.
3. Present [redacted]-OVRR joint review team recommendations at [redacted] on December 11, 2025, to obtain Center-level input and concurrence.
4. If [redacted] and Center director concurrence is obtained for this regulatory action, then [redacted]-OVRR review team will proceed to (a) issue class SLC notification letters to applicants, and (b) post letters at 2025 Safety and Availability Communications.
5. Consider also posting a safety communication to summarize above NSI.

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1 BACKGROUND

This memorandum presents findings from an aggregate review of cumulative U.S. VAERS pediatric death reports in patients who received any COVID-19 vaccine, 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 [redacted] individually examine death reports for COVID vaccines on a continuous basis.

This new VAERS-limited analysis was conducted in response to a request from the Office of Vaccines Research and Review (OVRR) for a structured causality assessment of VAERS reports of pediatric deaths following COVID-19 vaccination. While [redacted] staff have reviewed these cases previously as part of CBER's routine, ongoing monitoring of incoming VAERS data, typically [redacted] 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 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 pediatric death reports. There were 96 unique cases of US pediatric death reports as of 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), with the following search criteria:

- Location/Age: All U.S. VAERS reports with <18 years age restriction
- Vaccines: COVID-19 vaccine (both monovalent and bivalent formulations)

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 96 unique cases of U.S. pediatric death reports. For each VAERS report, cases were individually reviewed by [redacted] 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 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 96 unique cases retrieved by the query, 17 (18%) involved vaccination with Moderna COVID-19 vaccine (Spikevax), including 9 cases involving the monovalent formulation, 2 cases involving the bivalent formulation, and 6 cases where formulation was not reported. 79 (82%) involved vaccination with Pfizer COVID-19 vaccine (Comirnaty), including 72 cases involving a monovalent formulation, 3 cases involving the bivalent formulation, and 4 cases where formulation was not reported. Assessment of the 96 unique cases retrieved by the query described above resulted in causality determination of 2 cases as *probably* related to COVID-19 vaccination, 5 cases as *possibly* related, 62 cases as *unlikely* related, and 27 cases as *unassessable*.

The 7 cases assessed as *possibly* or *probably* related to vaccination involved a monovalent formulation of the Pfizer vaccine, with the exception of a single case involving a bivalent formulation of the Pfizer vaccine (VAERS [redacted]). Among these cases were 2 females and 5 males. Median age of the decedent was 13 years (range 7-16 years). Median time to onset of symptoms was 3 days (range 1-26 days). Additional information about these cases is summarized in Table 2 below.

Table 2. Summary of Cases Assessed as *Probable* or *Possible*

VAERS ID	Age	Sex	Date (year)	Dose #	Time to Onset	Days Since Previous Dose	Reported Cause of death	Assessment
[redacted]	15	Male	2021	2	2 days	21	Stress cardiomyopathy with perivascular coronary artery inflammation due to unknown etiology	Possible

VAERS ID	Age	Sex	Date (year)	Dose #	Time to Onset	Days Since Previous Dose	Reported Cause of death	Assessment
[redacted]	16	Male	2021	2	2 days	21	Stress cardiomyopathy following 2nd dose of the Pfizer-BioNTech COVID-19 vaccine (autopsy), CDC ID Branch Pathology Report indicates heart findings of acute myocarditis and fibrosis	Possible
[redacted]	13	Male	2021	2	3 days	41	Myocarditis of uncertain etiology (autopsy)	Probable
[redacted]	16	Male	2021	1	1 day	N/A	Terminal cardiac arrhythmia caused by areas of acute and ischemic changes with old scarring/fibrosis, caused by abnormal thin, narrow coronary vascular disease	Possible
[redacted]	13	Female	2022	3	2 weeks (14 days)	363	Complications of probable infectious myocarditis with insulin-dependent diabetes mellitus as a significant contributing condition	Possible
[redacted]	13	Female	2021	1	15 days	N/A	Fulminant myopericarditis (pancarditis) with extensive myocyte necrosis	Possible
[redacted]	7	Male	2022	1	12 days	N/A	Lymphocytic myocarditis	Probable

2.2 Limitations of VAERS data

VAERS data has significant inherent limitations that severely restrict its utility for assessing causality, and typically [redacted] 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 (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 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 for different pediatric age groups for COVID-19 vaccines 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 yrs
May 10, 2021	EUA for Pfizer COVID-19 Vaccine monovalent, 12-15 yrs
Aug 23, 2021	BLA for Pfizer COVID-19 Vaccine monovalent, ≥16 yrs
Oct 29, 2021	EUA for Pfizer COVID-19 Vaccine monovalent, 5-11 yrs
Jun 17, 2022	EUA Moderna COVID-19 Vaccine monovalent, > 6 months
Aug 19, 2022	EUA Novavax COVID-19 Vaccine, Adjuvanted, 12-17 yrs
Oct 12, 2022	EUA Moderna COVID-19 Vaccine bivalent, > 6 yrs; Pfizer COVID-19 Vaccine bivalent, > 5 yrs
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 Authorized Moderna COVID-19 Vaccine (2023-2024 Formula) for use in individuals 6 months through 11 years of age 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 yrs / EUA Pfizer BioNTech COVID-19 Vaccine 2024-2025, 6mo-11yr; BLA for Spikevax 2024-2025 Formula, >12 yrs / EUA Moderna COVID-19 Vaccine 2024-2025, 6mo-11yr
Aug 30 2024	EUA Novavax COVID-19 Vaccine, Adjuvanted (2024-2025 Formula) > 12 yrs.

May 16, 2025 BLA for Nuvaxovid, 12-64 yrs 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 for all approved or authorized ages prior to August 14, 2025, is summarized in Table 3 below. Distribution data for all approved ages <12 years as of August 14, 2025, was also available, and is summarized in Table 4 below.

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	796,268,520	4,240,654,402	5,036,922,922
Spikevax	629,242,006	1,231,366,546	1,860,608,552
Nuvaxovid	9,059,330	108,145,200	117,204,530

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).

Table 3. Summary of U.S. and Global COVID-19 Vaccine Distribution data through 8/14/2025, age <12 years*

Vaccine	U.S. doses distributed	Foreign doses distributed	Total (global) doses distributed
Comirnaty	95,571,750	399,554,560	495,126,310
Spikevax	42,570,884	131,010	42,701,894

*Comirnaty and Spikevax age-restricted distribution data available for products specifically labeled for individuals less than 12 years of age. Age-restricted distribution data not available for Nuvaxovid as there is one product approved for ages 12 years and older.
Source: Information request responses submitted on 12/3/25 to 1) 125742/804.0 (Comirnaty), 2) BLA 125752/343 (Spikevax), and 3) BLA 125817/64.0 (Nuvaxovid).

3 DISCUSSION

The query yielded 96 reports of fatal outcomes in children who received COVID-19 vaccination prior to 8/14/2025. Most cases were associated with the monovalent Pfizer vaccine, the first vaccine to receive pediatric authorization in the U.S. *Probable* and *possible* events of death were all due to cardiac disease, particularly 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) where 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) and at 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 reports required review of several clinical considerations relevant to multiple reports; these topics are discussed below.

Sudden Cardiac Death

Several events of sudden cardiac death (SCD) were reported among reports retrieved by the query, including among the cases assessed as possible or probable (VAERS [redacted]). 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).

Parvovirus B19 and Myocarditis

The presence of Parvovirus B19 in myocardium complicated the causality assessment of VAERS reports [redacted], [redacted], and [redacted] (among the possible/probable cases).

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.

Suicidality Among Adolescents

Suicide was one of the more common causes of death in the reviewed reports. Mental health disorders are common in adolescents. One systematic review and meta-analysis of 191 studies with 1,389,447 children and adolescents found a pooled prevalence of depressive symptoms of 31%, anxiety symptoms of 31%, and sleep disturbances of 42% (16). The CDC 2023 Youth Risk Behavior Survey found that continued feelings of hopelessness and sadness were experienced by 39.7% of students, 20.4% had suicidal ideation, and 9.5% attempted suicide (17). Furthermore, multiple studies found that the COVID-19 pandemic exacerbated mental health conditions in young people, including increased anxiety, depression, and drug use (18, 19). Given the high rate of mental disorders and attempted suicide in adolescents, 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 (20). The incidence of acute pulmonary embolism ranges from 53 to 162 per 100,000 people in the general population, and causes approximately 100,000 deaths annually (21, 22). Several large population-based studies have not found an association between mRNA COVID-19 Vaccines and pulmonary embolis (23-25).

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 (26). However, it should be noted that current evidence favors rejection of a causal relationship between TTS and mRNA COVID-19 vaccines (27).

Sudden Infant Death and Sudden Unexplained Death in Childhood

Sudden death among the very young was documented in multiple reports. Approximately 3500 infants die annually in the United States from sleep-related infant deaths, including sudden infant death syndrome (SIDS), ill-defined deaths, and accidental suffocation and strangulation in bed (28). Sudden unexpected infant death (SUID), also known as sudden unexpected death in infancy (SUDI), is a term used to describe any sudden and unexpected death, whether explained or unexplained

(including sudden infant death syndrome [SIDS] and ill-defined deaths), occurring during infancy. SIDS is the sudden unexpected death of an apparently healthy infant younger than age 12 months whose cause of death remains unknown despite a death scene investigation, a review of the clinical history, and an autopsy (29). SIDS remains one of the leading causes of infant death in the United States. It is reported that the U.S. SIDS rate was 40 deaths per 100,000 live births in 2013 (28). The Institute of Medicine has reviewed the topic of SIDS and concluded, "The evidence favors rejection of a causal relationship between exposure to multiple vaccines and SIDS" (30).

Sudden unexplained death in childhood (SUDC) is a rare phenomenon that occurs in children older than one year of age that is closely related to sudden infant death syndrome. The incidence is highest in children 1 to 4 years of age with an overall incidence rate of 0.6 deaths/100,000 births among children aged 1 to 17 years (31). By definition, SUDC is a diagnosis of exclusion after exhaustive autopsy and analyses are unable to determine a cause of death. However, recurring patterns among cases of SUDC include nocturnal death, prone positioning at discovery, hippocampal structural anomalies, and genetic polymorphisms associated with seizure disorders or cardiac dysrhythmias (32). Approximately 30% of SUDC cases have a history of febrile seizures, compared to 2-5% prevalence in the general population. However, there are many cases of SUDC that have no known history or association with febrile seizures suggesting that SUDC can occur as a result of multiple distinct pathophysiological pathways (33). Furthermore, just as there is no currently established causal relationship between vaccination and sudden unexplained infant death, there is also no currently established link between vaccination and this related disorder.

4 CONCLUSIONS

While myocarditis is a known serious risk and labeled event for mRNA COVID-19 vaccines, the 5 deaths involving myocarditis that are classified as *probably/possibly* related to Pfizer COVID-19 vaccine represent greater severity of the known risk of myocarditis, and the reporting of fatal outcomes is not currently described in the prescribing information for mRNA COVID-19 vaccines. Therefore, based on this new analysis of cumulative case-level review of all reported death cases in patients <18 years in the over 4 years of vaccine use we consider this information from postmarketing spontaneous adverse event reports to VAERS to be "new safety information" (NSI) as defined in section 505-1(b)(3) of the Federal Food, Drug, and Cosmetic Act (FDCA). Furthermore, we consider the NSI of myocarditis with fatal outcomes to be applicable to all mRNA COVID-19 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/probably* related to vaccination within the context of the distribution data provided above; it is also notable that most of these cases are associated with the

known risk of myocarditis. There is insufficient data from this review to draw further conclusions on other cardiac events like cardiomyopathy or arrhythmia, and additional active surveillance data may provide information on these outcomes.

5 [redacted] RECOMMENDATIONS

[redacted] recommendations and next steps are presented below:

i. Discuss NSI with OVRR during [redacted]-OVRR review team meetings.
ii. Discuss potential safety labeling changes (SLC) with OVRR in [redacted]-OVRR review team meetings.
   - Section 505(o)(4) of FDCA authorizes FDA to require holders of approved drug and licensed biological product applications to make safety-related labeling changes based upon NSI that becomes available after approval of the drug or biological product. [redacted] preliminary recommendation, pending OVRR input: class SLC for mRNA COVID-19 vaccines to include the NSI for myocarditis with fatal outcomes in the labeling for Comirnaty, Spikevax, and Mnexspike, in the following sections of the USPI: Addition of a *Boxed Warning*; Updates to *Warnings and Precautions – Myocarditis and Pericarditis*; Updates to *Adverse Reactions – Postmarketing Experience*; Updates to *Patient Package Insert*.
   - 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.
iii. Present [redacted]-OVRR joint review team recommendations at [redacted] on December 11, 2025, to obtain Center-level input and concurrence.
iv. If [redacted] concurrence is obtained for this regulatory action, then [redacted]-OVRR review team will proceed to (a) issue class SLC notification letters to applicants, and (b) post letters at 2025 Safety and Availability Communications.
v. Consider also posting a safety communication to summarize above NSI.

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Appendix A: Case narratives for COVID-19 vaccine pediatric US deaths reported to VAERS – probable (n=2) and possible cases (n = 8)

1. VAERS [redacted]: 15-year-old male with allergic rhinitis and acne experienced 100F fever, nausea and tiredness, and was subsequently found unresponsive at home in bed within 48 hours of his 2nd dose of Pfizer-BioNTech COVID-19 vaccine. Per the report, emergency services were called, and death was pronounced upon arrival of first responders.

   Per an email communication regarding preliminary autopsy findings, microscopic examination of cardiac tissue showed "inflammation in the heart around the coronary arteries, most notably around the larger arteries, the surrounding epicardial adipose tissue, and the immediately adjacent myocardium. This is not consistent with a diagnosis of myocarditis, it is possibly more consistent with some sort of arteritis/vasculitis that also involves the adjacent tissue and myocardium. There is not inflammation of the pericardium."

   The autopsy report lists the cause of death as "stress cardiomyopathy with perivascular coronary artery inflammation (hours to days) due to unknown etiology in setting of recent Pfizer-BioNTech COVID-19 vaccination (days)." Autopsy showed "mixed perivascular inflammation and hemorrhage involving coronary arteries, with focal myocardial inflammation and injury, pulmonary edema and congestion, chronic inflammation of epiglottis and, to a lesser extent, large airways." Microscopic examination of the heart indicated "inflammation infiltrates the surrounding adipose tissue and, to a lesser extent, the surrounding myocardium, without definitive myocarditis." A cardiac pathology consult found "scattered hypereosinophilic myocytes and contraction band necrosis/coagulative myocytolysis, consistent with catecholamine effect (clinically stress cardiomyopathy)."

   Autopsy microbiological testing was negative for respiratory pathogens and blood cultures were negative. CDC pathology testing detected complement C4d in the cardiomyocytes and gram-variable bacteria in the epiglottis and trachea, with molecular evidence of *Haemophilus* haemolyticus." The CDC pathology report comments indicate that "staining of complement C4d in cardiomyocytes in the context of minimal inflammatory cell infiltrates suggests injury related to an acute ischemic event; the specific relationship of myocardial injury to the multifocal perivascular and adventitial inflammatory cell infiltrates involving small and large vessels in the heart is unknown." Serology for COVID antibody testing was "positive for spike protein and negative for nucleocapsid protein (consistent with prior vaccination without natural infection)." Toxicology testing was negative. It was also noted that serum tryptase was "mildly elevated, consistent with postmortem interval (no evidence of anaphylaxis)." Genetic testing showed a "variant of uncertain significance" in [redacted] (arrhythmia and cardiomyopathy and Ehlers-Danlos syndrome panels)."

*Reviewer comment: This death case was assessed as **possibly** related to COVID-19 vaccination due to temporal association between vaccination and death and evidence of the contribution of inflammation to the death; however, the autopsy showed findings consistent with stress cardiomyopathy without definitive myocarditis. Autopsy findings suggested cardiac injury related to an acute ischemic event and raised concern for arteritis/vasculitis.*

Pediatric cardiologist reviewer comment: Although not mentioned in the report, the patient demonstrated perivascular inflammation that may be related to vasculitic disease. While there is a temporal relationship between the vaccination and the arrest, vasculitic disease would complicate causality determination as an alternative etiology. The stress cardiomyopathy appears to be secondary to the cardiac arrest.

2. VAERS [redacted]: 16-year-old male with PMH of nut allergies and attention deficit hyperactivity disorder (ADHD) and on Adderall during the school year received his 2nd dose of Pfizer COVID-19 vaccine and traveled to [redacted] He experienced malaise, headache and gastric upset over 2-days post-2nd dose, and was reported to have recovered by day 3. He was found dead in bed the following day (4-days post-2nd dose).

