Reporting Adverse Events Following COVID-19 Vaccination

The federal government takes all reports of adverse events following vaccination seriously. Both the U.S. Food and Drug Administration (FDA) and CDC are monitoring the safety of COVID-19 vaccines. CDC uses numerous vaccine safety monitoring systems, including VAERS, to monitor adverse events occurring after vaccination.

1. What is VAERS?

VAERS is the nation's early warning system used by FDA and CDC to collect reports of adverse events after vaccination. VAERS can provide scientists with valuable information to assess possible safety concerns related to vaccines, including new COVID-19 vaccines. VAERS is especially useful for detecting unusual or unexpected patterns of adverse event reporting that might signal a possible safety problem with a vaccine.

2. Who should submit a report to VAERS?

FDA *requires* **healthcare providers** to report **certain adverse events** that occur after administering COVID-19 vaccine, but **anyone** *can* **submit a report to VAERS**. Healthcare professionals, health departments, vaccine manufacturers, vaccine recipients, patients and parents or family members of people who have received a vaccine are encouraged to submit a VAERS report when an adverse event occurs after vaccination.

3. Types of adverse events to report

Healthcare providers are *encouraged* to report any adverse event they think is medically important or clinically significant, even if they think the event might not be related to the vaccine. However, healthcare providers are *required* to report the following adverse events after COVID-19 vaccines, in accordance with the emergency use authorization (EUA) for COVID-19 vaccines:

- Vaccine administration errors, whether associated with an adverse event or not
- Serious adverse events (as defined by federal law), regardless of causality, including:
  - death
  - a life-threatening event
  - inpatient hospitalization or prolongation of existing hospitalization
  - persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions
  - congenital anomaly/birth defect
  - an important medical event that, based on appropriate medical judgement, may jeopardize the individual and may require medical or surgical intervention to prevent one of the outcomes listed above
- Cases of Multisystem Inflammatory Syndrome (MIS-C or MIS-A)
- Cases of COVID-19 that result in hospitalization or death

Learn more about what to report to VAERS and how to submit a report.

www.cdc.gov/coronavirus/vaccines

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4. How can healthcare providers contact CDC in case of a COVID-19 vaccine safety emergency?

In case of a health emergency, and the patient needs urgent transportation to the hospital, providers should call 911. If the patient does not need transportation to the hospital, providers are encouraged to call the CDC Emergency Operations Center at (770) 488-7100. For complex vaccine safety questions, healthcare providers or health departments in the United States can request a consultation from the Clinical Immunization Safety Assessment (CISA) COVIDvax clinicians. For non-urgent concerns, providers may contact CDC-INFO.

5. What happens after a VAERS report is submitted?

The individual who submitted the VAERS report will receive electronic confirmation that the report was received. Experts from CDC and FDA monitor VAERS reports to identify adverse events that need to be studied further. Vaccine safety experts review all serious reports (those resulting in permanent disability, hospitalization, prolongation of existing hospitalization, life-threatening illness, congenital deformity, or death).

6. Strengths and limitations to VAERS

VAERS is a robust, nationwide reporting system, but it is subject to several important limitations. VAERS is not designed to assess cause and effect so VAERS reports alone cannot be used to determine if a vaccine caused or contributed to an adverse event or illness. Some reports may contain information that is incomplete, inaccurate, coincidental, or unverifiable. Most reports to VAERS are voluntary, which means they are subject to biases. Data from VAERS reports should always be interpreted with these limitations in mind.

7. CDC follow-up on VAERS reports

To better understand the circumstances around a particular adverse event, VAERS staff from CDC and FDA request follow-up medical records on reports that are classified as "serious." Serious reports include all adverse events resulting in death, life-threatening illness, hospitalization or prolongation of hospitalization, permanent disability, or congenital anomaly/birth defect. VAERS staff may also request follow-up medical records on adverse events of specific interest, like anaphylaxis.

9. What happens when a death is reported to VAERS

When a death following vaccination is reported to VAERS, CDC requests medical records about the person's death, including an autopsy report (if available) from medical authorities, as well as a death certificate and other relevant medical records. Physicians in the CDC's Immunization Safety Office review all reports of death following COVID-19 vaccination. CDC routinely analyzes death reports in a systematic way to detect unusual or unexpected patterns. This analysis is done through individual report reviews and reviews of records, analysis of automated data, and disproportionality analyses in the VAERS database. VAERS scientists do **not** routinely reach out to the individuals or family members who submitted the report. There is no expectation of state or local health departments to conduct investigations into reported deaths after vaccination.

10. How CDC reports potential vaccine safety issues

CDC regularly presents COVID-19 vaccine safety updates to the Advisory Committee on Immunization Practices (ACIP) and publishes the latest vaccine safety findings in medical literature, including the *Morbidity and Mortality Weekly Report (MMWR)*. You can learn more about COVID-19 vaccine safety monitoring. Also see CDC's clinical resources for COVID-19 vaccines. Additionally, VAERS data with patient identifiers removed are available to the public at HHS VAERS Data.