

The Vaccine Adverse Event Reporting System (VAERS)

VAERS is a national post-licensure vaccine safety monitoring program co-managed by the Centers for Disease Control and Prevention (CDC) and the U.S. Food and Drug Administration (FDA). VAERS collects and analyzes information from reports of adverse events following receipt of U.S.-licensed vaccines. In recent years, VAERS has received approximately 40,000 U.S. reports annually, most of which describe mild adverse events like fever and injection site reactions. Very rarely, people experience serious adverse events following immunization. By monitoring such events, VAERS can help to identify important new safety concerns.

VAERS is a spontaneous reporting system, meaning that reports about adverse events can be submitted voluntarily by anyone. VAERS has limitations; data may, and often do, include incorrect and incomplete information. Underreporting and failure to report events occurs as well. Serious medical events are more likely to be reported than minor ones. Importantly, VAERS generally cannot determine cause and effect. A report to VAERS does not indicate that a vaccine caused an adverse event, only that the adverse event occurred sometime after vaccination. VAERS accepts all reports without judging the clinical seriousness of the adverse event or whether it was caused by the vaccine. More information on VAERS data can be found at:

<https://vaers.hhs.gov/data/dataguide.html>

WHO CAN REPORT? Anyone can submit a VAERS report. Most reports are sent in by vaccine manufacturers and health care providers, but vaccine recipients, parents, and others may also submit reports.

WHAT SHOULD BE REPORTED? VAERS encourages reporting of any clinically significant adverse event that occurs after the administration of any vaccine licensed in the United States.

The National Childhood Vaccine Injury Act of 1986 requires health care providers to report:

- Any health event listed by the vaccine manufacturer as a contraindication to subsequent doses of the vaccine
- Any event listed in the Reportable Events Table that occurs within the specified time period after the vaccination.

A copy of the Reportable Events Table can be found on the following page, or at

https://vaers.hhs.gov/docs/VAERS_Table_of_Reportable_Events_Following_Vaccination.pdf

HOW TO REPORT? There are two ways to report to VAERS:

- **Online.** Submit a VAERS report using the online reporting tool at <https://vaers.hhs.gov/esub/index.jsp>. Before you begin, review the Checklist for Completing the VAERS form at <https://vaers.hhs.gov/reportevent.html>. Information submitted using the online reporting tool is transmitted securely to VAERS.
- **Writable PDF Form.** Download the writable PDF form (located at <https://vaers.hhs.gov/uploadFile/index.jsp>) to your computer, complete it and then return to the VAERS website to upload the completed form. It is important that you use a desktop or laptop computer on which you can securely save a document that contains protected health information, personal identifiers or other sensitive personal or patient information. When you upload the form, the information is transmitted securely to VAERS.

If you need further assistance with reporting to VAERS, please email info@vaers.org or call 1-800-822-7967. Operators are on duty from 9:00 a.m. to 5:00 p.m., Eastern Time, Monday through Friday.