   Autopsy report noted myocardial bridging of the left anterior descending coronary artery. Reported cause of death was stress cardiomyopathy following 2nd dose of Pfizer-BioNTech COVID-19 Vaccine and manner of death as "therapeutic complication."

   CDC Infectious Disease Branch Pathology Report indicates heart findings of acute myocarditis and fibrosis with molecular evidence of human parvovirus B19 and immunohistochemical (IHC) staining for complement component C4d within the myocardium. Microscopic examination of heart sections showed fibrosis, myocyte necrosis and multifocal mixed inflammatory infiltrate composed of lymphocytes, neutrophils, eosinophils and rare mast cells. The CDC pathology report indicates that the significance of detecting parvovirus B19 is 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. Also, the CDC report indicates that the IHC evidence of C4d is consistent with myocardial injury associated with myocarditis. Lung findings included intra-alveolar edema and hemorrhage; no molecular evidence of SARS-CoV-2. Toxicology was negative and COVID-19 testing was negative.

   *Reviewer comment: This case was assessed as **possibly** related to COVID-19 vaccination due to temporal association and autopsy findings of acute myocarditis and immunohistochemical evidence of C4d which was noted to be*

consistent with myocardial injury associated with myocarditis. The detection of parvovirus B19 in the heart provides a possible alternate etiology although the clinical significance of parvovirus B19 detection is unclear; please see Discussion section, subsection on Parvovirus B19 and Myocarditis. Additionally, myocardial bridging of the left anterior descending coronary artery has been associated with sudden death (34). Please see Discussion section, subsection on Sudden Cardiac Death.

Of note, this case has been discussed extensively in published literature. An article by Gill, et al describing case reports of cardiac events associated with COVID-19 vaccination notes that the "histopathology did not demonstrate a typical myocarditis," such as lymphocytic infiltrates with adjacent myocyte necrosis but rather "showed areas of contraction bands and hypereosinophilic myocytes distinct from the inflammation" [(35), case is referred to as "Boy A" in the article]. The authors indicated that "this injury pattern is similar to what is seen in the myocardium of patients who are clinically diagnosed with Takotsubo, toxic, or stress cardiomyopathy" which is a catecholamine-mediated ischemic process in the absence of coronary artery disease or spasm. The authors comment that they suspect the acute cardiac changes were the result of epinephrine-mediated effects on cardiomyocytes and that "this postvaccine reaction may represent an overly exuberant immune response, with the myocardial injury mediated by similar immune mechanisms to those described with SARS-CoV-2 and multisystem inflammatory syndrome cytokine storms." In addition, the article indicates that the etiology of the fibrosis in this case is unclear and "it remains possible that the fibrosis represents arrhythmogenic cardiomyopathy." However, the authors indicate that if the arrhythmia had been due to the myocardial scar/fibrosis, then the fulminant, global myocardial injury would not be an expected finding, and that the clinical history supports the etiology of acute myocardial injury as a primary factor.

This case was further discussed in a letter to the editor by Paddock et al (36 in response to the aforementioned article by Gill, et al. The letter by Paddock described findings from CDC's ID Pathology Branch autopsy, including the detection of parvovirus B19 DNA using PCR. The letter states that "parvovirus B19 can cause myocarditis and has also been detected in normal heart tissues." The letter comments that the contribution of parvovirus B19 to the observed pathology cannot be definitively excluded and suggests an alternate cause of death for "patient A."

The authors of the Gill article issued a reply to the Paddock et al. letter. With respect to "patient A," they noted that the CDC did not diagnose this death as caused by parvovirus B19 myocarditis and commented that the CDC report indicated that the significance of detecting parvovirus B19 was unclear. The authors stated that "the histologic features in patient A were not those of viral

myocarditis, nor would the ischemic injury be explained by such an infection." The authors concluded that detection of parvovirus B19 was an incidental finding.

Pediatric cardiologist reviewer comment: The detection of Parvovirus B19 in the cardiac tissue is neither an incidental finding nor a diagnostic finding. Parvovirus B19 is a common cause of viral myocarditis but it can also be found in non-infected cardiac tissue on biopsies or autopsy; please see Discussion, subsection on Parvovirus B19 and Myocarditis.

Likewise, the presence of a myocardial bridge can be either causative, contributory, or incidental; please see Discussion, section on Sudden Cardiac Death. Similar to the parvovirus infection noted above, myocardial bridges are often incidental findings on autopsy. Thus, no definitive determination of causality can be made.

3. VAERS [redacted]: 13-year-old male with past medical history (PMH) of obesity (100-pound weight gain in the past 18 months per one autopsy report), ADHD, and developmental coordination disorder experienced flu-like symptoms for 2-days and then was found deceased 3-days post-dose 2 of Pfizer-BioNTech COVID-19 vaccine. Autopsy-reported cause of death was myocarditis of uncertain etiology. Autopsy report findings included cardiomegaly with biventricular dilatation, microscopic evidence of myocarditis with a diffuse, mixed interstitial inflammatory infiltrate predominantly composed of lymphocytes and neutrophils, bilateral serous pleural effusions, serous pericardial effusion, marked pulmonary edema and congestion, moderate degree of diffuse cerebral edema, and obesity. The patient was negative for COVID-19 infection and influenza A/B.

   Specimens were submitted to the CDC Infectious Diseases Pathology Branch (IDPB) for further evaluation of myocarditis; CDC autopsy findings included clostridial sepsis (evidence of intravascular clostridia in multiple organs and molecular evidence of *Clostridium septicum*), myocarditis with subepicardial infarcts and immunohistochemical evidence of complement C4d in cardiomyocytes, adrenal hemorrhage, pulmonary hemorrhage, acute tubular necrosis, autolysis of pancreas, congestion of spleen and thymus gland, and cerebral edema. The CDC pathology report notes that "immunohistochemical distribution of C. septicum in the heart is sparse relative to the distribution and abundance of bacterial antigens in other tissues, to suggest that predominant cardiomyocyte injury, as highlighted by staining of complement C4d, is mediated by a clostridial toxin." An addendum pathology report from CDC indicated that Clostridial sepsis was particularly evident in the vasculature of the liver, spleen, and kidneys and that extensive bacterial invasion of these organs suggests an intraabdominal source of infection; the report notes that *Clostridium septicum* infections are rapidly progressive and are often fatal. The addendum CDC pathology report also notes that "additional section of heart revealed diffuse and

extensive myocarditis with abundant mixed inflammatory cell infiltrates comprising lymphocytes, neutrophils, and macrophages, and multiple foci of cardiomyocyte necrosis. Inflammatory infiltrates were largely transmural and also involved the epicardial adipose tissue."

Reviewer comment: This case was assessed as ***probable*** *in relation to COVID-19 vaccination. There was temporal association of death following vaccination and autopsy findings showed myocarditis of uncertain etiology as the cause of death. Notably, this individual did not have clinical signs or symptoms of myocarditis although did experience flu-like symptoms in the days prior to death. CDC concluded that the death was attributable to C. septicum sepsis (please see additional literature article comments below). However, C. septicum findings may have been more likely attributable to postmortem bacterial overgrowth. Other potential confounding factors for this death included the finding of cardiomegaly with biventricular dilatation which could have contributed to a fatal arrhythmia. In addition, the toxicology was positive for caffeine, which can have cardiovascular effects mediated by release of catecholamines; excessive caffeine intake can contribute to cardiomyopathy, cardiac arrest, and sudden death in young individuals (37). Please see Discussion section, subsection on Sudden Cardiac Death.*

Of note, this case was discussed in the aforementioned literature article by Gill, et al. The authors noted that the "histopathology did not demonstrate a typical myocarditis," such as lymphocytic infiltrates with adjacent myocyte necrosis but rather "showed areas of contraction bands and hypereosinophilic myocytes distinct from the inflammation" (case is referred to as "Boy B" in the article). The authors indicated that "this injury pattern is similar to what is seen in the myocardium of patients who are clinically diagnosed with Takotsubo, toxic, or stress cardiomyopathy" which is a catecholamine-mediated ischemic process in the absence of coronary artery disease or spasm. The authors comment that they suspect the acute cardiac changes were the result of epinephrine-mediated effects on cardiomyocytes and that "this postvaccine reaction may represent an overly exuberant immune response, with the myocardial injury mediated by similar immune mechanisms to those described with SARS-CoV-2 and multisystem inflammatory syndrome cytokine storms." In addition, the article indicates that "the cardiac hypertrophy in case B may have made the heart more susceptible to an arrhythmia." However, if the arrhythmia had been due to the cardiomegaly "then the fulminant, global myocardial injury would not be an expected finding."

This case was further discussed in the aforementioned response letter to the editor by Paddock et al. The letter by Paddock described findings from CDC's IDPB autopsy, including the detection of Clostridium species in the adrenal glands, liver, pancreas, kidneys, heart, lungs, and spleen. The letter indicates that "the conclusion of IDPB, based on the composite histologic,

immunohistochemical, and molecular findings, was death attributable directly to C. septicum sepsis."

The authors of the Gill article issued a reply to the Paddock et al. letter (38). For "patient B," the authors commented that CDC "misinterpreted common postmortem findings, including bacterial overgrowth." They indicated that the autopsy was performed two days after the patient's death and that "practicing forensic pathologists routinely see this type of postmortem bacterial overgrowth at autopsy." They assert that "this bacterial invasion is not the cause of death but a consequence of death." The authors stated that "the clinical history and cardiac findings simply do not support a diagnosis of clostridial sepsis."

Pediatric cardiologist reviewer comment: The findings related to cardiomegaly were not secondary to the acute event associated with the patient's demise (i.e. the cardiac arrest). The temporal relationship of the demise to the vaccination and the myocardial findings consistent with myocarditis suggest a diagnosis of myocarditis is probable but not a definitive cause of death given the other findings which could be consistent with an alternative etiology.

4. VAERS [redacted]: 16-year-old previously healthy athletic male vaccinated with dose 1 of monovalent Pfizer vaccine on 4/19/2021 arrived pulseless at the ED on 4/24/2021, one hour after collapse and witnessed cardiac arrest. Per ER report he was sprinting in a race, fell and hit his head. Seizure activity was also reported but not witnessed by EMS. CPR was performed on the scene by patient's father, but he was pulseless on EMS arrival, then went into V-fib twice and was defibrillated. Per EMS he briefly regained a pulse but ultimately did not achieve ROSC.

   Toxicology screen was negative. Autopsy report noted the "heart weights 540 grams and is remarkably enlarged and firm." Per the report, the septum was 3 cm in thickness, there was extensive scarring/paleness of the myocardium along the left ventricle and septum. Microscopic examination of the heart also noted "some areas of medial and intimal hyperplasia of coronary vessel walls," in addition to "myocyte hypertrophy, acute inflammatory cells, thin degenerating myopathy, eosinophilia cellular changes, increased vascular formations, and areas of necrotic cells." Per pathologist conclusion: "COD is terminal cardiac arrhythmia caused by areas of acute and ischemic changes with old scarring/fibrosis, caused by abnormal thin, narrow coronary vascular disease."

   *Reviewer comment: This case is assessed as **possibly** related to Covid-19 vaccination, given temporality and autopsy findings of cardiomegaly and inflammatory cells on histopathology; however, the autopsy also suggests a prior cardiac process due to presence of chronic fibrosis. Per pediatric cardiology reviewer, despite cardiomegaly, the ventricles and interventricular septum are normal size; coronary vessel narrowing is of uncertain significance, as is myocyte hypertrophy on histopathology, given no mention of hypertrophic cardiomyopathy*

on the pathology report, and lack of report of previous symptoms in a healthy athletic male. Please see Discussion section, subsection on Sudden Cardiac Death.

5. VAERS [redacted]: On 12/02/2022, 13-year-old female with history of T1DM received 3rd dose of Pfizer bivalent COVID-19 vaccine. Approximately 2 weeks later, she developed general malaise and was seen at urgent care where labs were reportedly not indicative of DKA. She was discharged and advised to follow-up with PCP. PCP office note on 12/21/2022 remarked HgbA1C of 8.3% and hyperglycemia to 350mg/dL; at that time, the decedent had reported that she began experiencing dull, aching chest pain and increased heart rate a few days prior and that an ECG done at urgent care showed HR of 107, 1st degree AV block, and possible septal infarct. Outpatient cardiology referral was made to follow-up on this abnormal ECG. Of note, there is no reported personal or familial history of cardiac arrhythmia or early MI.

   On 12/24/2022, she was transported by EMS to the ED for palpitations, pallor and diaphoresis. On arrival to the ED, the decedent was in unstable polymorphic v-tach vs torsades with rapid decompensation to monomorphic v-tach on arrival to the PICU eventually failing resuscitation. Pertinent positive clinical findings included elevated troponin to 909ng/mL and CRP to 37.1mg/L. CXR demonstrated diffuse bilateral airspace infiltrates, normal heart size, and no visualized pleural effusion. Echo was done at bedside but there is no available report. Limited respiratory viral panel was negative though it was noted that a full viral panel was not assayed. In consultation with cardiology, the working diagnosis at the time of death was viral vs bacterial myocarditis.

   Due to [redacted] postmortem examination was limited to external findings and antemortem/ancillary studies. The cause of death on autopsy was listed as "complications of probable infectious myocarditis with insulin-dependent diabetes mellitus as a significant contributing condition."

   Reviewer comment: This case was reviewed in collaboration with a pediatric cardiologist within [redacted] *and assessed as* ***possibly*** *related to COVID-19 vaccination due to plausible temporality (shortened latency if accounting for date of symptom onset) and ECG patterns consistent with myocarditis. The underlying etiology was documented as presumed infectious in the setting of markedly elevated CRP, though no pathogens were identified on a limited viral panel. Lack of an autopsy and other available diagnostic elements preclude conclusive determination. The decedent's history of T1DM remains a strong confounding factor, particularly with markers suggesting uncontrolled disease.*

6. VAERS [redacted]: 13-year-old female with elevated BMI, history of asthma, and thoracic scoliosis experienced shortness of breath, dizziness and vomiting 15-days post-1st dose of the Pfizer-BioNTech COVID-19 vaccine and then

experienced syncope and unresponsiveness at home 16-days post-1st dose. EMS arrived and cardioverted the individual who became responsive and started answering questions. She subsequently experienced ventricular tachycardia, pulseless ventricular tachycardia, and then pulseless electrical activity. She died 16-days post-1st dose.

COVID-19 PCR was negative. Autopsy showed a final diagnosis of fulminant myopericarditis (pancarditis) with extensive myocyte necrosis and noted "sarcoplasmic hypereosinophilia associated with cardiac tissue necrosis." The autopsy report comments that "a direct cause and effect relationship between the vaccine and the development of myocarditis in this case cannot be determined without first excluding other potential causes of myocarditis, including viral genome and auto-antibody testing." This case was submitted to the CDC ID Pathology Branch for evaluation of myocarditis. CDC review found lymphocytic pancarditis with extensive cardiomyocyte necrosis, molecular evidence of human parvovirus B19, chronic bronchitis, lungs with diffuse congestion and marked intravascular leukocytosis, and liver with mild steatosis. The CDC Pathology report comments that "parvovirus B19 has been associated with myocarditis and dilated cardiomyopathy although there are still controversial study results regarding the pathogenesis and related pathology. Parvovirus B19 can induce vascular damage in the heart and is associated with circulating endothelial microparticles. Such endothelial cell-mediated injury associated with parvovirus B19 infection may cause severe or fatal myocarditis clinically mimicking ischemic heart disease."

Reviewer Comment: This case is assessed as ***possibly*** *related to COVID-19 vaccination given the temporal association. This individual had autopsy confirmed fulminant myopericarditis.* [redacted] *ID physician also noted that "the presence of lymphocytes and presumably degranulating eosinophils suggests an immune-mediated reaction to the vaccine." However, the CDC ID Pathology Branch evaluation of myocarditis found molecular evidence of parvovirus B19 and noted this infection can be associated with endothelial cell-mediated injury that may cause severe or fatal myocarditis. Parvovirus B19 infection may be a plausible alternate etiology for this case of fatal myocarditis. Please see Discussion section, subsection on Parvovirus B19 and Myocarditis.*

7. VAERS [redacted] 7-year-old male with no PMH received the Pfizer COVID-19 vaccine on 2/3/2022 and developed fever, abdominal pain and lethargy 12 days post-vaccination, followed by cardiac arrest and death 14 days post-vaccination. Per the report, while being driven to the ED by his family 2 days after onset of symptoms, he vomited and then become unresponsive. Upon arrival at the ED, he was found to be in shock and cardiac arrest. He was not able to be resuscitated and died. The preliminary autopsy reported diffuse lympho-histiocytic infiltrate involving the left and right heart ventricles leading to a pathological diagnosis of lymphocytic myocarditis as the cause of death. The autopsy report also noted "incidental volvulus." The CDC IDPB also reviewed this

case and reported pancarditis with extensive cardiomyocyte injury highlighted by C4d immunohistochemistry, no molecular evidence of SARS-CoV-2, enteroviruses, human parvovirus B19, or influenza A or B viruses, and no immunohistochemical evidence of CMV or adenoviruses. The CDC pathology report commented that "Negative results do not rule out the possibility of infection, as the duration of illness, prior treatment, and tissue collection and fixation/processing may affect the sensitivities of assays performed."

