Vaccine Safety Systems

AUGUST 7, 2024

About the Vaccine Adverse Event Reporting System (VAERS)

AT A GLANCE

- The Vaccine Adverse Event Reporting System (VAERS) is one of several different systems CDC uses to monitor the safety of vaccines.
- VAERS accepts and analyzes reports of adverse events (any side effect or health problem after vaccination that is concerning to you, even if you are not sure if the vaccine caused the event).
- Anyone — patients, family members, healthcare providers and vaccine manufacturers — can submit a report to VAERS. Healthcare providers and vaccine manufacturers are legally required to report certain events after vaccination.
- A report to VAERS does not mean that a vaccine caused an adverse event.
- If it looks as though a vaccine might be associated with a health problem, CDC and FDA investigate further and take action if needed.

Overview

The Vaccine Adverse Event Reporting System (VAERS) is the nation's early warning system that monitors the safety of FDA-approved vaccines and vaccines authorized for use for public health emergencies. The system accepts and analyzes reports of possible adverse events after vaccination and is co-managed by CDC and FDA. The number of reports submitted varies each year. VAERS accepts reports regardless of seriousness or how likely the vaccine may have caused the adverse event.

A report to VAERS does not mean the vaccine caused the event.

A VAERS report alone does not indicate whether a vaccine caused or contributed to an adverse event. Only scientists and public health professionals can make this determination after thorough investigation.

Most VAERS reports involve mild side effects such as fever, arm soreness or mild irritability. Federal law defines reports of certain adverse events as serious reports. These include reports of the following after vaccination:

- Permanent disability.
- Hospitalization.
- Extension of an existing hospitalization.
- Life-threatening illness.
- Congenital (present at birth) deformity/birth defect.
- Death.

VAERS staff attempt to collect additional information from healthcare providers and clinicians about adverse events described in serious reports. While serious adverse events can happen after vaccination, they are rarely caused by the vaccine.

Report an adverse event to VAERS

Anyone can submit a report to VAERS. Learn more about which adverse events to report and how to report them.

VAERS: Access and Use

What data VAERS collects

- The type of vaccine received.

- The date of vaccination.
- When the adverse event began.
- Current illnesses and medications.
- Medical history.
- Past history of adverse events following vaccination.
- Demographic information.

How data collection works

VAERS is a passive surveillance system, meaning it relies on people sending in reports of their experiences after vaccination.

Keep Reading:
About CDC's Vaccine Safety Monitoring Program

How the data are used

CDC and FDA use VAERS reports to:

- Assess the safety of newly licensed or authorized vaccines.
- Detect new, unusual or rare adverse events that happen after vaccination.
- Monitor increases in known side effects, like arm soreness where a shot was given.
- Identify potential patient risk factors for particular types of health problems related to vaccines.
- Identify and address possible reporting clusters.
- Recognize safe-use problems and administration errors.
- Watch for unexpected or unusual patterns in adverse event reports.
- Serve as a vaccine safety monitoring system in public health emergencies.
- Add to and improve scientific literature and understanding of vaccine safety monitoring.

Signals

Patterns or an unusually high number of adverse events reported for a vaccine are called "signals." If they detect a signal, scientists may conduct further studies in VSD or CISA to find out if it represents an actual risk. CDC and FDA investigate further and act if needed.

Strengths and limitations of VAERS data

When evaluating VAERS data, it is important to understand the strengths and limitations.

Strengths

- VAERS accepts reports from anyone. This also allows VAERS to act as an early warning system to detect rare adverse events.
- VAERS collects information about the vaccine, the person vaccinated, and the adverse event. Scientists obtain follow-up information on serious reports.
- All data from the initial VAERS report (without identifying patient information) are available to the public.

Limitations

- VAERS is a passive reporting system, meaning that reports about adverse events are not automatically collected. Instead, someone who had or is aware of an adverse event following vaccination must file a report.
- Anyone can submit VAERS reports. Some reports can lack details or contain errors. After investigation, scientists find that most events reported to VAERS are not associated with vaccination.
- The number of reports submitted to VAERS can change in response to media attention and public awareness. Such changes in reporting can complicate interpretation of VAERS data.

