

Physician's Guide to the Vaccine Adverse Event Reporting System (VAERS)

What is VAERS? The Vaccine Adverse Event Reporting System (VAERS) is a national program that collects information about adverse events following vaccinations for the purpose of monitoring vaccine safety in the United States. Adverse events are defined as health effects that occur after vaccination that may or may not be related to the vaccine. The National Childhood Vaccine Injury Act (NCVIA) of 1986 mandated the reporting of certain adverse events, and VAERS was created in 1990 to provide a database management system for the collection and analysis of these reports. It is operated jointly by the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA). These agencies monitor VAERS data to detect previously unknown adverse events or increases in known adverse events for each vaccine and each lot number.

How do you report? Reports should be made on a VAERS form or submitted electronically through the VAERS web site at <https://secure.vaers.org/VaersDataEntryintro.htm>. The forms are pre-addressed and postage-paid and may be photocopied. Events associated with privately purchased vaccine should be reported directly to VAERS. Contact (800) VAC-RXNS for forms and information, or print a VAERS form from the VAERS web site at http://vaers.hhs.gov/pdf/vaers_form.pdf. All requested information should be recorded. The vaccine manufacturer, lot number, and injection site are very important. The VAERS form also requests the type of vaccine received, the timing of vaccination and onset of the adverse event, a description of the event, current illnesses or medication, past history of adverse events following vaccination, and demographic information about the recipient (age, gender, etc.). In Texas, reports of events following vaccination at public health clinics or with vaccine provided through public funding such as the Texas Vaccines for Children (TVFC) program may be reported through the **Texas Department of State Health Services, Immunization Branch MC-1946, P.O. Box 149347, Austin, TX 78714-9347**. Forms with this address can be obtained by calling the Immunization Branch at (800) 252-9152.

What should be reported? Report all clinically significant adverse events occurring after administration of any vaccine. Required reports include events listed in NCVIA Reportable Event Table and any event listed in the package insert as a contraindication to subsequent doses. A current Reportable Event Table is attached. For periodic updates see <http://vaers.hhs.gov/reportable.htm>, or call VAERS at (800) 822-7967. However, required reports cover known vaccine-associated adverse events. For VAERS to be an effective discovery tool, all significant events must be reported. This is especially important for newly licensed vaccines that may not be included in the table yet. A report to VAERS is not documentation that a vaccine caused the event.

How can I assure complete and accurate VAERS reporting?

Educate patients using a current Vaccine Information Statement (VIS). Information about what to do if they experience a moderate or severe reaction is included in each VIS statement, including information about VAERS. Encourage patients to call you if they experience problems.

Record complete information for each vaccine in the patient's chart: date given, site and route of administration; manufacturer and lot number; name of person who administered the vaccine; address where vaccine was given (or where medical record resides); and the revision date of the VIS used. Use the most recent version of each VIS. You can check dates and print copies at <http://www.cdc.gov/vaccines/pubs/vis/default.htm>. VIS are available in foreign languages at <http://www.immunize.org/vis>.

Record a description of the adverse event in the patient's medical history and any follow-up information. Assess the event for vaccine contraindications, and advise the patient.

Why should I report to VAERS? The effectiveness of a national surveillance system is directly dependent on the participation of health professionals. VAERS provides vital information of clinical importance. Trends in VAERS surveillance data initiate further investigation of potential problems in vaccine safety or efficacy. Complete reporting of post-vaccination events supplies public health professionals with the information they need to ensure the safest strategies of vaccine administration. The process is dependent on voluntary submission of reports of possible vaccine-associated events to VAERS by physicians and health professionals.

For more information visit: DSHS at http://www.dshs.state.tx.us/immunize/safety/vac_safety.shtm, VAERS at <http://vaers.hhs.gov/>, FDA at <http://www.fda.gov/cber/vaers/vaers.htm>, or CDC at http://www.cdc.gov/od/science/iso/about_iso.htm.