*Reviewer comment: This case was assessed as **probably** associated with COVID-19 vaccination due to the 12-day symptom onset fitting into the known risk window.*

Appendix B: Case narratives for COVID-19 vaccine pediatric US deaths reported to VAERS – cases assessed as unlikely (n = 62) or unassessable (n = 27)

VAERS [redacted]: 8-year-old female with a PMH of ADD and alopecia whose current medications included methylphenidate, minoxidil, dexamethasone, and topical mometasone presented to urgent care with a fever, abdominal pain, nausea, vomiting, sore throat, congestion, runny nose, and cough 26 days after receiving her first Pfizer COVID-19 vaccine. She had a fever of 103.5 degrees Fahrenheit and a mildly tender abdomen on exam. COVID-19, Influenza and Strep rapid tests were negative and she was diagnosed with viral syndrome and sent home with supportive care. The reporter states she was playing outside 11 days later (37 days after vaccination) when she suddenly collapsed and appeared to have seizure-like activity. She went into cardiac arrest and could not be resuscitated. There were no medical records in VAERS describing the evaluation and/or interventions related to this event. There was no autopsy report in VAERS. The cause of death listed in the death certificate was florid lymphocytic myocarditis *and additionally noted "SARS-CoV-2" as a significant contributing factor to death*.

Reviewer Comment: This case is determined to be unassessable. Available death certificate noted "florid lymphocytic myocarditis" as cause of death, and additionally noted "SARS-CoV-2" as a significant contributing factor to death. There were no medical records in VAERS describing the evaluation and/or interventions related to the event. Death occurred >28 days following vaccination. It was not possible to ascertain whether the fever and upper respiratory symptoms this child exhibited represented myocarditis symptoms or a separate infectious process that could provide an alternate etiology for the myocarditis described in the death certificate. Furthermore, her negative COVID-19, influenza, and strep tests do not preclude an alternate infectious etiology since a multitude of viruses have been implicated in infectious myocarditis, and the death certificate noted "SARS-CoV-2" as a significant contributing factor to death. (Of note, VAERS contractors made multiple attempts to obtain the autopsy report for this case but were unsuccessful.)

VAERS [redacted]: 15-year-old male with PMH of pityriasis alba died of drowning 6-days post-dose 2 of the Pfizer-BioNTech COVID-19 vaccine. The report did not note chest pain, shortness of breath, or palpitations. The individual was swinging from a rope swing at a pond. After landing in the water feet first, he surfaced, laughed, told his friends "Wow, that hurt!", then began swimming underwater toward shore but did not re-emerge from the water. His body was subsequently retrieved by local authorities more than an hour later.

The autopsy reported cause of death was drowning with a contributory condition of myocarditis. Autopsy findings included no external indication of scalp injury, a 4 x1 cm faint left occipital subgaleal hemorrhage and normal epidural, subdural, and subarachnoid evaluations. Toxicology was negative and screening for SARS-CoV-2 was negative. Cardiac findings from the autopsy included a "somewhat enlarged and

thickened heart for age and body habitus" and septal and lateral left ventricular sections showed small foci of myocardial inflammation with associated myocyte necrosis in the left ventricular section; the heart was negative for myocyte disarray. There was a normal pericardial appearance, normal coronary artery origins from the aorta that were free of atherosclerosis. The left ventricular free wall and intraventricular septum had a thickness of 1.8 cm, and the right ventricular free wall had a thickness of 0.3 cm. There was normal gross appearance of the endocardium, myocardium, and cardiac valves. The autopsy report noted that "myocarditis, which often is secondary to viral infection (which may not even be symptomatic) is a potential cause of sudden irregular heart rhythms that fail to adequately circulate the blood (cardiac dysrhythmias), and provides the most likely explanation in this case for why (the patient) became unresponsive while in the water."

Ambry Genetics CardioNext analysis of 92 genes associated with inherited cardiomyopathies and arrhythmias was negative for pathologic findings and positive for two variants of unknown significance [redacted] which are potentially associated with hypertrophic cardiomyopathy).

This case was also sent to the CDC Infectious Diseases Pathology Branch for evaluation of myocarditis. The CDC autopsy report noted myocyte injury/damage highlighted by C4d immunohistochemistry; there was no cardiac evidence of spirochetes (including Borrelia burgdorferi), enterovirus, or human parvovirus B19. Other CDC findings of note included lung vascular congestion, very mild and patchy interstitial chronic inflammation/pneumonia, mild and focal chronic bronchiolitis, and focal features compatible with aspiration.

This case was also sent for cardiac autopsy evaluation with [redacted] Their report indicated that there was evidence of abnormal myocardial hypertrophy symmetrically involving the left ventricle with borderline right ventricle hypertrophy. The report also noted that the patient carried the [redacted] which raised suspicion for hypertrophic cardiomyopathy. The report described two very small foci of inflammation with minimal myocyte necrosis and noted that although these findings met the strict criteria for myocarditis, these findings were unlikely to be a cause of death, because small foci, often more extensive than this, have been reported in 20% of autopsies of drowning victims. The report noted that the presence of eosinophils would be more consistent with myocarditis, particularly hypersensitivity myocarditis which could be consistent with a vaccine-related process; however, the minimal inflammation and myocyte damage observed suggested a mild process in this case.

Reviewer Comment: This case was assessed as unlikely related to COVID-19 vaccination. This individual died from drowning 6-days after the 2nd dose of the Pfizer-BioNTech COVID-19 vaccine and had minimal cardiac autopsy findings consistent with myocarditis. However, autopsy also noted genetic markers possibly associated with hypertrophic cardiomyopathy. Additionally, autopsy noted evidence for abnormal myocardial hypertrophy symmetrically involving the left ventricle with borderline right ventricle hypertrophy, raising the likelihood of underlying hypertrophic cardiomyopathy

as an alternate etiology more consistent with the clinical picture. Please see Discussion section, subsection on Sudden Cardiac Death.

Pediatric cardiologist reviewer comments: The patient's left ventricular dimensions, clinical history (drowning, with no previous symptoms), and genetic testing are all consistent with hypertrophic cardiomyopathy (HOCM). Given the autopsy findings are not typical for myocarditis it seems likely that the cause of death is HOCM and unlikely that it is myocarditis of any etiology.

VAERS [redacted]: A 12-year-old female with past medical history of infantile seizures received a second dose of Pfizer monovalent COVID-19 vaccine on July 29th, 2022, developed nausea and vomiting 3 days post-vaccination, and died August 2nd, 2022, 4 days post-vaccination.

The child was asymptomatic until bedtime on August 1st, 2022, when she began experiencing vomiting. The next morning, she vomited again before being found unresponsive in the bathroom by her mother. She was transported to the emergency room while requiring resuscitation efforts. The child had bi-cytopenia (red cells and platelets), lymphocytosis, elevations in AST / ALT and hypoalbuminemia. Despite initial ROSC, ventricular tachycardia and cardiac arrest persisted. Significant bleeding was noted from the ET tube after a non-traumatic intubation. The patient was pronounced dead after an hour of resuscitation efforts.

Autopsy was performed with results including positive post-mortem SARS-COV-2 testing (nasal swab), diffuse myocarditis evidenced by mottled-appearing myocardium and inflammation and granulation tissue on histology, prominent pulmonary congestion and edema, fluid in pleura and peritoneal cavities, lymphoid hyperplasia in the spleen, and mild cerebral edema. No evidence of pneumonia was noted. Blood cultures were also positive for Streptococcus mitis. The pathologist stated in her report, "the relationship between the COVID-19 infection and myocarditis in this case is uncertain." Histological evaluation of tissues at CDC indicated lymphocytic pancarditis with early fibroplasia. There was no molecular (PCR) evidence of SARS-COV-2 in either her heart or her lung tissue Immunohistochemical testing was also negative for streptococcus species in all tissues. However, there was molecular evidence of human parvovirus B19 in the patient's heart tissue.

The VAERS record includes an initial death certificate dated [redacted] and an amended death certificate, dated [redacted] The initial cause of death was determined to be myocarditis with COVID-19 infection listed as a significant contributing condition on the autopsy. The amended death certificate lists the cause of death as pancarditis with Parvovirus B19 infection.

*Reviewer comment: The causal relationship between death due to pancarditis and vaccination was determined to be **unassessable**. This case involved a close temporal relationship of 4 days and at least one plausible alternative etiology of pancarditis being COVID-19 infection (symptomatic infection and SARS-COV-2 in nasal swab specimen*

at initial autopsy). The initial autopsy stated the cause of death to be myocarditis, with a significant contributing factor of COVID-19. With respect to the autopsy finding of molecular evidence of parvovirus B19 in cardiac tissue, the amended death certificate notes Parvovirus B19 infection in the cause of death. However, review of case details by an infectious disease specialist noted that, in the absence of testing demonstrating recent active viral infection/replication, the finding of Parvovirus B19 in the myocardium is of uncertain significance; please see Discussion, subsection on Parvovirus B19 and Myocarditis. S. mitis in this context is considered most likely a contaminant. Taken together, the likelihood of either virus leading to pancarditis weighed against the likelihood of vaccine-induced pancarditis led to extended deliberation and disagreement among reviewers. Agreement was reached that the case should be categorized as unassessable based on conflicting information in the VAERS record regarding cause of death. It is not possible to quantify the relationship likelihood of each potential etiology through causal assessment (WHO). This case lacks supporting information (further clinical information and pathology testing) that could lead to a different categorization.

VAERS [redacted]: Patient was a [redacted]-month old male breast-fed infant whose mother received the second dose of Pfizer-BioNTech COVID-19 vaccine. Twenty-four hours later, the infant developed a full-body rash, was inconsolable, refused to eat, and developed fever. The patient was hospitalized for two days, was noted to have elevated liver function tests, but declined and died two days later. The patient had a diagnosis of thrombotic thrombocytopenic purpura. No other information is available.

*Reviewer comment: This case was considered **unassessable**/unclassifiable given the limited case details. No information was provided on platelet count, ADAMST13 levels, autoantibodies, or a peripheral blood smear results to confirm a diagnosis of microangiopathic hemolytic anemia.*

VAERS [redacted]: Patient is a 15-year-old female with a past medical history of Down Syndrome, endocardial cushion defect s/p repair, and duodenal atresia. The patient had several previous weeks of failure to thrive with decreased PO intake and alteration of bowel habits. Three days after vaccination with the second dose of Moderna COVID-19 vaccine, she was noted to be unresponsive in the backseat of a vehicle with her mother, who drove to the Emergency Department, where she was found pulseless by ED staff. CPR was initiated and return of spontaneous circulation (ROSC) was obtained. Abdominal x-ray showed severely distended loops of bowel suggestive of obstruction. The patient died the day following hospital admission. Autopsy report concluded that cause of death was cardiac arrest due to acute cecal volvulus and global hypoxia related brain injury and multisystem organ failure following eventual resuscitation; the underlying proximate cause of death was reported as incomplete retroperitoneal fixation of the cecum and ascending colon in the setting of trisomy 21.

*Reviewer comment: This case was considered **unlikely** to be related to vaccination as the patient's underlying condition of trisomy 21 and related congenital abnormalities were considered the patient's cause of death per the autopsy report.*

VAERS [redacted]: Patient is a 17-year-old female with a past medical history of spina bifida, high lumbar myelomeningocele, VP shunted hydrocephalus, and neurogenic bowel and bladder requiring catheterization. Patient was at baseline health status and received her first Pfizer-BioNTech COVID-19 vaccine approximately one week prior to developing chest pain and difficulty breathing while in the process of self-catheterization. She collapsed moments later and EMS found her apneic with PEA rhythm. She obtained ROSC after initial intervention and was transported to the ED, but died after a second arrest. Autopsy reported that cause of death was bilateral pulmonary emboli occluding and near occluding her right and left upper pulmonary arteries, respectively. Patient risk factors for pulmonary embolism described in the autopsy report include obesity, estrogen/progesterone combination oral contraceptive, and immobility/wheelchair dependence.

*Reviewer comment: This case is assessed as **unlikely** related to vaccination given the multiple preexisting risk factors for pulmonary embolism. Please refer to Discussion above, subsection on COVID-19 Vaccination and Thromboembolic Events.*

VAERS [redacted]: The patient is a 16-year-old female with a history of obesity, asthma, depression, ADHD, and oral contraceptive use who experienced groin pain and passed out in from of mother nine days after first vaccination with Pfizer-BioNTech COVID-19 Vaccine. She had similar symptoms two days prior, but quickly returned to baseline. She had prompt CPR initiation and ECMO cannulation in the ED. CT of her chest showed large bilateral pulmonary embolism and CT of the head showed diffuse cerebral and cerebellar edema with bilateral uncal herniation. ECMO support was continued over 24 hours. Assessment of brain function including apnea testing confirmed brain death, and the patient was pronounced dead two days after hospital admission (11 days after vaccination). Autopsy report stated cause of death was due to pulmonary embolism, most likely related to oral contraceptive use. Testing was negative for Factor V Leiden and Prothrombin gene mutation.

*Reviewer comment: This case was considered **unlikely** related to vaccination given the preexisting risk factor of oral contraceptive use. Please refer to Discussion above, subsection on COVID-19 Vaccination and Thromboembolic Events.*

VAERS [redacted]: Fifteen-year-old male reported to have experienced heart failure one day after vaccination with Pfizer-BioNTech COVID-19 Vaccine. Outcome was reported as death. No other information was provided.

*Reviewer comment: This case was considered **unassessable**/unclassifiable given the limited case details.*

VAERS [redacted]: Seventeen-year-old male with history of unspecified mental illness committed suicide [redacted] eight days after vaccination with Pfizer-BioNTech COVID-19 Vaccine.

*Reviewer comment: This case is considered **unlikely** related to vaccination due to alternative etiology of suicide in a person with preexisting mental illness. Additional contributory factors include the high prevalence of mental health disorders in adolescents exacerbated by the COVID-19 pandemic. Please see Discussion section above, subsection on Suicidality Among Adolescents.*

VAERS [redacted]: One-year-old male reportedly experienced increased body temperature, seizure, and death two days after vaccination with Moderna COVID-19 vaccine. No other information is available.

*Reviewer comment: This case was considered **unassessable**/unclassifiable given the limited case details.*

VAERS [redacted]: 17-year-old male with no past medical history received 2nd dose of Pfizer-BioNTech COVID-19 Vaccine. On the same day as vaccination, he developed headache, fatigue, and diarrhea lasting at least 2 days. Four days after vaccination, the patient [redacted]. Cause of death was suicide [redacted].

*Reviewer comment: This case was considered **unlikely** related to vaccination given the high prevalence of mental health disorders in adolescents exacerbated by the COVID-19 pandemic. Please refer to Discussion above, subsection on Suicidality Among Adolescents.*

VAERS [redacted]: 18-year-old male with no reported past medical history, but taking Vyvanse, had a seizure within three minutes of receiving the first dose of Pfizer-BioNTech COVID-19 Vaccine. He was sent to the hospital by ambulance. However, death certificate reports cause of death as mixed drug intoxication (fentanyl, despropionyl fentanyl) complicated by drowning. No other information is available.

*Reviewer comment: This case is considered **unassessable**, as the VAERS report and the death certificate contain insufficient and conflicting information. It is also noted that the VAERS report states this patient's age is 17 years; however, the death certificate states an age of 18 years. The age stated on the death certificate is likely more accurate.*

VAERS [redacted]: 17-year-old female with obesity (BMI=39) and no reported medications received her first dose of Pfizer-BioNTech COVID-19 vaccine on 4/18/21, a second vaccine dose on 5/23/21, and was subsequently found unresponsive at home on 6/7/21. Two to three weeks prior to being found unresponsive she experienced sudden onset of a left frontal headache with neck stiffening that resolved after several days. However, shortly thereafter, she again experienced severe pounding headaches with vomiting that began 2-weeks prior to being found unresponsive. She saw her PCP twice for the headache; of note, management of these symptoms delayed her second vaccine dose.

She was transferred to the emergency department after being discovered unresponsive at home but was exhibiting tonic extensor posturing with leftward gaze deviation and

seizure by the time of arrival. Head CT showed acute parenchymal hemorrhage with left frontal lobe/inferior basal ganglia with diffuse intraventricular hemorrhage. She was admitted with persistent increased intracranial pressure which was not able to be controlled, and she subsequently died.