- When more people hear about vaccine side effects, they may report any health outcomes they experience after vaccination.
- This increase in reporting can complicate detecting patterns of adverse events that should be further assessed in a strong, reliable data analysis system.
- Such increased reporting can also create the misconception that vaccines are dangerous, leading to fear and hesitation about vaccination.

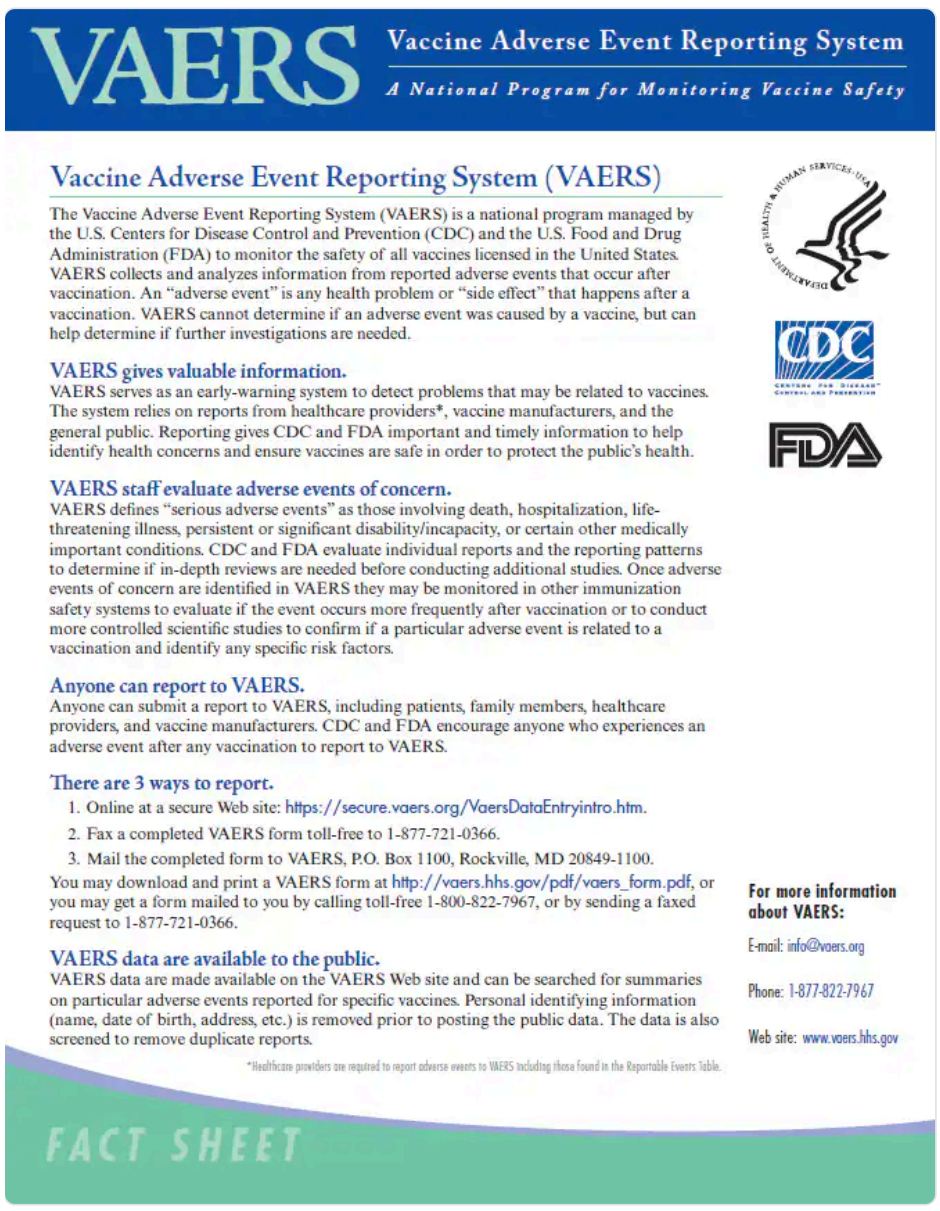
- It is usually not possible to use VAERS data to calculate how often an adverse event occurs in a population.
  - The number of people receiving a vaccine is usually not available (a notable exception was during the COVID-19 public health emergency when the number of doses of COVID-19 vaccine administered was reliably reported to CDC).
- **VAERS data alone cannot determine if the vaccine caused the reported adverse event**. Establishing a causal relationship requires rigorous scientific assessment and consideration of multiple factors beyond just VAERS reports alone.

