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)

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

Examples:

- 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
- Safety of new vaccines

Report adverse events to the 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:

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

Your report can help advocate for changes in:

- Vaccine names
- Packaging and labelling
- Other modifications that could reduce the likelihood of vaccine

Report vaccine administration errors to the Institute for Safe Medication Practices
(ismp.org/form/verp-form)

VAERS, VERP, and MedWatch continued

MedWatch:

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. Adverse reactions to nirsevimab/Beyfortus™ would be reported through MedWatch.

Examples of adverse reactions are:

- Unexpected side effects or adverse events can include everything from skin rashes to more serious complications.
- Product quality problems such as information if a product 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 risk for approved medical products.
- Providing timely new safety information on human drugs, medical devices, vaccines, and other biologics.

Report nirsevimab/Beyfortus™ adverse events and immunization errors to the MedWatch reporting Form (accessdata.fda.gov/scripts/medwatch/index.cfm)