The autopsy report listed the cause of death as complications of cerebral venous sinus thrombosis (CVST). The autopsy final diagnosis included CVST with early thromboses of dural, leptomeningeal, and intraparenchymal vessels, bilateral uncal herniation, right to left midline shift, right cingulate gyrus herniation, intraventricular hemorrhage, subarachnoid hemorrhage, moderate cerebral edema, and hypoxic-ischemic changes and necrosis.

*Reviewer comment: This case was assessed as **unlikely** related to COVID-19 vaccination due to the presence of multiple preexisting risk factors for CVST, including obesity, female sex, and young age; the case is likely representative of the background risk of CVST associated with this patient's clinical characteristics (39). Of note, active safety surveillance for mRNA COVID-19 vaccines in the CDC's Vaccine Safety Datalink did not identify a signal for CVST (25). Further, FDA near real-time surveillance for safety outcomes in U.S. COVID-19 vaccine recipients aged 12 to 64 years did not identify signals for common or unusual site thromboses with thrombocytopenia (40). For further discussion about association of COVID-19 and TEEs, please also see Discussion section, subsection on COVID-19 Vaccination and Thromboembolic Events.*

VAERS [redacted]: Patient is a 16-year-old female with a history of ataxia-telangiectasia, EBV-associated Stage IV Hodgkin's lymphoma (off treatment since [redacted]), and chronic aspiration who was admitted with presumed septic shock with a moderate pericardial effusion and subsequently developed ARDS. She had a prolonged and complicated ICU course. She developed pancytopenia with a hyperinflammatory state including hyperferritinemia and hemophagocytosis on bone marrow aspirate (unclear etiology). She was treated with steroids, anakinra, ruxolitinib and broad spectrum antibiotics. She continued to worsen with progressive lung disease with respiratory failure. [redacted] Death was 48 days after the second dose of Pfizer-BioNTech COVID-19 Vaccine (per medical records).

*Reviewer comment: This case is considered **unlikely** related to vaccination given the patient's multiple medical conditions including Stage IV malignancy that predispose to a dysregulated immune state (alternative etiology).*

VAERS [redacted]: Seventeen-year-old female with past medical history of obesity and depression was found unresponsive in her home four days after receiving her first dose of Pfizer-BioNTech COVID-19 Vaccine. Patient complained of blurred vision approximately five hours before being found unresponsive by a family member. CPR was initiated by family, continued by EMS, and remained in asystole at ED arrival. Autopsy report showed large pulmonary embolism occluding the vasculature of the left lung and extending into the main pulmonary artery; cause of death was cardiorespiratory arrest due to large pulmonary embolism. Toxicology was positive for cotinine. Of note, a previous coagulopathy workup had been reported as negative, but

patient had significant family history of heritable clotting disorders: per medical records, [redacted] no other details available).

*Reviewer comment: This case is considered **unlikely** related to vaccination. Family history is remarkable for inherited clotting disorder, although medical records evaluating this patient for a clotting disorder are not available. Toxicology is positive for cotinine suggesting patient was a smoker, which is a risk factor for pulmonary embolism. Please see Discussion section, subsection on COVID-19 Vaccination and Thromboembolic Events.*

VAERS [redacted]: 13-year-old male with previous history of COVID-19 was swimming with family and began vomiting and feeling unwell 17-days post-1st dose of Pfizer-BioNTech COVID-19 vaccine. He was taken home and later found foaming at the mouth, vomiting profusely, and unresponsive. EMS was called and they found him pulseless with asystole. Head CT showed midbrain hemorrhage and tonsillar herniation. Hospital death summary indicates "official cause of death was brainstem herniation from intracranial hemorrhage."

Autopsy showed pathologic diagnoses of glioneuronal tumor, cerebellar vermis and fourth ventricle; obstructive hydrocephalus secondary to exophytic component of glioneuronal tumor involving the fourth ventricle; and global cerebral edema secondary to obstructive hydrocephalus. Comments in the autopsy report indicate that while "no definite cerebellar tonsillar herniation was identified at brain autopsy examination, sudden acute obstructive hydrocephalus secondary to the cerebellar mass-forming lesion with accompanying hemorrhage in the context of mild tonsillar herniation is the likely cause of death."

*Reviewer comment: This death case was assessed as being **unlikely** related to COVID-19 vaccination due to the alternate etiology of autopsy confirmed glioneuronal tumor with obstructive hydrocephalus.*

VAERS [redacted]: 15-year-old male with PMH of autism, ADHD, and developmental delay experienced coughing that began just prior to dose 2 of the Pfizer-BioNTech COVID-19 vaccine on 6/19/25. He was seen by his primary care provider 6-days post-dose 2 and chest x-ray showed fluid in the lungs and possible pneumonia. He did not have fever or rash. He did not improve on albuterol and antibiotics; respiratory symptoms and malaise continued to worsen. On 7/4/21, he fell and hit his head on a wall, couldn't breathe, and was taken to the ED. He experienced cardiac arrest ×2 at the hospital and was resuscitated, intubated and air transported to another hospital for further care. He had elevated cardiac enzymes and an echocardiogram showing severe global left ventricular dysfunction and severe left ventricular dilatation. A pediatric cardiology consult note listed active problems of acute myocarditis, heart failure, and dilated cardiomyopathy (DCM). COVID-19 PCR and nucleocapsid antibody testing was negative. During his hospitalization he required increasing inotropic support and

experienced decompensated heart failure with cardiogenic shock and multiorgan dysfunction with acute kidney injury, respiratory failure, transaminitis, and coagulopathy. He was transferred to another hospital 2-days after his initial admission and placed on ECMO. An ID consultant evaluated him for MIS-C; the note indicated that he was not suspected to have MIS-C and that his clinical syndrome was not consistent with acute myocarditis. Viral myocarditis and respiratory panels were negative. He continued to be hemodynamically unstable and ultimately developed necrotizing pneumonia with severe acute respiratory distress syndrome (ARDS). [redacted] and he died approximately 2.5 months after hospitalization.

Autopsy reports noted the patient was found to have a [redacted] gene mutation and [redacted] DMD gene [redacted] A separate autopsy report from [redacted] noted cardiac findings of dilated and hypertrophic cardiomyopathy with enlarged pulmonary valve circumference, and patchy cardiomyocyte hypertrophy with possibly altered dystrophin staining. Respiratory system findings included acute necrotizing pneumonia with extensive consolidation in bilateral lungs, and musculoskeletal findings included findings compatible with Becker Muscular Dystrophy (BMD), including mild muscular atrophy, most prominent in the bilateral lower extremities, "spolly" myofiber degeneration with fiber size variation, and aberrant staining of dystrophin protein. The autopsy report further noted that the clinical phenotype and histopathologic findings in skeletal muscle were compatible with Becker-type muscular dystrophy, which has a frequency of cardiac involvement estimated at approximately 75% and is the most frequent cause of death.

*Reviewer comment: This case was assessed as **unlikely** related to COVID-19 vaccination. While there was temporal association with COVID-19 vaccination, the more likely etiology was dilated and hypertrophic cardiomyopathy related to muscular dystrophy. The autopsy report indicates that genetic testing ([redacted] DMD gene) and autopsy findings were compatible with BMD which has a frequency of cardiac involvement between 60-75% (41). Cardiomyopathy is the number one cause of death in patients with BMD and the average age of onset of cardiac involvement in BMD is 28.7 ± 7.1 years (41). Severe dilated cardiomyopathy in individuals under age 20 years is rare, but it should be noted that mutations involving exon 12 and 14 to 17 or 31 to 42 are associated with early onset cardiomyopathy (41,42), and this patient had [redacted].*

Of note, the autopsy report indicates that genetic testing showed a [redacted] gene mutation (variant of unknown significance); the contribution of this defect was uncertain. [redacted] known to cause dilated cardiomyopathy and [redacted] Hypertrophic cardiomyopathy follows an autosomal dominant inheritance pattern (43).

Pediatric cardiologist reviewer comments: The probable cause of death is the Becker's Muscular Dystrophy cardiomyopathy. The patient's genetic defects are likely responsible for an earlier onset cardiomyopathy – while cardiomyopathy is not usually

fatal until the third decade of life, the clinical course in this patient is consistent with the type of cardiomyopathy seen with this genetic profile.

VAERS [redacted]: Thirteen-year-old male with unknown medical history who received the Moderna COVID-19 Vaccine on an unknown date and died. Death was reported three days after vaccination in one part of the narrative, and one day in another part. The cause of death was not reported. No other information is available.

*Reviewer comment: This case was considered **unassessable**/unclassifiable given the limited case details.*

VAERS [redacted]: Sixteen-year-old male with history of language delay, seizures and recurrent syncopal episodes with unremarkable cardiac workup was found unresponsive at home face down on the floor 27 days after vaccination with Pfizer-BioNTech COVID-19 Vaccine. He had last been seen normal two hours prior. Family started CPR. EMS found patient apneic and in PEA and continued CPR. ROSC was established in the field, but he became pulseless en route with resumption of CPR. The patient neurologically declined during hospitalization and progressed to brain death (35 days after vaccination). The autopsy concluded that cause of death was probable seizure disorder, not otherwise specified. Heart was not examined during the autopsy [redacted]

*Reviewer comment: This case is considered **unlikely** related to vaccination given the alternate cause of death of seizure disorder.*

VAERS [redacted]: Sixteen-year-old male with history of cardiomegaly, morbid obesity, microcytic anemia, systolic hypertension, played in a football game six days after 2nd dose of Pfizer-BioNTech COVID-19 Vaccine. He collapsed during a water break. CPR was started immediately. EMS found him in ventricular fibrillation, received defibrillation four times, but converted to asystole. EMS noted the patient was not sweating in 90-degree weather with high humidity. The patient never achieved a pulse or electrical activity at the Emergency Department. Cause of death per the autopsy report was hypertensive cardiovascular disease; cardiomegaly with fibrous scar and remodeling was noted. Although COVID-19 test was positive, autopsy report notes no evidence of myocarditis.

*Reviewer comment: This case is considered **unlikely** related to vaccination given the alternate cause of death of cardiomegaly and hypertensive cardiovascular disease, and absence of myocarditis findings on the autopsy. Please see Discussion section, subsection on Sudden Cardiac Death.*

VAERS [redacted]: 15-year-old male with history of COVID-19 infection in [redacted] and a diagnosis of hypertrophic cardiomyopathy in [redacted], on Lopressor 25mg BID but recently nonadherent, received his second Pfizer-BioNTech COVID-19 vaccine on 7/18/21 and collapsed on the field while playing soccer at a local camp on 7/22/21. CPR was initiated immediately. EMS arrived and found him in ventricular tachycardia. He

received “shock x 5”, ACLS, and intubation was attempted. He was in asystole on arrival to the medical center. After 45 minutes of ACLS protocol, death was pronounced. His mother indicated that he had no reported symptoms of chest pain, shortness of breath, or fever prior to cardiac arrest.

The autopsy reported cause of death was hypertrophic cardiomyopathy with contributory cause of death of clinical history of COVID-19 infection. Autopsy findings included hypertrophic cardiomyopathy with left ventricle thickness of 1.5 cm and interventricular septum thickness of 2.3 cm. Histology showed myocyte disarray with foci of fibrosis within the myocardium of the interventricular septum and left ventricle The autopsy report also indicated that genetic testing identified [redacted] which is associated with a spectrum of autosomal dominant and recessive cardiac and neuromuscular conditions. In addition, testing of nasopharyngeal swabs detected SARS-CoV-2 RNA and human rhinovirus/enterovirus RNA. Postmortem toxicology was positive for caffeine.

*Reviewer comment: This case was assessed as **unlikely** related to COVID-19 vaccination. While his cardiac arrest was temporally associated with his second dose of vaccine, he had a recent diagnosis of hypertrophic cardiomyopathy which can lead to sudden cardiac death due to ventricular tachyarrhythmia or ventricular tachycardia. It appeared he had not been recently taking his prescribed cardiac medication. Autopsy confirmed the cause of death as hypertrophic cardiomyopathy and noted his clinical history of COVID-19 infection as a contributory cause of death. Please see Discussion section, subsection on Sudden Cardiac Death.*

Pediatric cardiologist reviewer comment: The subject had a severe case of hypertrophic cardiomyopathy. The upper limit of normal for the thickness of a ventricular septum in a 15-year-old male is 1.1-1.2 cm. This subject’s septum is twice the upper limit of normal. No echocardiogram results are provided but it is likely the patient had Left Ventricular Outflow tract obstruction and if so, competitive contact sports put him at high risk for sudden cardiac death. The [redacted] also increased his risk of arrhythmias and sudden cardiac death. These factors are the likely etiology of his cardiac arrest.

VAERS [redacted]: 12-year-old nonverbal, nonmobile male with neuromuscular disorder and history of seizures received a second dose of Pfizer-BioNTech COVID-19 vaccine on 6/25/2021. He experienced fever and respiratory distress and was taken by EMS to the ED on 8/19/21. He experienced four seizures in the ED. and died on 8/24/21 after being transferred to another hospital for a higher level of care. No autopsy report is available. The death certificate lists the cause of death as static encephalopathy due to intractable seizures.

*Reviewer comment: This case was assessed as **unlikely** related to COVID-19 vaccination. The death was not temporally associated with vaccination, and the individual had an underlying neuromuscular disorder and history of seizures that provide a plausible alternate etiology for his death from static encephalopathy due to intractable seizures.*

VAERS [redacted]: 13-year-old female was vaccinated on an unknown date with a second dose of Pfizer-BioNTech COVID-19 vaccine and died on an unknown date. Past medical history and medications were not reported. It is not known if an autopsy was performed.

*Reviewer comment: Causality for this case was determined as **unassessable** related to COVID-19 vaccination due to inadequate information. It was not possible to establish temporality between COVID-19 vaccination and death, and no additional clinical information was available, including no autopsy report, death certificate, or medical records.*

VAERS [redacted]: 17-year-old male with past medical history of Stage IV testicular embryonal rhabdomyosarcoma (diagnosed in [redacted]) complicated by multiple lung and bone metastases, was vaccinated with Pfizer vaccine on 4/17/2021 (unknown dose number) prior to undergoing lung mass resection on 5/18/2021. He presented with right malignant pleural effusion on 7/6/2021 requiring chest tube placement and was subsequently diagnosed with COVID-19 pneumonia on 7/20/2021 while hospitalized. He was intubated on 8/7/2021, and died 134 days post vaccination, on 8/29/2021. Death certificate lists cause of death as COVID-19 pneumonia with hypoxic respiratory failure in the setting of metastatic stage IV paratesticular rhabdomyosarcoma with pulmonary relapse.

*Reviewer comment: This death case was assessed as **unlikely** related to COVID-19 vaccination due to lack of temporality with vaccination as well as the alternate etiology of COVID-19 pneumonia with hypoxic respiratory failure superimposed on extensive metastatic cancer with pulmonary relapse.*

VAERS [redacted]: 16-year-old female with no past medical history, felt fatigued on the same day after her 2nd dose of Pfizer monovalent vaccine on 10/2/2021 and died the next morning. Per inspector report she was found unresponsive the next morning in the fetal position, on her knees with torso draped over the bathtub. The water was not running and there was no water in the bathtub and no obvious signs of trauma. Patient remained in asystole upon arrival to the ED despite several rounds of ACLS by EMS. In the ED, patient was still in asystole with no brainstem reflexes. Bedside ultrasound was negative. Pt subsequently died.

[redacted] only a postmortem inspection was done, which was notable for abraded contusion of left forehead, left cheek, and right mandible. Additionally, there were bilateral hemothoraces on fine needle aspiration. Vitreous fluid chemistry was normal. Postmortem tox screen was negative except for Naloxone, and an Invitae cardiac genetic panel revealed [redacted] that were classified as of uncertain significance. Per medical examiner conclusion, cause of death was undetermined.

Reviewer comment: *Despite temporality this case is **unassessable** due to lack of autopsy and undetermined cause of death per medical examiner. Bilateral hemothoraces and bruising noted on inspection report seem consistent with injury from fall and the way patient was found positioned over the bathtub.*

VAERS [redacted]: 12-year-old female with PMH of microcephaly, seizures, and developmental delay received the second dose of Pfizer-BioNTech COVID-19 vaccine on 7/8/21 and was found unresponsive and underwater while taking a bath on 8/11/21. She was brought by EMS to the ED in asystole following an hour of PALS protocol and multiple rounds of epinephrine with no return of spontaneous circulation. PALS protocol was continued in the ED, and she remained in asystole with no brainstem reflexes. She was pronounced dead on 8/11/21. Of note, the VAERS report submitted by the parent/guardian/caregiver indicates an event onset date of 7/8/21 for the adverse events of "Seizure during second, insomnia, extremely fatigue."