For more information, visit the VAERS website at <https://vaers.hhs.gov/>

VAERS Table of Reportable Events Following Vaccination*

Vaccine/Toxoid	Event and Interval from Vaccination
Tetanus in any combination: DTaP, DTP, DTP-Hib, DT, Td, TT, Tdap, DTaP-IPV, DTaP-IPV/Hib, DTaP-HepB-IPV	<p>A. Anaphylaxis or anaphylactic shock (7 days)</p> <p>B. Brachial neuritis (28 days)</p> <p>C. Shoulder Injury Related to Vaccine Administration (7 days)</p> <p>D. Any acute complications or sequelae (including death) of above events (interval - not applicable)</p> <p>E. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)</p>
Pertussis in any combination: DTaP, DTP, DTP-Hib, Tdap, DTaP-IPV, DTaP-IPV/Hib, DTaP-HepB-IPV	<p>A. Anaphylaxis or anaphylactic shock (7 days)</p> <p>B. Encephalopathy or encephalitis (7 days)</p> <p>C. Shoulder Injury Related to Vaccine Administration (7 days)</p> <p>D. Vasovagal syncope (7 days)</p> <p>E. Any acute complications or sequelae (including death) of above events (interval - not applicable)</p> <p>F. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)</p>
Measles, mumps and rubella in any combination: MMR, MMRV, MM	<p>A. Anaphylaxis or anaphylactic shock (7 days)</p> <p>B. Encephalopathy or encephalitis (15 days)</p> <p>C. Shoulder Injury Related to Vaccine Administration (7 days)</p> <p>D. Vasovagal syncope (7 days)</p> <p>E. Any acute complications or sequelae (including death) of above events (interval - not applicable)</p> <p>F. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)</p>
Rubella in any combination: MMR, MMRV	<p>A. Chronic arthritis (42 days)</p> <p>B. Any acute complications or sequelae (including death) of above event (interval - not applicable)</p> <p>C. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)</p>
Measles in any combination: MMR, MMRV, MM	<p>A. Thrombocytopenic purpura (7-30 days)</p> <p>B. Vaccine-strain measles viral infection in an immunodeficient recipient</p> <ul style="list-style-type: none"> • Vaccine-strain virus identified (interval - not applicable) • If strain determination is not done or if laboratory testing is inconclusive (12 months) <p>C. Any acute complications or sequelae (including death) of above events (interval - not applicable)</p> <p>D. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)</p>
Oral Polio (OPV)	<p>A. Paralytic polio</p> <ul style="list-style-type: none"> • in a non-immunodeficient recipient (30 days) • in an immunodeficient recipient (6 months) • in a vaccine-associated community case (interval - not applicable) <p>B. Vaccine-strain polio viral infection</p> <ul style="list-style-type: none"> • in a non-immunodeficient recipient (30 days) • in an immunodeficient recipient (6 months) • in a vaccine-associated community case (interval - not applicable) <p>C. Any acute complication or sequelae (including death) of above events (interval - not applicable)</p> <p>D. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)</p>
Inactivated Polio in any combination: IPV, DTaP-IPV, DTaP-IPV/Hib, DTaP-HepB-IPV	<p>A. Anaphylaxis or anaphylactic shock (7 days)</p> <p>B. Shoulder Injury Related to Vaccine Administration (7 days)</p> <p>C. Vasovagal syncope (7 days)</p> <p>D. Any acute complication or sequelae (including death) of above events (interval - not applicable)</p> <p>E. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)</p>
Hepatitis B in any combination: HepB, HepA-HepB, DTaP-HepB-IPV, Hib-HepB	<p>A. Anaphylaxis or anaphylactic shock (7 days)</p> <p>B. Shoulder Injury Related to Vaccine Administration (7 days)</p> <p>C. Vasovagal syncope (7 days)</p> <p>D. Any acute complications or sequelae (including death) of above events (interval - not applicable)</p> <p>E. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)</p>

