12 Things States Need to Know about the Vaccine Adverse Event Reporting System (VAERS)

The federal government takes all reports of vaccine adverse events seriously, and CDC and the U.S. Food and Drug Administration (FDA) are actively engaged in safety monitoring of COVID-19 vaccines. CDC uses numerous vaccine safety monitoring systems, including VAERS, to watch for adverse events (possible side effects) after vaccination.

Q. What is the Vaccine Adverse Event Reporting System?

After a vaccine has been authorized or approved by the FDA, post-approval monitoring using VAERS begins. VAERS is a national system used by FDA and CDC to collect reports of adverse events that happen after vaccination. VAERS can provide vaccine safety experts with valuable information to assess possible safety concerns. VAERS is especially useful for quickly detecting unusual or unexpected patterns of adverse event reporting that might signal a possible safety problem with a vaccine.

Q. Who can report post-vaccination adverse events to VAERS?

Anyone can submit a report to VAERS. Healthcare professionals, health departments, vaccine manufacturers, vaccine recipients, and parents or family members of people who have received a vaccine are encouraged to submit a VAERS form if they experience any adverse events after getting any vaccine.

Q. What do CDC and FDA do when a VAERS report is submitted?

Experts from CDC and FDA monitor VAERS reports to identify adverse events that need to be studied further. All serious reports are reviewed daily by vaccine safety experts. Scientists at CDC and FDA use statistical models to help understand whether there are any safety signals for a vaccine product and compare them with safety signals for other vaccines to determine if further investigation is needed.

Helpful Hints for States:

- Work with your communications team when considering developing statements about reporting adverse events after COVID-19 vaccination.

- Each state has a vaccine safety coordinator who can serve as a liaison with local health departments, providers, and partners on vaccine safety issues.

- CDC staff is available to provide state and local health departments with technical support and communications around adverse events after COVID-19 vaccination.

- Contact COVID19VaxSafety@cdc.gov to reach CDC for non-urgent matters. For urgent matters, call **(770) 488-7100** to reach the CDC Emergency Operations Center.

Q. When does CDC follow up on reports submitted to VAERS?

VAERS staff obtains follow-up medical records for reports classified as serious. A serious report describes an event that resulted in permanent disability, hospitalization, life-threatening illness, or death. VAERS staff may also obtain follow-up medical records for adverse events of interest, like anaphylaxis. Reviewing these records can help CDC and FDA medical staff better understand cases.

www.cdc.gov/coronavirus/vaccines

Q. Will CDC follow up with people who submit VAERS reports?

The person who submits a VAERS report will receive a confirmation that VAERS has received the report or a reminder if important information was left out of the initial report. If additional information is needed, CDC may reach out to healthcare providers relevant to the case.

Q. What happens when a death is reported to VAERS?

When a death is reported to VAERS, CDC obtains medical records about the person's death, including an autopsy report, if available. If no autopsy was performed, CDC will obtain a death certificate and other relevant medical records. VAERS scientists will **not** reach out to the person who submitted the report, unless the name of the hospital or vaccination provider is **not** included.

Q: Do CDC and FDA provide VAERS reporters with an assessment following reports of serious adverse events, including death?

No. One of the limitations of VAERS is that VAERS generally cannot assess causality. However, as a hypothesis-generating system, VAERS is valuable for identifying potential vaccine safety concerns that can be studied further.

Q. Who are vaccine safety coordinators?

Vaccine safety coordinators are public health officials at jurisdiction health departments that serve as CDC's "eyes and ears" on vaccine safety issues and coordinate with CDC on incident response. They also serve as primary educators for vaccine safety reporting at the state and local level and coordinate local efforts to report vaccine adverse events to VAERS.

Q. What information from VAERS does CDC make available to vaccine safety coordinators each week?

Each week, CDC makes available via Epi-X a summary of VAERS reports received within the jurisdiction in the last week and a summary of VAERS data from other jurisdictions. CDC also sends a daily email notification whenever VAERS receives death reports from the jurisdiction. These reports are available via Epi-X.

Q. Do we need to follow up on VAERS reports filed in our jurisdiction?

Public health jurisdiction staff does **not** need to follow up on VAERS reports. VAERS staff will routinely follow up to obtain medical records for all reports of serious adverse events or death.

Q. When should we consider contacting CDC about COVID-19 vaccine adverse event reports?

Vaccine safety coordinators, immunization program managers, and other health department staff are welcome to contact CDC about vaccine safety issues at any time. Consider contacting CDC about:

- Unusual or unexpected vaccine adverse event reports
- Clusters of adverse events
- Vaccine administration errors
- Events that may impact public confidence in vaccination programs
- CDC laboratory and/or pathology support
- Requests for investigation by high-ranking state or local health officials
- Adverse event reports that may generate an increased level of media attention

Q. How can we contact CDC if there is an emergency relating to COVID-19 vaccine safety?

For public health emergencies, jurisdictions and providers may call the CDC Emergency Operations Center at **(770) 488-7100**.

For non-urgent concerns, jurisdictions and providers may email covid19vaxsafety@cdc.gov. For medical emergencies call **911**.