The death certificate lists the cause of death as sudden unexpected death in epilepsy. The autopsy report lists the cause of death as sudden unexpected death in epilepsy with pathological diagnoses of congenital microencephaly, cortical dysplasia and subependymal heterotopias, hippocampal sclerosis, craniosynostosis, and pulmonary and cerebral edema. Nasopharyngeal swab was negative for viruses, including COVID-19.

*Reviewer comment: This case was assessed as **unlikely** related to COVID-19 vaccination. This individual's death was not temporally associated with the Pfizer-BioNTech COVID-19 vaccine, and her death is more likely due to her underlying medical conditions and pathologic findings on autopsy.*

VAERS [redacted]: 12-year-old female with PMH of Trisomy 18, scoliosis, closed ventricular septal defect, ectopic kidney, GERD, and obstructive sleep apnea received a first dose of Pfizer-BioNTech COVID-19 vaccine on 7/11/21. On 8/2/21, she presented to the ED from home via EMS after being found unresponsive. She was pronounced deceased in the ED after resuscitative efforts were unsuccessful.

The autopsy report listed the cause of death as acute intracerebral hemorrhage due to chronic small vessel vasculopathy of brain with an "other significant condition" of Trisomy 18. The final autopsy diagnoses included acute intracerebral hemorrhage of brain with extension of blood into lateral and third ventricles; chronic vasculopathy of intracerebral small vessels; pulmonary congestion and edema, severe, with bland intra-alveolar hemorrhage, consistent with increased intracranial pressure; ventricular septal defect of heart, status post-surgical repair; ectopic left kidney, situated anterior to distal abdominal aorta; generalized skeletal muscle atrophy; surgical hardware of vertebral column present and intact, and history of Trisomy 18. Toxicology was negative and nasopharyngeal swab testing for respiratory pathogens by PCR was negative.

*Reviewer comment: This case was assessed as **unlikely** related to COVID-19 vaccination. This individual's death was not temporally associated with the Pfizer-BioNTech COVID-19 vaccine, and her death is more likely due to her underlying medical conditions and pathologic findings noted on autopsy.*

VAERS [redacted]: 17-year-old obese female with unknown past medical history was found unresponsive with agonal breathing on 7/23/2021, 33 days after her 2nd dose of

monovalent Pfizer vaccine (administered on 6/18/2021). Per ED report she "recently had a long drive" with "recent headaches and emesis, as well as anxiety" for which she had been taking Benadryl. She was "not feeling well" and was unable to walk by herself; she needed assistance to go to bed at 5 pm that day. She reportedly took 4 Benadryl pills to help her sleep and was found unresponsive on the sofa the next morning. EMS noted her to be unresponsive with blood glucose > 500 and undetectable blood pressure. She was transported to ER with bag mask ventilation due to decreased oxygen saturation and intubation attempt en route was unsuccessful. In ED patient's pupils were fixed and dilated, and she was pulseless but had "electrical activity" on monitor. Focused physical exam was otherwise within normal and she had clear bilateral breath sounds and her pulse ox normalized after intubation. Bedside ultrasound after many rounds of CPR revealed no cardiac activity and a hyperechoic focus consistent with a possible thrombus. Covid-19 rapid antigen test was negative. Toxicology screen was positive for Naloxone, caffeine, and a Benadryl level of 130 ng/ml (which is only slightly above therapeutic level and not in a toxic range). Notably, blood tests also revealed markedly elevated acetone and beta hydroxybutyric acid. ROSC was never obtained and the patient died.

Autopsy cardiac pathology report noted blood clots in ventricles only, with no significant histopathologic abnormalities in myocardium, coronary arteries, and SA node, and no structural valve abnormalities. There was no gross evidence of pulmonary thromboemboli. No other findings determinative of cause of death were noted.

*Reviewer comment: Causality to COVID-19 vaccine is **unlikely**, given temporality and alternate cause of probable DKA in the setting of morbid obesity with unspecified recent episodes of headaches and emesis.*

VAERS [redacted]: 16-year-old female with past medical history of depression (on fluoxetine 10 mg QD), daily vaping, and occasional marijuana and alcohol use, was found unresponsive and incontinent by parents in her room, 92 days after first dose of Pfizer monovalent vaccine was administered on 7/13/2021 (2nd dose administered on unknown date). Parents started CPR but she was in PEA with fixed and dilated pupils on EMS arrival. There was no evidence of fluoxetine overdose. She was transported to ED, where bedside ultrasound did "not show any cardiac contractility, only mild motion of leaflets, which is likely the cause of the PEA." Further attempts at resuscitation were unsuccessful.

Autopsy was only notable for lymphocytic myocarditis by histology. Covid-19 antigen test was negative, and vitreous glucose and electrolytes were normal. Tox screen was only positive for naloxone. Per medical examiner's report "limited genetic screening panel (Sanford Precision Medicine Screening Array report) was noted as negative," but results are not available in source documents. Cause of death was noted as sudden cardiac death due to lymphocytic myocarditis.

*Reviewer comment: Role of vaccine is **unassessable**, as the temporality between 2nd vaccine dose and death is unknown. While the most common cause of lymphocytic myocarditis is a viral infection, there is no further medical information such as documentation of any recent illness that could have contributed to the myocarditis. Role*

of marijuana is less likely as patient's tox screen was negative and there are only rare case reports of marijuana-induced myocarditis (Alirezaei et al, 2022). Additionally, per cardiology SME reviewer daily vaping is not known to be associated with lymphocytic myocarditis and there are no corresponding case reports in literature.

VAERS [redacted]: 17-year-old female with recent history of COVID-19 infection in August 2021, and status post 2 doses of the Pfizer monovalent vaccine on 9/3/2021 and 9/15/2021, presented to the ED on 10/23/2021 with complaints of chest pain, dyspnea with exertion, anorexia, chills and subjective fevers for 48 hours. She had no other past medical history or sick contacts and was feeling well in the interim since last vaccination. Her physical exam and initial vital signs were normal, but labs showed elevated Troponin at 21 ng/ml, elevated D-Dimer of 2.09 ug/ml, markedly elevated CRP of 61 mg/L, and markedly elevated NT-proBNP of 5,556 pg/ml. Respiratory panel was only positive for COVID-19 PCR.

Initial CXR was normal, and CTA chest was negative for PE or pneumonia, with a normal heart and no pericardial effusion, but was notable for "enlarged pulmonary artery, which could be indicative of pulmonary hypertension." Initial EKG showed sinus rhythm but with "ST elevation in leads I and aVL, and steep depressions in II, III, aVF, V3-V6a; + STEMI." EKG 6 hours later was notable for "more pronounced ST elevations in the lateral leads and ST depressions throughout." Echo showed normal LV size, but with mild concentric hypertrophy, mildly reduced systolic function with EF 40-45%, and regional wall motion abnormalities. Per cardiology consult note, the working diagnosis was suspected acute myocarditis.

While waiting for transport to cardiac cath lab, patient became more tachycardic with more ischemic changes on EKG and developed V-Tach and cardiac arrest. She failed resuscitation despite 65 minutes of ACLS. No autopsy was done [redacted] and there is no toxicology report in source documents. Per both the ED physician and the [redacted] county health department assistant deputy chief, the likely diagnosis was COVID-19 myocarditis.

Reviewer comment: Role of vaccine is unlikely given the alternate etiology of COVID-19 induced myocarditis, especially given patient's symptomatology 48 hours prior to presentation. It is notable that she was reportedly doing well in the interim 5 weeks after the 2nd vaccination. Per pediatric cardiology SME reviewer, mild concentric hypertrophy of the Left ventricle noted on echo is more consistent with mild hypertrophic cardiomyopathy and likely not related to COVID-19 or vaccine-induced myocarditis.

VAERS [redacted]: 16-year-old female with metastatic squamous cell lung cancer diagnosed in [redacted], on chemotherapy, died 3 days after vaccination with 2nd dose of Pfizer monovalent ((first dose was administered on 8/13/2021, second dose administered on 9/7/2021). Per parent report, patient was very tired with sore muscles on 9/9/2021 and found dead the next morning at 5:30 am with excessive amounts of vaginal blood and blood clots.

There is no additional information about the course of events or the cause of death in the narrative, there are no other source documents such as ER records or death certificate, and per parent "no autopsy was ordered."

*Reviewer comment: Role of vaccine is **unassessable**, despite recent vaccination. There is no information regarding course of events leading to death, including an explanation for excessive vaginal bleeding/clots, and autopsy was not performed.*

VAERS [redacted]: 16-year-old female with ALL diagnosed in [redacted], severe obesity, essential hypertension, and type 2 DM, presented to ED on 11/7/2021 with 5 days of abdominal pain, diarrhea, and scant blood in stool, starting after last chemotherapy treatment on the same day. Patient was noted to be neutropenic and thrombocytopenic, with hyponatremia, elevated ALT/AST, increased BUN, and hematuria. Patient was admitted to the hospital and found to have C-diff and started on Vancomycin. Per initial VAERS form, Pfizer monovalent vaccine (3rd dose) was noted to have been administered on 3rd day of hospitalization (11/9/2021), but vaccination was not noted in any of the hospital records. On 11/10/2021, patient developed fever, pancytopenia, hypotension, and somnolence, and found to have RML effusion on CXR. She was intubated due to worsening respiratory distress, with ensuing pulmonary hemorrhage, septic shock, DIC, and multi-organ failure, including cardiac dysfunction in the presence of hyperkalemia with eventual asystole on 11/11/2021; resuscitation efforts failed. There is no autopsy report. Cause of death was noted as pulmonary hemorrhage with suspected sepsis, with acute lymphoblastic leukemia.

*Reviewer comment: Role of vaccine is **unlikely** due to more likely alternate etiology of immunocompromised patient with ALL, in the setting of preceding C-diff infection and pancytopenia prior to vaccination, leading to septic shock, pulmonary hemorrhage, and multiorgan failure.*

VAERS [redacted]: 16-year-old patient of unknown sex and unknown past medical history received Pfizer COVID-19 vaccine (unknown dose) on an unspecified date and died on an unknown date after administration (likely in 2021 as report completion date was in 2021). There is no further information available.

*Reviewer comment: Role of vaccine is **unassessable** due to lack of any medical information.*

VAERS [redacted]: 17-year-old male with no past medical history, with occasional marijuana use, was found unresponsive at a party on 10/30/2021, almost 6 months after receipt of 2nd Pfizer monovalent vaccine (first dose administered on 4/14/2021, second dose administered on 5/05/2021). Per parent report, patient had been in a soccer game earlier in the day and felt fine afterwards. According to witnesses he had vaped marijuana during the party prior to becoming unresponsive. Per report there was bystander CPR, but he was pulseless upon EMS arrival. While receiving ACLS, he went into V-fib and was shocked once en route to the ED. In ED, there was no contractility of the heart and no pericardial effusion on bedside ultrasound. COVID-19 PCR was negative. Tox screen was positive for Narcan, caffeine, and Marijuana. ACLS continued for 55 more minutes before patient was pronounced.

On autopsy, microscopic examination of the heart revealed “interstitial edema with foci of myocardial fibrosis, foci of lymphocytic infiltrates, associated with myocardial necrosis, consistent with viral myocarditis.” Additionally, lung histology showed

"expanded interstitium with edema, fluid, and inflammatory infiltrates with increased peribronchial area." Per pathologist conclusion cause of death was lymphocytic myocarditis with interstitial pneumonia as a contributory cause.

*Reviewer comment: Role of vaccine is **unlikely** given distant history of vaccination/lack of temporal association and alternate likely etiology of viral myocarditis with possible interstitial pneumonia. Areas of myocardial fibrosis could be suggestive of more chronic cardiac pathology, but the finding is of undetermined significance. Contributory role of marijuana use is unclear.*

VAERS [redacted] 6-year-old female with complex history of anoxic brain injury (due to near drowning) in [redacted] a 5-month medically induced coma for intractable grand mal seizures, spastic quadriplegic CP, refractory dystonia, dysautonomia, bowel/bladder incontinence, and bilateral hip subluxation, died 12 days after receiving 2nd dose of Pfizer Monovalent Covid vaccine in 2021 during a prolonged inpatient stay. She was transferred to [redacted] due to worsening hypertonia/spasticity, urinary retention and recurrent UTIs, elevated LFTs with hepatomegaly and hepatic steatosis. During her prolonged 10-month PICU stay she had bilateral hip ostomies, multiple UTIs and bouts of tracheitis, multiple respiratory infections requiring ventilator support for respiratory failure, SIBO, dysautonomia and central hypertension.

Patient developed worsening lactic acidosis of unknown etiology with a waxing and waning course beginning on 11/01/2021. Per hospital records a metabolic genetic workup was negative and the most likely explanation was SIBO for which she was placed on empiric Rifaximin. She developed Pseudomonas UTI on 11/06/2021 and started on antibiotics. She received the flu vaccine on 11/08/2021 and was also noted to have left knee fracture on the same day and was splinted. She received the 2nd dose of the Pfizer vaccine on 11/10/2021 and was reported to be at baseline until 11/14/2021, when she began exhibiting fevers of unknown origin. Blood and urine cultures, respiratory panel, and CXR were negative, and antibiotics were stopped on 11/18/2021.

Patient was reportedly doing well and back to baseline again on 11/20/2021 but she then decompensated acutely overnight with progressive metabolic/respiratory acidosis of unclear etiology, hypotension, sepsis, and heart failure with ensuing multisystem organ failure. She was intubated for hypoxic respiratory failure and exhibited evidence of acute on chronic heart failure with decreased cardiac function and BNP > 7000. CT demonstrated diffuse pancolitis and hepatomegaly, and she exhibited AKI with multiple electrolyte abnormalities. [redacted] 11/22/2021 [redacted]. A limited autopsy, excluding brain and brainstem [redacted], noted normal heart, lungs, colon and small intestine, and hepatomegaly with yellow discoloration, but no documentation of cause of death. A death certificate was not provided.

*Reviewer comment: Role of Pfizer COVID vaccine is **unlikely** due to alternative etiology of death of worsening lactic acidosis of unknown etiology and recent UTI which preceded vaccination, with subsequent fever of unknown origin, septic shock and*

multiorgan failure, superimposed on severe chronic illness and frequent exacerbations during a prolonged hospitalization.

VAERS [redacted]: 5-year-old female with a complex medical history of placental twin to twin transfusion syndrome, Hydrocephalus with VP shunt, loss of gray-white matter, Cerebral palsy with global spasticity, global developmental delay, GJ-tube dependence, upper airway obstruction/OSA on CPAP, and seizure disorder was hospitalized from 12/16//2021 to 12/20/2021 for 2 weeks of worsening cough and ensuing respiratory distress. Per the report, there was a sick contact at home with sinusitis. She was diagnosed with rhinovirus URI and mycoplasma pneumonia vs aspiration event. COVID, flu, and RSV tests were negative. CXR showed bilateral perihilar infiltrates and stable "heart size and other mediastinal contours." She was admitted to PICU but stepped down to regular service after 2 days, on 12/18/2021, when she received the Pfizer Covid vaccine (unknown dose number); she remained stable on room air for 2 more days prior to discharge on 12/20/2021.

She was then found pulseless and not breathing at home in the morning on 12/22/2021, four days after receipt of Pfizer monovalent vaccine. Per report she was doing well and at baseline the prior evening. She received CPR for 20 minutes prior to ED arrival, where she was still pulseless with no cardiac activity on EKG, a pH < 6, and a critically high pCO2 > 200 mmHg. She failed resuscitation efforts and passed away. Cause of death is listed as systemic viral illness in the setting of chronic lung disease. It is unknown if an autopsy was performed.

*Reviewer comment: Role of vaccine is **unlikely**, despite temporality, given alternate etiology of concomitant pulmonary infection with mycoplasma pneumonia or possible aspiration in the setting of multiple comorbidities.*

VAERS [redacted]: 17-year-old female with complex medical history including Moebius syndrome and tracheostomy dependence, on nursing home care, died on 11/30/2021, 6 months after receiving 2nd dose of Pfizer COVID-19 vaccine (dose administered 5/21/2021). Per the report, a few days prior to death, she began exhibiting onset of respiratory symptoms that caused her to newly require supplemental oxygen, Per the home nurse she spiked a fever and subsequently went into cardiac arrest. CPR was started and patient was transported by EMS to ED, where she arrived with fixed and dilated pupils and in asystole. Bedside US during ongoing resuscitation efforts demonstrated no cardiac activity, and patient passed away. Flu, COVID-19, and RSV testing were negative. No autopsy was done but death certificate lists cause of death due to respiratory failure and moebius syndrome. There are no further records about patient's medical history.

