

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).

VAERS is part of a larger system that makes sure that vaccines are safe and work as intended. Steps to make sure that vaccines are safe begin before a vaccine is licensed and continue afterward. Before a vaccine is licensed, FDA requires that it go through extensive safety testing. After a vaccine is licensed, VAERS is used to watch for any problems, or "adverse events," that happen after vaccination. Even though careful and complete studies are done before a vaccine is licensed, rare side effects may not be found until a vaccine is given to millions of people with different backgrounds and medical histories. VAERS helps to make sure that the benefits of vaccines continue to be far greater than the risks.

There are things that VAERS cannot do. VAERS cannot prove that a vaccine either did cause or did not cause a problem. In fact, vaccines are not the cause of many of the problems reported to VAERS. Sometimes people who get vaccinated coincidentally will get sick from some other cause—they get a stomachache, cold, or flu—and it has nothing to do with the

vaccine. Rarely, people who have been vaccinated will get unexpected reactions that are serious and should be reported to VAERS.

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

Does VAERS Provide Medical Advice?

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



Who Can Report to **VAERS?**

Anyone can report to VAERS. FDA and CDC encourage patients, parents, and others to

report any significant problems experienced after vaccination, even if they are not certain that a vaccine caused them.

To report a possible problem after vaccination, visit the VAERS web site at www.vaers.hhs.gov. Also see the section in this brochure on "How Do I Report?"





Why Should I Report to VAERS?

Better reporting helps keep vaccines safe for you and your family, and for everyone who receives

vaccinations. Each VAERS report provides valuable information that helps FDA and CDC make sure that vaccines are safe. The more accurate and complete the VAERS reports, the better the system works. Remember, no vaccine (or any medicine) is completely free of risk and some side effects are possible.



What Types of Events Should Be Reported?

You should report any serious problem that happens after getting a vaccine, even if you are not sure that the vaccine caused the problem. It is especially important to report any problem that resulted in hospitalization, disability, or

death. Health care providers are required by law to report certain problems. To get a list of these, please call 800-822-7967 or go to



www.vaers.hhs.gov/reportable.htm or www.hrsa.gov/osp/vicp/table.htm. If you are not sure that a certain type of problem should be reported to VAERS, talk with your health care provider.



How Do I Report?

It's very easy to report to VAERS. After you submit a report, VAERS staff may contact you for follow-up information.

- Internet: Report on-line at secure.vaers.org/VaersDataEntryintro.htm.

 Or print the report form at www.vaers.hhs.gov, and mail or fax the completed form to VAFRS.
- **VAERS Hotline:** Report forms are available by calling 800-822-7967. Operators are on duty from 8:00 a.m. to 6:00 p.m., Eastern Standard Time.
- Fax: Fax the completed report form to 877-721-0366 (toll-free).
- Mail: Mail the completed report form to VAERS, P.O. Box 1100, Rockville, MD, 20849-1100.
- **E-mail:** Send VAERS inquiries to info@vaers.org.

For More Information

- Food and Drug Administration 800-835-4709 or 301-827-1800; www.fda.gov/cber/vaers/vaers.htm. For safety and effectiveness information on FDA-licensed vaccines.
- Centers for Disease Control and Prevention 800-232-2522 (English) or 800-232-0233 (Spanish); www.cdc.gov/nip. For general information on vaccines and immunization schedules.



Everyone has a part to play!

VAERS www.vaers.hhs.gov

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