Vaccine/Toxoid	Event and Interval from Vaccination
<i>Haemophilus influenzae</i> type b in any combination (conjugate): Hib, Hib-HepB, DTaP-IPV/Hib, Hib-MenCY	<p>A. Shoulder Injury Related to Vaccine Administration (7 days)</p> <p>B. Vasovagal syncope (7 days)</p> <p>C. Any acute complication or sequelae (including death) of above events (interval - not applicable)</p> <p>D. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)</p>
Varicella in any combination: VAR, MMRV	<p>A. Anaphylaxis or anaphylactic shock (7 days)</p> <p>B. Disseminated varicella vaccine-strain viral disease</p> <ul style="list-style-type: none"> • Vaccine-strain virus identified (time interval unlimited) • If strain determination is not done or if laboratory testing is inconclusive (42 days) <p>C. Varicella vaccine-strain viral reactivation (time interval unlimited)</p> <p>D. Shoulder Injury Related to Vaccine Administration (7 days)</p> <p>E. Vasovagal syncope (7 days)</p> <p>F. Any acute complication or sequelae (including death) of above events (interval - not applicable)</p> <p>G. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)</p>
Rotavirus (monovalent or pentavalent) RV1, RV5	<p>A. Intussusception (21 days)</p> <p>B. Any acute complication or sequelae (including death) of above events (interval - not applicable)</p> <p>C. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)</p>
Pneumococcal conjugate (7-valent or 13-valent) PCV7, PCV13	<p>A. Shoulder Injury Related to Vaccine Administration (7 days)</p> <p>B. Vasovagal syncope (7 days)</p> <p>C. Any acute complication or sequelae (including death) of above events (interval - not applicable)</p> <p>D. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)</p>
Hepatitis A in any combination: HepA, HepA-HepB	<p>A. Shoulder Injury Related to Vaccine Administration (7 days)</p> <p>B. Vasovagal syncope (7 days)</p> <p>C. Any acute complication or sequelae (including death) of above events (interval - not applicable)</p> <p>D. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)</p>
Seasonal influenza (trivalent inactivated influenza, quadrivalent inactivated influenza, live attenuated influenza): IIV3, IIV4, RIV3, ccIIV3, LAIV4	<p>A. Anaphylaxis or anaphylactic shock (7 days)</p> <p>B. Shoulder Injury Related to Vaccine Administration (7 days)</p> <p>C. Vasovagal syncope (7 days)</p> <p>D. Guillain-Barré Syndrome (42 days)</p> <p>E. Any acute complication or sequelae (including death) of above events (interval - not applicable)</p> <p>F. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)</p>
Meningococcal: MCV4, MPSV4, Hib-MenCY, MenACWY, MenB	<p>A. Anaphylaxis or anaphylactic shock (7 days)</p> <p>B. Shoulder Injury Related to Vaccine Administration (7 days)</p> <p>C. Vasovagal syncope (7 days)</p> <p>D. Any acute complication or sequelae (including death) of above events (interval - not applicable)</p> <p>E. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)</p>
Human Papillomavirus (quadrivalent, bivalent, or 9 valent): 9vHPV, 4vHPV, 2vHPV	<p>A. Anaphylaxis or anaphylactic shock (7 days)</p> <p>B. Shoulder Injury Related to Vaccine Administration (7 days)</p> <p>C. Vasovagal syncope (7 days)</p> <p>D. Any acute complication or sequelae (including death) of above events (interval - not applicable)</p> <p>E. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)</p>
Any new vaccine recommended by the Centers for Disease Control and Prevention for routine administration to children.	<p>A. Shoulder Injury Related to Vaccine Administration (7 days)</p> <p>B. Vasovagal syncope (7 days)</p> <p>C. Any acute complication or sequelae (including death) of above events (interval - not applicable)</p> <p>D. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)</p>

* Effective date: March 21, 2017. The Reportable Events Table (RET) reflects what is reportable by law (42 USC 300aa-25) to the Vaccine Adverse Event Reporting System (VAERS) including conditions found in the manufacturer package insert. In addition, healthcare professionals are encouraged to report any clinically significant or unexpected events (even if not certain the vaccine caused the event) for any vaccine, whether or not it is listed on the RET. Manufacturers are also required by regulation (21CFR 600.80) to report to the VAERS program all adverse events made known to them for any vaccine. Note that the RET differs from the Vaccine Injury Table (VIT) regarding timeframes of adverse events. Timeframes listed on the RET reflect what is required for reporting, but not what is required for compensation. To view timeframes for compensation, please see the VIT at <https://www.hrsa.gov/vaccinecompensation/vaccineinjurytable.pdf>

**Represents the onset interval between vaccination and the adverse event. For a detailed explanation of terms, see the Vaccine Injury Table at <https://www.hrsa.gov/vaccinecompensation/vaccineinjurytable.pdf>