*Reviewer comment: Death was **unlikely** related to Pfizer vaccine as it occurred more than 6 months following the 2nd dose and was more likely related to patient's febrile respiratory illness.*

VAERS [redacted]: 13-year-old female with no past medical history, vaccinated with the 2nd dose of the Pfizer monovalent COVID-19 vaccine near the end of August 2021, presented on 10/30/2021 with 2 weeks of midsternal chest pain, sore throat, intermittent

low-grade fever and cough, intermittent dyspnea, and fatigue. Five days prior, she had been diagnosed with pneumonia and small left pleural effusion on CXR at a different hospital; COVID-19, influenza, and RSV tests were negative. She was initiated on antibiotics but again presented to ED for care due to ongoing symptoms.

ED exam was only notable for bilateral lower decreased breath sounds, but the hospital admission physical exam noted a 2/6 systolic murmur and pericardial rub, and nonspecific T wave inversion with ST segment elevation in the anterior leads on EKG. Patient had normal Troponin and BNP but increased CRP and elevated D-Dimer. Echo on 10/31/2021 showed small pleural and pericardial effusion and possible compression of left atrium from an extra atrial mass; chest CT on 11/4 confirmed subcarinal mass and soft tissue density.

Subsequent echocardiograms within the next week showed a rapidly enlarging atrial mass that seemed to arise from the pulmonary veins, with significant pericardial thickening vs infiltrative process and "tamponade physiology." She underwent a left atrial mass resection on 11/11/2021. Chest CT on 11/13/2021 showed extensive infiltrative soft tissue with scattered cystic/necrotic foci in the mediastinum, "between the great vessels and pericardium, and mass effect on the lower SVC."

Pathology result on 11/17/2021 was positive for mediastinal epithelioid sarcoma and patient was started on chemo on 11/19/2021. Serial echocardiograms showed persistently enlarging mass impinging various cardiac structures despite chemotherapy. Patient was placed on mechanical ventilation due to increasing tamponade and respiratory distress [redacted] 12/01/2021 [redacted] there is no autopsy report in the source documents. The death certificate listed cause of death as cardiac tamponade, liver and kidney failure, epidermoid sarcoma and mediastinal mass infiltrating into the heart.

Reviewer comment: Role of COVID-19 vaccine is unlikely given the alternate diagnosis of aggressive mediastinal tumor compressing the heart and causing cardiorespiratory failure.

VAERS [redacted]: 17-year-old male with medical history of benign cardiac murmur and ADHD received a second dose of Pfizer Monovalent COVID-19 vaccine on 6/26/2021, and died on 1/24/2022, 212 days post-vaccination. He was found unresponsive in bed at 9:30 AM by his mother. EMS noted asystole. Cause of death was determined to be cardiac arrhythmia of unknown etiology. Autopsy was performed with results including findings of pulmonary edema; superficial abrasions on hands; leg contusions; toxicology positive for diphenhydramine (0.38 mg/L, therapeutic range); no pathogenic genetic mutations associated with sudden cardiac death. Autopsy examination of the heart revealed no structural disease to explain sudden death, no evidence of myocardial infarction, no pulmonary embolism, no significant toxicological findings, and no trauma or obvious cause of death. There was no direct evidence of arrythmia.

Reviewer comment: The causal relationship to vaccination was determined to be ***unlikely*** *based on the time from vaccination to event that makes a relationship improbable.*

VAERS [redacted]: 15-year-old female with past medical history of arthrogryposis multiplex congentia with significant upper and lower extremity contractures and neuromuscular scoliosis, developmental delay, chronic constipation, colitis, asthma/reactive airway disease, restrictive lung disease, history of pneumonia, and BiPAP dependence at night received a second dose of Pfizer Monovalent COVID-19 vaccine on 8/20/2021 and died on 1/20/2022, 153 days post-vaccination. She first presented with abdominal pain on 1/15/2022. Workup suggested exacerbation of constipation without an acute process and asymptomatic COVID-19 infection. She was hospitalized for stool management, and her course was complicated by respiratory decompensation requiring increasing biPAP needs above her baseline. On 1/20/2022, she became unresponsive and was intubated; 'extremely stiff lungs and significant flash pulmonary edema' were noted in the report. A review of records and telemetry revealed progressive bradycardia leading to junctional rhythm and later, asystole. [redacted] The cause of death was determined to be cardiac arrest secondary to COVID-19. Autopsy information was not available.

*Reviewer comment: The causal relationship to vaccination was determined to be **unlikely** based on the time from vaccination to event that makes a relationship improbable. Alternative possible etiology of COVID-19 infection was identified.*

VAERS [redacted]: A 9-year-old male with past medical history of asthma received Pfizer monovalent COVID-19 vaccine on 12/1/2021 and experienced sudden death on 2/3/2022, 64 days post-vaccination. Per the report, he was well the night prior but was found unresponsive in bed at 6:30 AM by his father. He was determined to be in asystole by EMS and was not able to be resuscitated. Of note, the child was evaluated by a cardiologist at 2 years of age for a murmur. Evaluation included examination, echocardiogram and EKG. No pathology was found. The murmur, a "vibratory grade 2/6 slightly coarse sounding medium to long systolic murmur at the left sternal border second, third intercostal space," was determined to be a benign flow murmur. No other apparent contributory or confounding factors were identified. Autopsy information was not available.

*Reviewer Comments: The causal relationship to vaccination was determined to be **unlikely** based on the time from vaccination to event that makes a relationship improbable. The benign murmur was not considered to be a confounding factor.*

VAERS [redacted]: A 14-year-old female with past medical history/concurrent conditions of T-lymphoblastic lymphoma, bone marrow transplant, and graft versus host disease received a second dose of Pfizer monovalent COVID-19 vaccine on 8/27/2021, developed COVID-19 infection 29 days post-vaccination and died 60 days after vaccination. She developed COVID-19 that progressed from mild to critical illness and multi-organ failure despite antibody infusion starting 9/26/2021. On day of death, she developed rapidly progressive refractory hypotension and bradycardia. The cause of death was determined to be COVID pneumonia leading to respiratory failure, acute kidney injury, and cardiac arrest. Autopsy Information was not available.

*Reviewer comment: The causal relationship to vaccination was determined to be **unlikely** based on the alternative etiology of COVID-19 infection.*

VAERS [redacted]: A 9-year-old female with no significant past medical history received Pfizer monovalent COVID-19 vaccine [dose number not reported] on 12/4/2021, developed COVID-19 infection 172 days post-vaccination, and died 6/3/2022, 181 days post-vaccination. Three days prior to death, she exhibited fever, nausea, headache, and lethargy. She visited urgent care and ED, was diagnosed with COVID-19 infection, and was treated with IV fluids, dexamethasone, fluticasone, acetaminophen, ibuprofen, antiemetics, and benzonatate. On day 3 of illness, she was resting in bed at home until her father found her unconscious, shaking and foaming at the mouth, and covered in vomit. She lost her pulse on the way to the ED. CPR was initiated, and she was intubated and stabilized. She was noted to be COVID, adenovirus, and rhinovirus positive. MRI showed global hypoxic brain injury and tonsillar herniation, and brain death was subsequently confirmed. Cause of death determined to be COVID-19 infection leading to cardiorespiratory arrest and anoxic brain injury. Autopsy performed with results consistent with covid pneumonia, meningoencephalitis, diffuse cerebral edema, neuronal hypoxia, and brain herniation.

*Reviewer comment: The causal relationship to vaccination was determined to be **unlikely** based on the time from vaccination to event that makes a relationship improbable, and the plausible alternative etiologies of viral infections that contributed to death.*

VAERS [redacted]: An 8-year-old female with no significant PMH received Pfizer monovalent COVID-19 vaccine dose 2 on 1/18/2022, developed fever and lymphadenopathy 71 days post-vaccination, and then died at least 105 days post-vaccination (date of death not provided).

Beginning 3/30/2022, the child developed left inguinal swelling and lymphadenopathy (at largest, measuring 2.3 x 1.2 x 1.3 cm). She visited her primary care doctor on an unknown date, and an ultrasound on 4/4/2022 demonstrated lymphadenopathy thought most likely reactive at that time. She developed fever on 4/12/2022 (T-max 105F) and full-body maculopapular rash, prompting two visits in the emergency department 4/14/2022 and 4/16/2022.

During the two emergency room visits, significant findings included tachycardia, pharyngeal redness, elevated SED rate and CRP, and moderate red blood cells in urine. She tested negative for influenza, COVID-19, and Group A Strep. Blood cultures were negative. Working diagnosis at the visit on 4/16/2025 was incomplete Kawasaki disease, viral syndrome, or lymphadenitis. Her fever improved with acetaminophen, ibuprofen and IV fluids. Her clinical condition was stable [redacted]

According to the narrative, she was later hospitalized from 4/24/2022 - 5/3/22 with a chief complaint of persistent fever of 3 weeks duration and increased left inguinal volume. Her symptoms progressed to include arthralgias, myalgias, and later, respiratory failure and ascites. Laboratory testing demonstrated elevated ferritin level.

Parvovirus antibody test (IgG) was positive, SARS COV-2 antibody test (IgG) was positive, but SARS-COVID-2 test was negative. Differential diagnosis included MIS-C and macrophage activation syndrome at that time. Treatment included steroids, IVIG, and the janus kinase (JAK) inhibitor Baricitinib. Details regarding patient's passing were unclear from report, and date of death is not provided. Cause of death was not provided and no autopsy information is available.

*Reviewer comment: This case was assessed as **unlikely** related to vaccination based on the time from vaccination to event of 71 days that makes a relationship improbable. Based on available information, the differential of conditions that may have contributed to death include Kawasaki's disease (fever, rash, lymphadenopathy elevated inflammatory markers), MIS-C (COVID-19 antibody positivity, fever, rash, multi-organ involvement), and macrophage activation syndrome or hemophagocytic lymphohistiocytosis (HLH) (fever, lymphadenitis, rash, ascites, cytopenias, elevated ferritin and inflammatory markers). Use of barcitinib and differential diagnosis of MIS-C provided in narrative suggest that COVID-19 may have been suspected despite negative PCR test during 4/24-5/3 hospitalization. Altogether, an infectious process cannot be ruled out based on available information.*

VAERS [redacted]: A 12-year-old male with no significant PMH received second dose of Pfizer monovalent COVID-19 vaccine on 1/3/2022, developed COVID-19 infection and hemorrhagic myocarditis approximately 4 months later, and died 112 days post vaccination. Per report, on 4/24/2022 the child developed congestion and mucus production. The following morning, the child was found unresponsive in bed. EMS noted froth at nares and mouth, asystole, apnea, and fixed and dilated pupils. The child was transported to hospital and pronounced dead. Autopsy reported that COVID-19 was detected by PCR (nasal swab). No sequence variants for familial arrhythmia or cardiomyopathy were detected. Heart was grossly normal. Microscopic examination of the heart revealed small, scattered foci of inflammation, myocytolysis, and interstitial hemorrhage consistent with hemorrhagic myocarditis. Lung tissue exhibited foci of inflammation, edema, congestion, and intra-alveolar erythrocyte extravasation. Congestion was noted in liver, kidney, and section of brain.

*Reviewer comment: The causal relationship to vaccination was determined to be **unlikely** based on the time from vaccination to event of 112 days that makes a relationship improbable. Alternative plausible etiology of COVID-19 infection was identified that can explain death.*

VAERS [redacted]: 9-year-old female with no significant past medical history received a first dose of Pfizer monovalent COVID-19 vaccine on 12/13/2021, developed symptoms starting 11 days post-vaccination and died 12/27/2021,14 days after vaccination. Beginning on 12/24/2021, the child developed stomach ache, sore throat and chest pain. On the morning of 12/27/2021, the child became unresponsive. She was taken to the ER where she was pronounced dead.

Autopsy was performed. Postmortem nasopharyngeal swab was SARS-CoV positive by PCR. Toxicology was positive for caffeine and acetaminophen in therapeutic range. Pericardial effusion was present. Histologic sections of the heart revealed myocarditis: interstitial, predominantly chronic (lymphocytes and macrophages) inflammation, with occasional neutrophils and eosinophils, and associated myocyte injury. Mild cerebral edema with early hypoxic-ischemic neuronal changes was also noted.

Specimens of heart, lung, and trachea were sent to the CDC for further pathological analysis. The CDC reported the following findings: the lungs, heart and trachea had molecular evidence of SARS-CoV-2 (PCR). The lungs and trachea with immunohistochemical evidence of SARS-COV-2. The heart had myocyte injury highlighted by C4d immunohistochemistry, suggesting lymphohistiocytic myocarditis. Other evidence of myocarditis included moderate chronic inflammatory infiltrate, occasional neutrophils distributed diffusely in the myocardium and foci of myocyte injury with cytoplasmic eosinophilia. The lungs showed mild to moderate interstitial chronic inflammation/pneumonia, intra-alveolar fibrin deposition, and vascular congestion. The trachea had mild and patchy chronic inflammation. The child's cause of death was determined to be fulminant myocarditis due to COVID-19 infection.

Reviewer comments: The causal relationship to vaccination was determined to be ***unlikely*** *based on the more likely alternative etiology of COVID-19 infection causing fulminant myocarditis and death. Although SARS-COV-2 RNA can be detected in the heart without clinical myocarditis and without histological evidence of inflammation (44), in this autopsy, virus was detected in multiple organs in the setting of fulminant myocarditis, suggesting active infection. When she became infected, the child likely lacked the protective immunity from vaccination that develops in 14 days. The autopsy finding of serum caffeine positivity is an additional potential contributory factor that may have exacerbated myocarditis.*

VAERS [redacted]: A 13-year-old female with no significant past medical history received a first dose of Pfizer monovalent 19 vaccine on 8/9/2021 and died 3/3/2022, 206 days after vaccination. Beginning 2/24/2022, approximately one week prior to death, the child experienced "heart flutters," including while playing basketball the day before death. She was found unresponsive the morning of 3/3/2022 by her mother and pronounced dead at the scene.

Autopsy was performed. SARS-COV-2 was detected by nasopharyngeal swab. Internal examination of the heart revealed slightly dilated-appearing right ventricle but was otherwise normal. Histopathological examination of the heart was normal. The only other finding was scattered foci of peribronchiolar chronic inflammation on lung histology. Arrhythmia and cardiomyopathy genetic testing was negative for pathogenic variants known to cause disease. Toxicology was normal. According to the autopsy report, "there was no definitive gross, histologic, or genetic etiology to explain her cardiac arrhythmia." Cause of death determined to be cardiac arrhythmia of uncertain etiology.

*Reviewer comment: The causal relationship to vaccination was determined to be **unlikely** based on the time from vaccination to event of 206 days that makes a relationship improbable.*

VAERS [redacted]: A 10-year-old male with past medical history of neurometabolic disorder of uncertain etiology, hypotonia and immobility; global developmental delay, seizure disorder, nutrition via G-tube, restrictive lung disease from scoliosis, and airway obstruction with mild OSA received a first dose of Pfizer monovalent COVID-19 vaccine on August 12th, 2022, suffered cardiac arrest 13 hours post-vaccination, and died August 16th, 2022, 4 days after vaccination.

The child was originally hospitalized July 15th, 2022, for leakage, firmness, and redness surrounding G-Tube which was concerning for cellulitis and obstruction. The child underwent G-tube replacement and was incidentally found to be COVID-19 positive on July 16th, 2022. Prior to admission, he had no fever, rhinorrhea, congestion, cough, or vomiting. After G-Tube replacement, providers were unable to extubate the patient, due to desaturation, need for significant PEEP and extensive tracheal secretions, and "whiteout" lung noted on CXR. The patient was admitted to the PICU and treated for COVID-19 pneumonia with a course of remdezivir and dexamethasone. His course was complicated by pseudomonas pneumonia, for which he was treated with 10 days of antibiotics July 23rd - August 1st. He had a repeat COVID test (nasal swab) that was negative July 30th, 2022. He was extubated after 2 weeks on August 4th, 2022 but continued to have fluctuating oxygen needs; he was on high-flow nasal cannula and needed airway and secretion management. On August 5th,2022, he exhibited abnormal movements concerning for seizure. On August 12, 2022, he was vaccinated with the Pfizer COVID-19 vaccination. 13 hours later, he became bradycardic and hypotensive, then pulseless with wide complex rhythms. CPR was initiated and the patient was stabilized and sent to the ICU. Echo demonstrated severely diminished LV function (EF=15%), echogenic aortic valve leaflets and small pericardial effusion. EKG 8/13/22 showed normal sinus rhythm, left axis deviation, non-specific T-wave abnormality and prolonged QT. Cardiomyopathy genetic testing August 15th revealed a [redacted] He sustained another cardiac arrest on August 16th, 2022 and resuscitation was discontinued after more than 30 minutes. The cause of death was determined to be decreased left ventricular function secondary to COVID-19. Autopsy information was not available.

