



Guide to Reporting Adverse Events after Vaccination

The Vaccine Adverse Event Reporting System (VAERS) is the national program that monitors the safety of vaccines after they are licensed and is jointly administered by the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA). FDA and CDC analyze VAERS data to identify potential new vaccine safety concerns that may need further study. The National Childhood Vaccine Injury Act of 1986 mandates that health care providers report specific adverse events that occur after vaccination.

What Types of Events Should I Report?

After a vaccine is licensed, VAERS is one of the mechanisms used to monitor for any problems or “adverse events” that happen after vaccination.

- Please report all adverse events that occur after vaccination of adults and children, even if you are not sure whether the vaccine caused the adverse event.
- Report any adverse event that resulted in hospitalization, disability, or death.
Healthcare providers are required by law to report certain adverse events. To obtain a list of these events, please call 1-800-822-7967 or go to <http://www.vaers.hhs.gov/reportable.htm>. Providers are also encouraged to report adverse events that are not listed in the Table of Reportable Events.
- For seasonal or 2009 H1N1 Monovalent Influenza Vaccines, please report the following medical errors to VAERS:
 - All medical errors that are associated with a clinically significant adverse event after vaccination
 - Administration of live, attenuated vaccine to women in any stage of pregnancy (but not post-partum)
 - Other medical errors associated with live, attenuated vaccine (e.g., administering both seasonal and H1N1 intranasal vaccines on the same day)
 - Other medical errors associated with inactivated influenza vaccines if the healthcare provider has safety concerns

How Do I Report?

It is very easy to report to VAERS. VAERS reports may be reported two ways:

1. Directly to VAERS via the Internet at <http://www.vaers.hhs.gov> by fax at 1-877-721-0366 (toll-free), or by mail at VAERS, P.O. Box 1100, Rockville, MD, 20849-1100
2. Directly to the Texas DSHS via fax at:1-866-624-0180 (toll-free), or by mail at: DSHS, Immunization Branch, MC 1946, P.O. Box 149347, Austin, TX 78714-9347

A VAERS report form may be downloaded from the VAERS web site at <http://www.vaers.hhs.gov>. Alternatively, you may request a VAERS form by sending an email to info@vaers.org, by calling toll-free 800-822-7967, or by sending a faxed request to 877-721-0366.

VAERS report forms are also available for printing at www.dshs.state.tx.us/immunize/docs/c-76.pdf or by calling the Department of State Health Services, Immunization Branch Information Line at (800) 252-9152. After you submit a report, a staff member may contact you for additional information.

Important note: CDC and FDA do not provide individual medical treatment, advice, or diagnosis. If you need individual medical or health care advice, consult a qualified health care provider.

Additional VAERS information may be obtained at the following links:

DSHS at: www.ImmunizeTexas.com

VAERS at: <http://vaers.hhs.gov/>

FDA at: <http://www.fda.gov/cber/vaers/vaers.htm>

CDC Vaccine Safety at: <http://www.cdc.gov/vaccinesafety/>

Vaccine Safety and Adverse Events at: <http://www.cdc.gov/vaccines/vac-gen/safety/default.htm>

National Vaccine Injury Compensation Program (VICP): <http://www.hrsa.gov/vaccinecompensation/>