

What Types of Events Should I Report?

You should report any adverse event that happens after getting a vaccine, even if you are not sure that the vaccine caused the adverse event. It is especially important to report any adverse event that resulted in hospitalization, disability, or death. If you are not sure that a certain type of adverse event should be reported to VAERS, talk with your healthcare provider.

Healthcare providers are required by law to report certain adverse events. To get a list of these, please call 1-800-822-7967 or go to <http://www.vaers.hhs.gov/reportable.htm>.

How Do I Report?

It's very easy to report to VAERS.

- Report to VAERS online at <https://secure.vaers.org>.
- Fax a completed VAERS form to: 1-877-721-0366.
- Mail the completed report form to:
VAERS,
P.O. Box 1100
Rockville, MD 20849-1100.

Report forms are available for printing at <http://www.vaers.hhs.gov> or by calling the VAERS Information Line at 1-800-822-7967. Operators are on duty from 9:00 a.m. to 5:00 p.m., Eastern Time, Monday through Friday. After you submit a report, VAERS staff may contact you for additional information.

FDA and CDC use VAERS data to monitor vaccine safety. VAERS data are also available to the public, after all identifying information, such as names and addresses, are removed to protect the privacy of the patient.

National Vaccine Injury Compensation Program

The National Vaccine Injury Compensation Program (VICP) is a separate federal program that provides compensation to individuals whose injuries may have been caused by certain vaccines. Please be aware that reporting an event to VAERS does not constitute filing a claim with the VICP. Information on the VICP can be obtained by calling 1-800-338-2382 or visiting their website at <http://www.hrsa.gov/vaccinecompensation/>.

For More Information

• Food and Drug Administration

For safety and effectiveness information on FDA-licensed vaccines you can call 1-800-835-4709 or 301-827-2000 and visit <http://www.fda.gov/cber/vaers/vaers.htm>.

• Centers for Disease Control and Prevention

For general information on vaccines and immunization schedules you can call 1-800- CDC-INFO (1-800-232-4636) or visit <http://www.cdc.gov/vaccines>.

VAERS

<http://www.vaers.hhs.gov>

P.O. Box 1100
Rockville, MD 20849-1100
Tel: 1-800-822-7967
Fax: 1-877-721-0366
info@vaers.org

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention
Food and Drug Administration

CS205446-A

Do Your Part for Vaccine Safety —

Report to

VAERS

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





Limitation and Usefulness of VAERS

VAERS is unable to determine that a vaccine caused or did not cause an adverse event. Sometimes people who are vaccinated get sick from another cause unrelated to the vaccine.

Even though VAERS cannot determine that a vaccine caused an adverse event, it can give FDA and CDC important information that might signal a problem. If it looks as though a vaccine might be causing an adverse event, FDA and CDC will investigate further.



What is VAERS?

The Vaccine Adverse Event Reporting System (VAERS) is a national program that monitors the safety of vaccines after they are licensed. VAERS is managed by the U.S. Centers for Disease Control and Prevention (CDC) and the U.S. Food and Drug Administration (FDA).

Vaccines prevent serious illnesses and even death in persons who receive them. Before a vaccine is licensed, FDA takes steps to make sure the vaccine is safe. FDA requires that a vaccine goes through extensive safety testing. After a vaccine is licensed, VAERS is one of the mechanisms used to monitor for any problems, or “adverse events,” that happen after vaccination.

Not all events reported to VAERS are caused by the vaccine. Even though careful studies are done before a vaccine is licensed, rare adverse effects may not be found until a vaccine is given to millions of people with different backgrounds and medical histories. By continued monitoring, VAERS helps to make sure that the benefits of vaccines are far greater than the risks.

Anyone who receives a vaccine should be informed about both the benefits and risks of vaccination. Any questions or concerns should be discussed with a healthcare provider.



Does VAERS Provide Medical Advice?

No, VAERS does not provide medical advice. For medical advice, please contact your healthcare provider or state health department.

Who Can Report to VAERS?

- Parents
- Patients
- Healthcare Providers
- Others

FDA and CDC encourage anybody who experiences any problems after vaccination to report to VAERS. Healthcare providers are required by law to report certain problems.

Why Should I Report to VAERS?

- Reporting gives valuable information that helps CDC and FDA make sure that vaccines are safe.
- Reporting strengthens VAERS so it can be used to assess public health response to vaccines.
- Reporting allows for evaluating public health prevention and control measures.

Remember, no vaccine (or any medicine) is completely free of risk and adverse events are possible. If you have an adverse event after a vaccine, please report to VAERS. Each report is important!