Reviewer comments:
*The causal relationship to vaccination was determined to be **unlikely** based on multiple other ongoing clinical factors/diseases that provide plausible explanations for cardiac arrest and death. These alternative etiologies include critical illness due to COVID-19 and pseudomonas pneumonia in the context of severe neurometabolic disorder. Myocyte injury and fibrosis are a plausible mechanism for COVID-19 to lead to cardiac arrest, even after acute infection (45). Further, the [redacted] gene variant has been associated with familial dilated cardiomyopathy and multiple types of arrythmia including Brugada syndrome (National Library of Medicine, accessed 2025). The cardiac findings*

of reduced LV function are difficult to fully interpret in the setting of recent cardiac arrest and critical illness but are likely represent a process that preceded vaccination and may be genetic. There were no prior echocardiograms mentioned or available for comparison.

VAERS [redacted]: A [redacted]-month-old female with past medical history of arachnoid cyst status-post left-sided craniotomy for cyst fenestration and lumbar drain placement at [redacted] months of age received a first dose of Moderna monovalent COVID-19 vaccine on August 5th, 2022. She then developed fever and neurological symptoms 14 days post-vaccination and died 36 days after vaccination on September 10, 2022.
She had reportedly tolerated vaccination well without apparent adverse events. Beginning August 20th, 2022, she developed fever, vomiting, dehydration and lethargy. She was negative for influenza, COVID-19 and RSV. In the hospital, she had altered mental status, witnessed seizure activity and was noted to have ptosis and a dilated, minimally reactive right pupil. CT imaging of her brain revealed a large left subdural hygroma with 7 mm midline shift. She was treated for seizures and underwent surgery August 22nd, 2022, to evacuate the left hygroma with Burr Holes and place a subdural drain. CSF studies from the procedure were consistent with bacterial meningitis (cloudy fluid, elevated RBCs and WBCs with neutrophilic predominance, elevated protein, glucose not detected) as well as gram-positive cocci. Treatment was initiated with antibiotics and dexamethasone. MRI imaging of her brain on August 23rd, 2022, showed multiple foci of abnormal signal which were consistent with white matter lesions throughout the brain. These were thought to represent either ischemic infarcts or septic embolic infarcts. MRI also revealed mastoiditis and paranasal sinusitis. CSF and blood cultures confirmed *S. pneumoniae.*

Her course was further complicated by hypotension, sepsis, ground glass opacity concerning for ARDS, pneumothorax, pancytopenia, atypical hemolytic uremic syndrome and acute kidney failure requiring dialysis, pancreatitis, and EEG evidence of further brain infarction / anoxia, [redacted] multiple organ failure and severe brain damage. A death certificate indicates that the cause of death was sepsis. Autopsy information was not available.

Reviewer comments: The causal relationship to vaccination was determined to be **unlikely** based on the more likely etiology of bacterial meningitis. Of note, this child was likely at increased risk of pneumococcal meningitis due to her underlying conditions and surgical history of craniotomy.

VAERS [redacted]: A 15-year-old female with past medical history not reported received a second dose of monovalent Moderna COVID-19 vaccine on an unknown date, developed cardiac arrest and died on an unknown date post-vaccination. The circumstances leading to death were not provided. It is unknown whether an autopsy status was performed and a death certificate is not mentioned or available for review.

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

VAERS [redacted]: 15-year-old female deceased from cardiac arrest as reported cause of death following vaccination with the second dose of Moderna mRNA-1273 on an unknown date. The date 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]: 1-year-old of unknown sex with no reported medical history died from seizure 2 days after receiving an unspecified dose number of Moderna mRNA-1273 on an unknown date. The actual date of death is unknown. The reported cause of death was “severe seizure” but autopsy status is unknown. 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, diagnostic elements, and clinical course.*

VAERS [redacted]: 13-year-old male with no reported medical history deceased from unknown cause after receiving an unspecified dose of Moderna mRNA-1273 on an unknown date. The date 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]: [redacted]-month-old male with history of reflux and “projectile vomiting” was found unresponsive by a daycare provider approximately 30 minutes after being laid supine with no apparent surrounding objects in a pack n play. Per vaccine record, the infant was vaccinated with Pfizer (dose 1) as well as Flulaval (dose 1), Prevnar13 (dose 3), Pediarix (dose 3), and Rotateq (dose 3) on 9/16/2022. The date of death was 9/26/2022, marking a 10-day interval onset. The decedent was in asystole upon EMS transport and ED arrival, and failed resuscitation.

The cause of death was sudden unexpected infant death/undetermined, with death certificate and autopsy noting infant was found unresponsive prone with face in mattress, anterior and posterior livor mortis (consistent with prone position), bowel malrotation of the midgut (no volvulus or ischemia) and tracheitis (“mild inflammation, suggesting a possible upper respiratory viral infection”). Respiratory virus panel was negative. Comprehensive internal cardiac exam with biopsies were negative.

*Reviewer comment: This case was assessed as **unlikely** related to COVID-19 vaccination due to alternate etiologies for sudden death identified on autopsy including evidence of prone positioning, malrotation, and tracheitis. Please see Discussion, subsection on Sudden Cardiac Death.*

VAERS [redacted]: 15-year-old female with unspecified epilepsy (seizure disorder) and spastic quadriplegic CP presented to the ED with fever and respiratory distress 12 days after first dose of Pfizer COVID-19 vaccine; she passed away 14 days after vaccination. She had known COVID-19+ sick contacts and experienced 2 days of fever and respiratory distress prior to seeking medical care. After presentation, she was noted to have COVID-19 disease (detected on NAA and initiated on remdesivir, tocilizumab, steroids) which rapidly decompensated to fulminant septic shock. She developed DIC and exhibited poor response to vasoactives leading to decline and elected for DNR. Per discharge summary, coroner was reportedly not notified due to "natural cause of death" from COVID pneumonia. Date of vaccination with single, first dose of Pfizer was 1/11/2022 and date of death was 1/25/2022, marking a 14-day interval onset.

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

VAERS [redacted]: 2-year-old of unknown sex deceased within 6 hours of a single Pfizer vaccine (reportedly dose 1) on an unknown date. 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]: 2-year-old male found unresponsive in bed on 10/7/2022, 58 days after receipt of the second dose of Moderna COVID-19 vaccine on 8/10/2022. Pediatric telephone encounter documented by NP the preceding day noted reported low-grade fever of 100.4F and ear pain; the family was advised to trial pain reliever and an appointment for the following morning was scheduled. Death certificate lists respiratory viral infection from rhino/enterovirus and RSV as cause of death. Autopsy was marked as performed but there is no available record. No other clinical information or records are available.

*Reviewer comment: This case was assessed as **unlikely** related to COVID-19 vaccination due to an implausible temporal relationship.*

VAERS [redacted]: 6-year-old female with Leigh syndrome, Lennox-Gastaut epilepsy syndrome, and G-tube dependence enrolled in home hospice care deceased of aspiration pneumonia and respiratory failure in the setting of COVID-19 pneumonitis (SARS-CoV-2 detected by NAA during hospitalization on 9/18/22). Pfizer vaccination

dates were recorded as 11/22/2021 and 12/17/2021 and the date of death was 9/20/2022, marking a 277-day interval onset from the latest vaccine dose. The decedent reportedly exhibited viral URI symptoms (rhinorrhea, cough, congestion) 7 days prior to admission and was concomitantly being treated for acute otitis media.

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

VAERS [redacted]: 2-year-old female with history of complex febrile seizures died one day after receipt of Moderna COVID-19 vaccine (dose 1) and Flulaval on 12/15/2022. No other clinical information, including symptomatology, were provided in corresponding VAERS reports detailing events preceding time of death. The decedent had been seen in PCP office for low-grade fever and URI symptoms on 12/7/2022. The child was reportedly "found dead in bed" on 12/16/2022.

Cause of death on autopsy is listed as unexplained sudden death. However, per the autopsy report, there were multiple intrinsic risk factors for sudden death including history of febrile seizures with evidence of focal cortical dysplasia and granule cell disaggregation, viral respiratory tract infection with multiple detected pathogens (influenza A/H3, rhino/enterovirus, parainfluenza, RSV), tracheobronchitis and interstitial pneumonia (on histology), pulmonary edema, [redacted] According to the autopsy report, there was "no documented fever or illness prior to death."

*Reviewer comment: This case was assessed as **unassessable**/unclassifiable in relation to COVID-19 vaccination due to conflicting/contradictory findings from the autopsy; although the autopsy documents multiple intrinsic factors and findings suggestive of a cause of death, including respiratory infection with pulmonary involvement as well as possible cortical predisposition to seizures, the reported cause of death is unexplained sudden death, which should be a diagnosis of exclusion. Please see Discussion, subsection on Sudden Infant Death and Sudden Unexplained Death in Childhood.*

VAERS [redacted]: 2-year-old female with reported sudden death 3 weeks following an unknown dose number of Moderna mRNA-1273, bivalent administered on an unknown date. The date of death is unknown. 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]: 2-year-old male vaccinated with unknown dose number of Pfizer on an unknown date deceased of unknown cause. It was not reported 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]: 5-month-old male received Pfizer COVID-19 vaccine, bivalent (presumably dose 1 based on age) concomitantly with Pediarix (3rd dose), Flulaval (1st dose), Prevnar13 (3rd dose), Rotateq (3rd dose) on 9/16/2022 and died 10 days later. Concurrent conditions reportedly included acute otitis media and reflux (on famotidine and omeprazole). On 9/26/2022 (reported 10-day interval onset), the decedent was found unresponsive following a nap. The reported cause of death was "shock, heart disorder and pulseless." No other clinical information or records are available. Autopsy status is unknown. Follow-up activity entailed the following response: [redacted]

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

VAERS [redacted]: 12-year-old female with history of chronic headaches (followed by neurology), ADHD (on Adderall), depression (on sertraline), and elevated BMI (28.42) presented to the ED in PEA arrest and died on 8/29/2022. Pfizer (3rd dose) was administered concomitantly with HPV9 (1st dose), MCV4P (1st dose), and Tdap (1st dose) on 8/3/2022. PCP office note on that day remarked that within the last month prior to the visit, the decedent had developed "some new versions of a headache" (brief and severe episodes of 5min duration). On the day of presentation, she reportedly complained of headache associated with vomiting, and went into PEA; EMS intubated her. Clinical status subsequently devolved to unresponsiveness with multiple intermittent episodes of ROSC but ultimately failed resuscitation.

Cause of death listed on death certificate is sudden cardiac death in a person with dilation of the frontal horns of the lateral ventricles, cerebral edema, and cerebellar tonsillar and bilateral uncal herniation. An autopsy was marked as performed but there is no available record.

*Reviewer comment: This case was assessed as **unlikely** related to COVID-19 vaccination due to an implausible temporal relationship. Alternate etiology is suggested by a clinical history of symptoms presumably related to cause of death ongoing at the time of vaccination, as well as autopsy findings indicative of progression of longstanding symptomatic ICP propagating herniation.*

VAERS [redacted]: 16-year-old male with past medical history of anxiety and alcohol abuse presented to the emergency department (ED) with a 4-day history of subjective fever, headache, nausea, vomiting, inability to tolerate food or liquids, and anuria 373 days after receiving his second dose of a Pfizer COVID-19 vaccine. His abdomen was nontender on exam and heart exam was unremarkable. Labs were notable for hyponatremia, and elevated transaminases. A computed tomography (CT) scan showed gallbladder wall thickening. Abdominal ultrasound demonstrated possible pericholecystic fluid and no gallstones. A surgery consultant thought results favored an infectious inflammatory process. The patient was given intravenous fluids and some improvement of his serum sodium level was noted on repeat labs. The patient was subsequently discharged from the ED with outpatient follow-up. According to VAERS reports, the patient died the next day. There were no records in VAERS describing the circumstances of the patient's death. The VAERS report states an autopsy was performed and that the cause of death was idiopathic myocarditis, but there was no autopsy report or death certificate available in VAERS.

*Reviewer Comments: This case was assessed as **unlikely** related to COVID-19 vaccination due to a temporal relationship inconsistent with a causal relationship.*

VAERS [redacted]: A [redacted]-month-old male with torticollis, plagiocephaly, and developmental delay received his first COVID-19 vaccine dose and died approximately 68 days later. Around the time of vaccination, the mother reported the onset of shaking episodes; it is unclear based on VAERS records whether these episodes started before or after vaccination. After two weeks of daily shaking episodes, the patient was evaluated in the ED and received a diagnosis of infantile spasms. He was started on Keppra and a prednisone taper. A month later, the infant was directed to the ED by their pediatrician to rule out seizure activity, as the infant had presented to the pediatrician with a 2-week history of lip-smacking and gaze deviation. ED exam was notable for torticollis and midline eye tracking. Emergent EEG was negative for active seizures but showed abundant epileptiform activity confirming his previous diagnosis of infantile spasms. He was given a one-time loading dose of Keppra and discharged home.

Twenty-four days later (68 days after vaccination), the infant was given formula and then laid on his back in the playpen which contained diapers, clothing and stuffed animals. He was found hours later unresponsive on his stomach with his head positioned to the right. The autopsy report stated that the cause of death was undetermined with no acute pathology noted, consistent with sudden unexplained death in infancy. However, the examiner stated that his death could have been caused by a terminal seizure but that an asphyxial component given his atypical sleep environment could not be excluded.

*Reviewer Comments: The relationship of the vaccine to sudden death in this case is **unassessable**; cause of death is undetermined, and temporal relationship between the onset of the infantile spasms and COVID-19 vaccination is unknown, so causality cannot be established. Of note, the child did have preexisting clinical evidence*

(developmental delay) possibly suggestive of neurological processes that could be related to seizure disorder.

VAERS [redacted]: A [redacted]-month-old male was taking a nap and was found unresponsive 22 days after vaccination with Moderna's bivalent COVID-19 vaccine. When EMS arrived, the patient was pulseless with asystole. CPR was performed for 30-40 minutes prior to the patient's arrival to the hospital emergency department. Intubation was reportedly difficult and there were multiple attempts prior to successful intubation. The ED clinician's impression of this patient's demise was possible aspiration from emesis while napping resulting in respiratory failure and subsequent cardiac arrest. The autopsy examination found no intrinsic or extrinsic factors contributing to this patient's death consistent with unexplained sudden death.

*Reviewer Comments: This case was assessed as **unlikely** related to vaccination since there was no autopsy evidence of an inflammatory process, myocarditis, or any other factor that would implicate the COVID-19 vaccine. Please refer to the subsection titled "Sudden Infant Death and Sudden Unexplained Death in Childhood" in the discussion section of this memorandum.*

VAERS [redacted]: A 16-year-old male with a history of hyperlipidemia and active airway disease sustained a concussion 34 days after vaccination with his 2nd dose of the Pfizer COVID-19 vaccine and died approximately 1 week later. Per VAERS records, 4 days prior to a PCP visit, he sustained a head injury while playing football which caused a momentary "black out" and two episodes of vomiting, but no loss of consciousness. The patient was apparently doing well during this PCP follow-up visit. Five days later, he collapsed during football practice without preceding additional trauma; the patient's mother noted that the patient had expressed a vague complaint of chest pain the day prior but that it had resolved and that he had no complaints on the day of the cardiac arrest. He was noted to be in cardiac arrest immediately after the collapse. CPR was initiated when EMS arrived, and the patient was intubated.

Upon arrival to the Emergency Department, the patient was in asystole and CPR was continued. Bedside ultrasound demonstrated no cardiac activity with "swelling" of both atria and ventricles. No pericardial effusion was noted. Despite multiple rounds of epinephrine, bicarbonate, calcium, magnesium, 50% dextrose, CPR, and active bag-valve-mask ventilation, the patient remained in asystole [redacted] The autopsy report noted cardiomegaly with myocyte disarray and ventricular hypertrophy, bilateral pulmonary edema, and cerebral edema and listed hypertrophic cardiomyopathy as the cause of death.

*Reviewer Comments: This case was assessed as **unlikely** related to COVID-19 vaccination, based on a temporal relationship inconsistent with a vaccine-mediated cause of death and a plausible alternate etiology of hypertrophic cardiomyopathy. Although this patient had no known history of hypertrophic cardiomyopathy based on his pediatric primary care records, autopsy findings, particularly ventricular septal*

hypertrophy, were consistent with this diagnosis. The characteristic finding of ventricular septal hypertrophy is thought to occur as a result of compensatory remodeling due to myocyte dysfunction. This remodeling typically takes place over the course of years (46). Thus, it is biologically implausible that COVID-19 vaccination weeks prior would lead to cardiac changes consistent with hypertrophic cardiomyopathy.

