

Surveillance for Vaccine Adverse Events: Vaccine Adverse Event Reporting System (VAERS)

Background

The Vaccine Adverse Event Reporting System (VAERS) is a national program which collects information about potential adverse events associated with vaccinations for the purpose of monitoring and improving the safety of vaccines which are licensed and used in the United States. The National Childhood Vaccine Injury Act (NCVIA) of 1986 mandated reporting of certain adverse events. The US Department of Health and Human Services created VAERS in 1990. The national database of VAERS reports provides a means for analyzing the occurrence and nature of possible adverse events related to immunizations. The VAERS system is operated jointly by the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA). These agencies monitor VAERS reports to determine if any vaccine or vaccine lot has a higher than expected rate of events and the types of events reported for each vaccine. They watch for associations between vaccines and rare events that may not have been identified during clinical trials. More information on the VAERS program is available at www.vaers.hhs.gov

Adverse events reported to the Vaccine Adverse Event Reporting System (VAERS) are not necessarily side effects caused by vaccination. An **adverse event** is a health problem that happens after vaccination that may or may not be caused by a vaccine. By definition, a **side effect** has been shown to be linked to a vaccine by scientific studies.

Reports to VAERS are potential signals that alert scientists of *possible* cause-and-effect relationships that need to be investigated further through other vaccine safety monitoring initiatives, such as the Vaccine Safety Data Link program. The VAERS program is not able to determine definitive associations and cause-and-effect relationships between vaccines and possible side effects

Content of VAERS Reports – What to report

Any clinically significant adverse event occurring after administration of any vaccine licensed in the US should be reported, even if it is not certain that the event was caused by the vaccine.

Required reports include any event listed in NCVIA [Reportable Event Table](https://vaers.hhs.gov/resources/infoproviders.html) (RET) (<https://vaers.hhs.gov/resources/infoproviders.html>)

as well as any event listed in the package insert as a contraindication to subsequent doses. The Reportable Event Table is subject to periodic change. A copy of the table can also be obtained by calling VAERS at (800) 822-7967. The Reportable Event Table specifically outlines the reportable post-vaccination events and the time frames of events that are reportable by law.

Note regarding reporting of vaccination errors:

VAERS is primarily concerned with monitoring adverse health events and we encourage reporting of clinically significant adverse health events following vaccination. Using clinical judgment, healthcare professionals can decide whether or not to report a medical error at their own discretion. For example, a healthcare professional may elect to report vaccination errors that do not have an associated adverse health event, especially if they think the vaccination error may pose a safety risk (e.g., administering a live vaccine to an immunocompromised patient) or that the error would be preventable with public health action or education.

In addition, reports of **vaccine administration errors** should also be made to the National Vaccine Error Reporting Program of the **Institute for Safe Medication Practices (ISMP)** at <http://verp.ismp.org/>. Examples of vaccine administration errors include wrong dosage, incorrect route, wrong age, wrong vaccine formulation, administration despite a contraindication, etc. ISMP will also securely share error data with the federal Vaccine Adverse Event Reporting System (VAERS) and when applicable, with the FDA and vaccine manufacturers.

Please note that providers should continue to report adverse events occurring after immunizations, whether given correctly or not, to VAERS.

Filing a claim with the **National Vaccine Injury Compensation Program (VICP)** is a separate process from submitting a VAERS report; see [National Vaccine Injury Compensation Program section](#) below for information on contacting the VICP.

Completing and submitting a VAERS report

Anyone may submit VAERS report. Most VAERS reports are submitted by health care providers, vaccine manufacturers, and vaccine recipients (or their parents/guardians). Patients or parents/guardians are encouraged to seek the help of their health care professional in filling out the VAERS form. It is important to fill out the VAERS report as completely as possible. Information about the vaccine (type, manufacturer, lot numbers, site of injection) and the event that occurred are especially important.

Reports can be submitted online, by fax, or by mail.

To report to VAERS online, go to <https://vaers.hhs.gov/esub/index.jsp> and follow the instructions.

To report by fax or mail, download the writable .PDF form from <https://vaers.hhs.gov/uploadFile/index.jsp>, complete it following the instructions provided, save it and then upload it to the VAERS program following the instructions provided.

If you need further assistance with reporting to VAERS, please email info@VAERS.org or call 1-800-822-7967.

National Vaccine Injury Compensation Program (VICP)

The National childhood Vaccine Injury Act of 1986 established the National Vaccine Injury Compensation Program. The program is a Federal “no fault” system designed to compensate those individuals, or families of individuals, who have been injured by childhood vaccines, whether administered in the private or public sector.

As previously mentioned, The VICP is separate from the VAERS program, and reporting an event to VAERS does not file a claim for compensation to the VICP.

Additional information can be obtained by contacting the program directly:

National Vaccine Injury Compensation Program (VICP)
Parklawn Building, Room 11C-26
5600 Fishers Lane
Rockville, Maryland 20857
1-800-338-2382
Internet/Web site: <http://www.hrsa.gov/vaccinecompensation/>

For information on the rules of the U.S. Court of Federal Claims, including requirements for filing a petition, contact:

Clerk
US Court of Federal Claims,
717 Madison Place N.W.
Washington, D.C. 20005
202) 357-6400