Vaccine Adverse Event Reporting System (VAERS)

Important Things To Know About VAERS

- VAERS is an early warning system used to monitor adverse events that happen after vaccination. VAERS is the frontline system of a comprehensive vaccine safety monitoring program in the United States. It is one of several systems CDC and the US Food and Drug Administration (FDA) use to help ensure all vaccines, including COVID-19 vaccines, are safe.
- VAERS gives vaccine safety experts valuable information so they can assess possible safety concerns related to vaccines, including new COVID-19 vaccines. It is especially useful for quickly detecting unusual or unexpected patterns of health problems (also called “adverse events”) that might indicate a possible safety problem with a vaccine.
- If a health problem is reported to VAERS, that doesn’t mean that the vaccine caused the problem. It warns vaccine safety experts of potential problems that may need investigation and alerts them to take further action, as needed.
- Millions of people in the United States have received COVID-19 vaccines. Other than rare reports of severe allergic reactions, analysis of VAERS reports has not detected any patterns that would indicate a safety problem with COVID-19 vaccines.

How reports come into VAERS

VAERS collects reports of possible adverse events that happen after vaccination. As a condition of a vaccine’s use under Emergency Use Authorization, the FDA requires healthcare professionals to report to VAERS certain adverse events

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that occur after COVID-19 vaccination.

However, anyone can submit a report to VAERS

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, including patients, family members, healthcare providers, and vaccine manufacturers, even if it isn’t clear if the vaccine caused the health problem.

How VAERS reports are reviewed

Vaccine safety experts review all reports of serious adverse events submitted to VAERS. A serious adverse event after vaccination is something that causes

- Permanent disability

- Hospitalization or an extended hospital stay (if vaccinated while in the hospital)
- Life-threatening illness
- Birth defects (congenital anomalies)
- Death

When VAERS staff members investigate a report of a serious adverse event, they ask for the patient's medical records related to the serious adverse event to learn more about what happened. They review these medical records and determine whether the vaccine caused the reported serious adverse event.

If vaccine safety experts find a connection between a serious adverse event and a vaccine, FDA and the vaccine manufacturer will work to find an appropriate solution to address the specific safety concern.

VAERS reports are available to the public but do not include any information that could identify the person. The medical records associated with VAERS reports of serious adverse events are sealed to protect patient privacy.

VAERS limitations

Because VAERS allows anyone to report possible side effects from vaccines, it includes reports that might or might not be caused by vaccines. VAERS is not designed to identify cause and effect. 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.

Also, VAERS is used only for monitoring adverse events. It does not provide medical advice.

Learn more about how VAERS is used to monitor vaccine safety.