VAERS [redacted]: A 12-year-old male presented from headache, low grade fever, fatigue, and chest pain approximately 1.5 years after COVID-19 vaccination in [redacted] He was brought to the hospital and was admitted to the intensive care unit, sustained a cardiac arrest, and was placed on extracorporeal membrane oxygenation (ECMO). He was diagnosed with acute myocarditis with poor heart function. He underwent heart transplantation but suffered a subarachnoid hemorrhage following transplant and lost brain stem functioning, resulting in his demise. This narrative was based entirely on a VAERS report from the boy's parent as there were no medical records or autopsy report available for review.

Reviewer Comments: VAERS is unable to collect source documents on this case since the medical events occurred outside of the United States. Regardless, this case was assessed as "unlikely" related to COVID-19 vaccination due to a temporal relationship inconsistent with a vaccine-mediated cause of death.

VAERS [redacted]: 14-year-old GJ tube-dependent female with multiple sulfatase deficiency, spastic quadriplegia, restrictive lung disease, chronic respiratory failure with hypoxia, renal insufficiency, blindness from optic atrophy, hypertrophic cardiomyopathy, neuromuscular scoliosis, subaortic stenosis, and sleep apnea died 5 days after vaccination. VAERS source documents consist only of the well-child visit where she was given an influenza vaccine and her fourth dose of a COVID-19 vaccine (Comirnaty). Patient had apparently recently been hospitalized for pneumonia. The cause of death listed on the death certificate was "multiple sulfatase deficiency." There were no medical records in VAERS that described the circumstances surrounding the patient's death. An autopsy was not performed.

*Reviewer Comment: Causal relationship of vaccination to death in this case is **unassessable**. According to VAERS, there have been multiple attempts to obtain inpatient hospital records for this case which have been unsuccessful. This patient has multiple plausible alternate etiologies for her death due to her underlying genetic condition complicated by multiple chronic medical problems. However, without hospital medical records, an explanation regarding the events that led up to her demise, or an autopsy report, it is uncertain what may have immediately contributed to her death.*

VAERS [redacted]: A 15-year-old female received her second dose of Pfizer's monovalent vaccine and died 158 days later. She was apparently a healthy athlete that went to sleep and never woke up. There were no signs of foul play or self-harm. This VAERS report was submitted by a parent and there were limited details and no medical records or other source documents available for this case in VAERS. The report states

an autopsy was performed but the results were not stated, nor is an autopsy report or death certificate available in VAERS.

*Reviewer Comment: This case was assessed as **unlikely** related to vaccination due to a temporal relationship inconsistent with a vaccine-mediated cause of death. This individual's cause of death cannot be verified by medical records, an autopsy report, or a death certificate since no source documents are available in VAERS. Further follow-up by VAERS has been unsuccessful despite multiple attempts.*

VAERS [redacted]: A 14-year-old reportedly healthy female developed flu-like symptoms following her second dose of Comirnaty which prompted a visit to an Emergency Room. She died that same week. It is not stated when these symptoms started in relation to COVID-19 vaccination. The report states the patient died of Comirnaty-vaccine-induced myocarditis. There are no source documents available in VAERS including medical records, autopsy report, or death certificate. There is no information on her date of vaccination nor the exact temporal relationship between vaccination and her demise. This case report was submitted by a lawyer of uncertain relationship to the patient.

*Reviewer Comment: This case is **unassessable** due to insufficient information regarding the temporal relationship between vaccination and this individual's demise. Additionally, a cause of death cannot be verified due to a lack of medical records, autopsy report, and death certificate. According to the VAERS report, multiple follow-up attempts were made to obtain additional information and were unsuccessful.*

VAERS [redacted]: 15-year-old male with a history of mild intermittent asthma died of suicide 5 days after receiving his third dose of the Pfizer COVID-19 vaccine. No medical records or other source documents are available in VAERS. A death certificate confirms cause of death as a [redacted]

*Reviewer Comment: This case was assessed as **unlikely** related to COVID-19 vaccination due to cause of death of suicide. Please see the Discussion section, subsection on Suicidality in Adolescents.*

VAERS [redacted]: 16-year-old female with Marfan syndrome, dilated aortic root, history of retinal detachment and multiple tendon injuries, history of sternum separation repair, and thyroid nodule died of an aortic dissection 211 days after her second dose of Pfizer's monovalent COVID-19 vaccine. The autopsy report stated that the patient became unresponsive on a cruise ship after complaining of throat and chest pain. Resuscitation attempts were unsuccessful. There were no medical records sourced from the medical team that managed her on the cruise ship or immediately thereafter. The autopsy report stated that the cause of death was aortic dissection and that the patient had a history of non-critical aortic root dilation.

*Reviewer Comment: This case was assessed as **unlikely** related to COVID-19 vaccination due to that fact that the temporal relationship between vaccination and this teenager's demise is inconsistent with a vaccine-mediated cause of death. Furthermore,*

there is a plausible alternate etiology for her death given it was more than likely precipitated by complications of Marfan's syndrome.

VAERS [redacted]: A 14-year-old male received SPIKEVAX NOS on an unknown date and experienced death with an unknown temporal relationship to vaccination. There are no records in VAERS and the patient's medical history, concomitant medications/vaccinations, medical evaluation, and cause of death are unknown. It is unknown if an autopsy was performed.

*Reviewer Comment: This case was classified as **unassessable** due to insufficient information regarding temporality, cause of death, and medical history.*

VAERS [redacted]: 13-year-old female with history of type 1 diabetes mellitus controlled on an insulin pump, bilateral hearing loss, major depressive disorder, and attention-deficit/hyperactivity disorder (ADHD), died of multiple organ failure 5 days after vaccination with Comirnaty (dose unknown) and influenza vaccine. Two days prior to vaccination with Comirnaty and influenza vaccine, she was noted to have nocturnal dyspnea and dyspnea with exertion. On the day of vaccination, she developed fever of unknown degree. Two days later she experienced multiple syncopal episodes and cardiac arrest at home. Despite initial achievement of ROSC, the patient continued to experience cardiac arrest refractory to resuscitation and was placed on extracorporeal membrane oxygenation (ECMO). Five days after vaccination, she died of multiple organ failure. Although the inpatient cardiology working diagnosis was fulminant myocarditis with possible arrhythmogenic component, the autopsy report concluded that the cause of death was [redacted] based on findings involving [redacted] Other autopsy findings include diffuse pulmonary edema and hemorrhage as well as patchy ischemic colitis.

This case did not meet the CDC case definition for myocarditis or pericarditis due to the presence of an autopsy-confirmed alternative diagnosis [redacted] to explain the cause of death and onset of cardiopulmonary symptoms two days prior to vaccination.

Pediatric Cardiologist Reviewer Comments: The 13-year-old who passed after the Comirnaty vaccination not only had an alternative cause of death on autopsy, her symptoms and past medical history are inconsistent with a vaccine induced myocarditis. [redacted]. While there are case reports of vaccination worsening this condition, the acute presentation of syncope and sudden death is consistent with long-standing disease (47). This patient was documented to have been in symptomatic congestive heart failure prior to the vaccination.

*Reviewer Comment: this case was assessed as **unlikely** related to COVID-19 vaccination due to the alternate etiology for this patient's demise* [redacted]

VAERS [redacted]: A [redacted]-month-old with congenital hip deformity was found deceased in his crib by his parents 1 day after receiving a Moderna COVID-19 vaccine (unknown dose number). No medical records related to this event are in VAERS and all information was obtained from the autopsy report. The child was put to sleep on his back and the parents reportedly witnessed him rolling to prone position via live camera footage. No seizure activity was witnessed. He was found deceased in the prone position an unknown period of time later. The pathologist noted pulmonary edema and bronchopneumonia on autopsy but stated it was unclear to what extent it may have contributed to death, as the child had not been experiencing cough or fever prior to demise. The autopsy report states that while a reactive febrile seizure could not be ruled out, such an event is unlikely to have resulted in these findings on autopsy. The autopsy report states there were no intrinsic or extrinsic factors identified that would explain this infant's death, and this lack of findings is consistent with a diagnosis of unexplained sudden death in childhood.

*Reviewer Comment: This case was classified as **unlikely** related to COVID-19 vaccination, as the pathologist asserted that febrile seizure (the only diagnosis potentially related to vaccination) was likely inconsistent with autopsy findings. Notably, there was no mention of any post-vaccination fever in the source documents. The examiner could find no intrinsic or extrinsic factors that would explain the infant's death, which is consistent with a diagnosis of sudden unexplained death in childhood (SUDC).*

VAERS [redacted]: 15-year-old female with no significant past medical history received Pfizer/BioNTech COVID-19 vaccine on 6/19/2021, she developed an acute headache and collapsed at home 166 days post-vaccination and died 183 days post-vaccination. In the ED following her collapse, imaging showed she had developed a ruptured cerebral aneurysm with intracranial hemorrhage. She died in the ICU 183 days post-vaccination, with bacteremia and a positive diagnosis of COVID-19. No autopsy records were available for review.

*Reviewer comment: This case is assessed as **unlikely** due to the lack of temporal association.*

VAERS [redacted]: 15-year-old female with past medical history of bipolar disease, type 2 diabetes, and obesity received Pfizer/BioNTech COVID-19 vaccine on 6/17/2021. She developed bilateral pulmonary emboli 177 days post-vaccination and died the same day in the ED after failed resuscitation measures. Autopsy was performed and showed negative toxicology results and no other unusual findings. Death certificate states the cause of death was bilateral pulmonary emboli.

*Reviewer comment: This case is assessed as **unlikely** due to the lack of temporal association.*

VAERS [redacted]: 17-year-old female with unknown past medical history received Moderna COVID-19 vaccine on an unknown date and died on an unknown date of

unknown with no information on the cause of death. No further information was provided.

*Reviewer comment: This case was classified as **unassessable** due to of missing critical information.*

VAERS [redacted]: 13-year-old male with an unknown past medical history received Moderna COVID-19 vaccine on 6/6/2021 and developed a myocardial infarction on 1/4/2022, 212 days post-vaccination and died that same day. No information about an autopsy was available.

*Reviewer comment: This case is assessed as **unlikely** due to the lack of temporal association.*

VAERS [redacted]: 16-year-old male with unknown past medical history received Moderna COVID-19 vaccine on an unknown date and died on an unknown date of unknown with no information on the cause of death. No further information was provided.

*Reviewer comment: This case was classified as **unassessable** due to of missing critical information.*

VAERS [redacted]: 13-year-old female with a complex past medical history including Kabuki syndrome, s/p liver transplant, end stage renal disease, interstitial lung disease (requiring supplemental oxygen), common variable immunodeficiency, and mitral valve stenosis received Pfizer/BioNTech COVID-19 vaccine on 7/10/2021. On 1/26/2022, 200 days after vaccination, she was hospitalized due to several days of cough, shortness of breath and increasing oxygen requirements from her baseline. She had tested positive for COVID-19 at home and again in the hospital. She developed sepsis and progressive respiratory failure and died on 2/14/2022, which was 220 days after vaccination. No autopsy was done.

*Reviewer comment: This case is assessed as **unlikely** due to the lack of temporal association as well as likely alternate etiology of COVID-19 infection.*

VAERS [redacted]: 14-year-old male with a past medical history of ADHD and mild asthma received Pfizer/BioNTech COVID-19 vaccine on 1/22/2022. One week later, he committed suicide on 1/29/2022. The death certificate lists the cause of death as [redacted]

*Reviewer comment: This case was assessed as **unlikely** due to alternate etiology of death (suicide). Please see Discussion section, subsection on Suicide in Adolescents.*

VAERS [redacted]: 14-year-old male with no significant past medical history received Pfizer COVID-19 vaccine on 2/24/2022 and on the following day developed altered mental status and posturing of upper extremities; he died 3 days post-vaccination. After

developing altered mental status, he was taken to the ED and ultimately admitted to the PICU. Imaging showed ruptured cerebral aneurysm and brain herniation The death certificate showed that the cause of death was cardiopulmonary arrest, brain herniation, brain hemorrhage with increased intracranial pressure, and ruptured brain aneurysm.

*Reviewer comment: This case was assessed as **unlikely** related to vaccination due to the alternate etiology of ruptured aneurysm.*

VAERS [redacted]: 7-year-old male with a past medical history of COVID-19 infection (about 4 weeks prior) and [redacted] received first dose of Pfizer COVID-19 vaccine on 1/8/2022 and second dose on 2/20/2022. Two days after his second dose, he developed recurrent vomiting progressing to bloody emesis, altered mental status, and cardiac arrest. In the ED, he was resuscitated, intubated, put on mechanical ventilation, and admitted to the ICU where he remained until 3/6/2022. During his hospital course, he was treated for cerebral edema, seizures, ventilator-associated pneumonia, acute kidney injury, and MIS-C. He decompensated and had a palliative extubation and comfort therapy, and was pronounced dead 14 days after vaccination. His diagnoses upon death were cardiac arrest, respiratory failure, multisystem inflammatory syndrome in children (MIS-C). The death certificate states his causes of death as sepsis, hypovolemic shock, and [redacted] but an autopsy was not available for review.

Reviewer comment: This case was assessed as **unlikely** due to the individual's significant underlying chronic conditions combined with MIS-C being a more plausible cause of death.

VAERS [redacted]: 17-year-old-male with a past medical history of Duchenne muscular dystrophy, chronic heart failure, chronic respiratory failure, chronic malnutrition, restrictive lung disease, and obstructive sleep apnea. He recently had a 7-month prolonged hospitalization from 6/27/2021 to 2/1/2022 due to medical neglect). He had a visit to primary care physician on 3/1/2022 due to a recent cough and congestion with think secretions. He received the second dose of Pfizer COVID-19 vaccine during that visit and later that day had a cardiac arrest at his skilled nursing facility for which he was taken to the ED. After initial resuscitation, he was admitted to the ICU. He died on 3/6/2022, 5-day post-vaccination, in the ICU. The autopsy found nothing remarkable, and the death certificate stated the cause of death as anoxic brain injury and brain death.

*Reviewer comment: This case was assessed as **unlikely** due to inconsistent temporality – he was vaccinated during doctor's visit to address symptoms possibly related to his demise. The individual's significant underlying chronic conditions likely contributed to death.*

VAERS [redacted]: 10-year-old female with a past medical history including Tetralogy of Fallot, quadriplegia, ventilator dependence, chronic respiratory failure, ESRD on

peritoneal dialysis, pulmonary atresia with ventricular septal defect, and von Willebrand disease received Pfizer COVID-19 vaccine on 12/28/2021. On 1/3/2021, 6 days after vaccination, she presented to the ED in with a 1-day history of bloody stools and decreased activity. She was found to be in severe shock with a GI bleed and was admitted to the PICU. Despite aggressive treatment measures, she experienced progressive deterioration with neurological decline, fluid overload, and thermoregulation issues. On 1/20/2022, 23 days after vaccination, she developed hyperkalemia followed by cardiac arrest and died. The death certificate listed the cause of death as: cardiac arrest, septic shock, spinal cord infarct, renal failure, congenital heart disease. No autopsy was available for review.

*Reviewer comment: This case was assessed as **unlikely** due to alternative etiology of death related to inciting incident of GI bleed and subsequent complications.*

VAERS [redacted]: 8-year-old male received his second dose of the Pfizer COVID-19 vaccine on 2/3/2022. On 2/9/2022, 6 days after vaccination, the patient's mother called clinic reporting that her son had gastroenteritis symptoms (nausea, vomiting, loss of appetite, dizziness) and he was prescribed Zofran through a telehealth visit. The next night, he was found unresponsive and cyanotic in bed and EMS was called. On 2/11/22, 8 days after vaccination, the boy died in PICU after multiple resuscitation attempts. The autopsy found evidence of COVID-19 infection (positive upper respiratory viral panels) and listed the cause of death as MIS-C associated with COVID-19 infection, pulmonary hemorrhage, and cerebral edema.

*Reviewer comment: This case was assessed as **unlikely** due to the alternative etiology of MIS-C associated with COVID-19 infection.*

VAERS [redacted]: 7-year-old female with no significant past medical history received the Pfizer COVID-19 vaccine on 11/29/2021, and developed fever with mild cough and congestion on 12/9/2021,10 days post-vaccination. She was treated at home with acetaminophen. Her entire family was sick with similar symptoms; her two siblings later tested positive for influenza and strep. The patient herself tested negative on COVID-19 PCR. On 12/10/21, she was found unresponsive in her bed, and she was pronounced dead after failed CPR, 11 days post-vaccination. She tested positive for influenza during the autopsy; the report also noted tracheitis and splenomegaly but reported "no anatomic case of death."

*Reviewer comment: This case was assessed as **unlikely** due to her influenza symptoms and positive autopsy testing, suggestive of an alternative etiology.*