VAERS, VERP and MedWatch

Report Immunization Adverse Events & Administration Errors

Reporting information to these national surveillance systems helps ensure patient safety.

Vaccine Adverse Event Reporting System (VAERS)

Providers must report clinically significant adverse events to VAERS.

VAERS collects information about reactions and possible side effects that occur after a vaccine is administered. Reactions may happen immediately or hours, days or even weeks after vaccination. Report a reaction even if you aren't sure that it was caused by a vaccine.

Examples of reactions or side effects:

- Fever, local reactions or other illnesses
- Rare serious reactions, hospitalizations, disability or death

Your report can help identify and assess

- risk factors for particular types of adverse events,
- vaccine lots with increased numbers of reported adverse events and
- safety of new vaccines.

Where to report adverse events: **VAERS website** (vaers.hhs.gov)

Vaccine Error Reporting Program (VERP)

VERP collects information about preventable vaccine administration errors. These types of errors may make vaccines ineffective, leaving patients unprotected. Report any errors even if the vaccine was not given to a patient.

Examples of administration errors:

- Incorrect dose
- Wrong or expired product
- Wrong administration site

Your report can help advocate for changes in

- labeling
- packaging and
- administration procedures.

Where to report vaccine administration errors: **Institute for Safe Medication Practices** (ismp.org/form/verp-form)

MedWatch

Providers must report all suspected adverse reactions for VFC monoclonal antibody immunizing products (e.g., nirsevimab/Beyfortus and clesrovimab/Enfonsia) to MedWatch when not co-administered with other vaccines.

Health Professionals, consumers and patients can voluntarily report observed or suspected adverse events for human medical products to FDA.

Report a reaction even if you are not sure that it was caused by a drug. Report any errors even if the drug was not given to a patient.

Examples of adverse reactions:

- Unexpected side effects or adverse events can include everything from skin rashes to more serious complications.
- Product quality problems such as information about a product that isn't working properly or if it has a defect.
- Product use/medication errors that can be prevented; these can be caused by various issues, including choosing the wrong product because of labels or packaging that look alike or have similar brand or generic names.
- Mistakes also can be caused by difficulty with a device due to hard-to-read controls or displays, which may cause you to record a test result that is not correct.

Your report can help FDA by

- identifying unknown risks for approved medical products and
- providing timely new safety information on human drugs, medical devices, vaccines, and other biologics.

Where to report suspected adverse reactions: MedWatch Online Voluntary Reporting Form (https://www.accessdata.fda.gov/scripts/medwatch/index.cfm)