A report to VAERS does not mean the vaccine caused the event

VAERS accepts all reports of adverse events following vaccination without judging whether the vaccine caused the adverse event. Some VAERS reports might represent true vaccine reactions or side effects; others might be coincidental adverse events not related to vaccination.
This limitation has caused confusion about the publicly available data.

Resources

Research articles using VAERS data



VAERS Vaccine Adverse Event Reporting System
A National Program for Monitoring Vaccine Safety

Vaccine Adverse Event Reporting System (VAERS)

The Vaccine Adverse Event Reporting System (VAERS) is a national program managed by the U.S. Centers for Disease Control and Prevention (CDC) and the U.S. Food and Drug Administration (FDA) to monitor the safety of all vaccines licensed in the United States. VAERS collects and analyzes information from reported adverse events that occur after vaccination. An "adverse event" is any health problem or "side effect" that happens after a vaccination. VAERS cannot determine if an adverse event was caused by a vaccine, but can help determine if further investigations are needed.

VAERS gives valuable information.
VAERS serves as an early-warning system to detect problems that may be related to vaccines. The system relies on reports from healthcare providers*, vaccine manufacturers, and the general public. Reporting gives CDC and FDA important and timely information to help identify health concerns and ensure vaccines are safe in order to protect the public's health.

VAERS staff evaluate adverse events of concern.
VAERS defines "serious adverse events" as those involving death, hospitalization, life-threatening illness, persistent or significant disability/incapacity, or certain other medically important conditions. CDC and FDA evaluate individual reports and the reporting patterns to determine if in-depth reviews are needed before conducting additional studies. Once adverse events of concern are identified in VAERS they may be monitored in other immunization safety systems to evaluate if the event occurs more frequently after vaccination or to conduct more controlled scientific studies to confirm if a particular adverse event is related to a vaccination and identify any specific risk factors.

Anyone can report to VAERS.
Anyone can submit a report to VAERS, including patients, family members, healthcare providers, and vaccine manufacturers. CDC and FDA encourage anyone who experiences an adverse event after any vaccination to report to VAERS.

There are 3 ways to report.
1. Online at a secure Web site: https://secure.vaers.org/VaersDataEntryintro.htm.
2. Fax a completed VAERS form toll-free to 1-877-721-0366.
3. Mail the completed form to VAERS, P.O. Box 1100, Rockville, MD 20849-1100.

You may download and print a VAERS form at http://vaers.hhs.gov/pdf/vaers_form.pdf, or you may get a form mailed to you by calling toll-free 1-800-822-7967, or by sending a faxed request to 1-877-721-0366.

VAERS data are available to the public.
VAERS data are made available on the VAERS Web site and can be searched for summaries on particular adverse events reported for specific vaccines. Personal identifying information (name, date of birth, address, etc.) is removed prior to posting the public data. The data is also screened to remove duplicate reports.

*Healthcare providers are required to report adverse events to VAERS including those found in the Reportable Events Table.

For more information about VAERS:

E-mail: info@vaers.org

Phone: 1-877-822-7967

Web site: www.vaers.hhs.gov

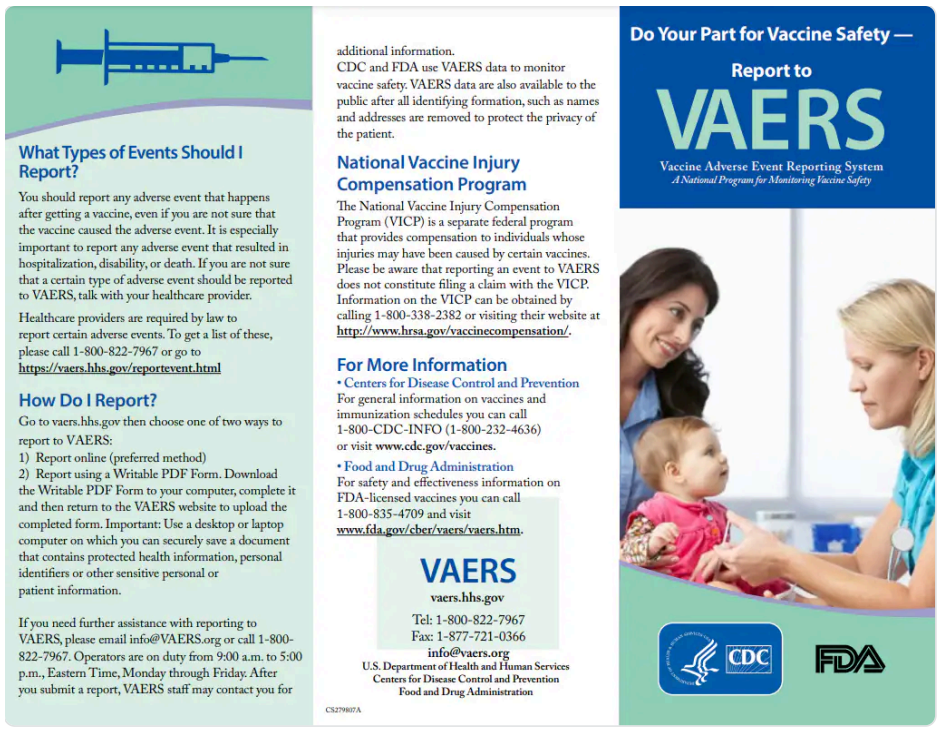
FACT SHEET

Vaccine Adverse Event Reporting System (VAERS) Fact Sheet with logos PDF

What is VAERS, who can submit reports, and more.

JULY 14, 2024

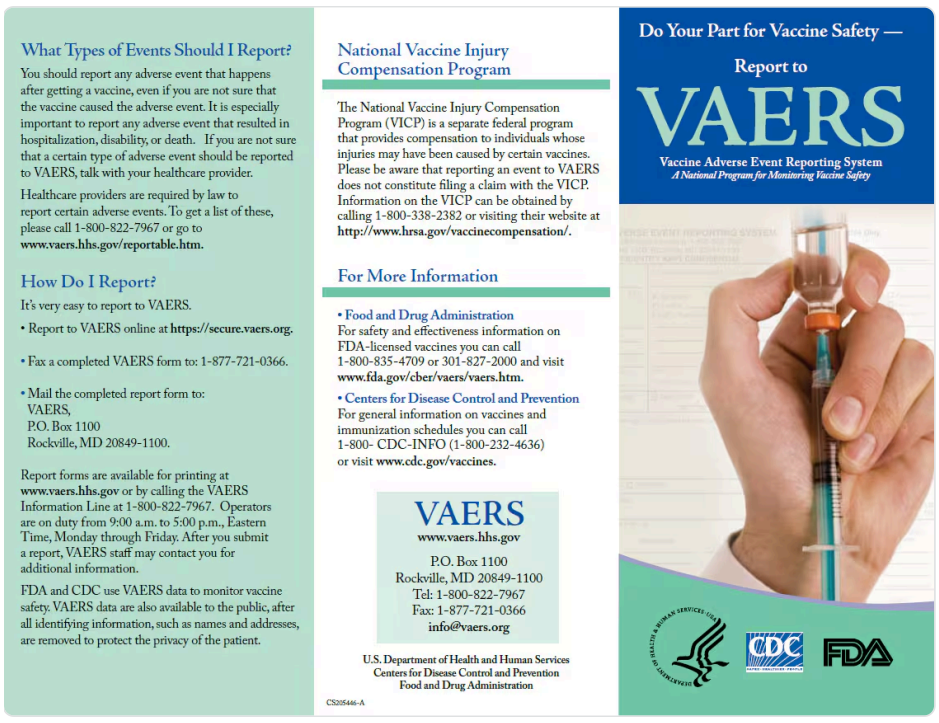
Download PDF



VAERS Brochure for Parents and Caregivers

VAERS information for parents and caregivers in English and Spanish.

AUG. 5, 2024



VAERS Brochure for Healthcare Providers

VAERS information for healthcare providers in English and Spanish.

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SOURCES

CONTENT SOURCE:

National Center for Emerging and Zoonotic Infectious Diseases (NCEZID)