Vaccine Adverse Event Reporting System (VAERS)

VAERS is a national post-licensure vaccine safety surveillance program co-managed by the Centers for Disease Control and Prevention (CDC) and the U.S. Food and Drug Administration (FDA). VAERS serves as an early warning system to detect possible safety issues with U.S. vaccines by collecting information about adverse events (possible side effects or health problems) that occur after vaccination. A report to VAERS does not indicate that a vaccine caused an adverse event, only that the adverse event occurred sometime after vaccination.

Who can report?

Anyone can submit a report to VAERS — healthcare professionals, vaccine manufacturers, and the general public. VAERS welcomes all reports, regardless of seriousness, and regardless of how likely the vaccine may have been to have caused the adverse event.

What should be reported?

Healthcare providers are **required by law** to report:

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

Healthcare providers are strongly **encouraged** to report:

- Any adverse event that occurs after the administration of a vaccine licensed in the United States, whether it is or is not clear that a vaccine caused the adverse event
- Vaccine administration errors

A copy of the Reportable Events Table can be found on the following page, or at https://vaers.hhs.gov/resources/infoproviders.html

Note: COVID-19 vaccines under an Emergency Use Authorization have additional VAERS reporting requirements. See https://vaers.hhs.gov/faq.html.

How do I report?

There are two ways to report to VAERS:

Option 1: Online (preferred). 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.

Option 2: Writeable 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.

Appendix D

What are the strengths and limitations of VAERS data?

When evaluating VAERS data, it is important to understand the strengths and limitations. VAERS data contain both coincidental events and those truly caused by vaccines.

Strengths:

- VAERS collects national data from all U.S. states and territories.
- VAERS accepts reports from anyone.
- The VAERS form collects information about the vaccine, the person vaccinated, and the adverse event.
- Data are publicly available.
- VAERS can be used as an early warning system to identify rare adverse events.
- It is possible to follow-up with patients to obtain health records, when necessary.

Limitations

- It is generally not possible to find out from VAERS data if a vaccine caused the adverse events.
- Reports submitted to VAERS often lack details and sometimes contain errors.
- Serious adverse events are more likely to be reported than mild side effects.
- Rate of reports may increase in response to media attention and increase public awareness.
- It is not possible to use VAERS data to calculate how often an adverse event occurs in a population.

Where can I find more information?

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	A. Anaphylaxis or anaphylactic shock (7 days) B. Brachial neuritis (28 days) C. Shoulder Injury Related to Vaccine Administration (7 days) D. Vasovagal syncope (7 days) E. Any acute complications or sequelae (including death) of above events (interval - not applicable) F. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)
Pertussis in any combination: DTaP, DTP, DTP-Hib, Tdap, DTaP-IPV, DTaP-IPV/Hib, DTaP-HepB-IPV	A. Anaphylaxis or anaphylactic shock (7 days) B. Encephalopathy or encephalitis (7 days) C. Shoulder Injury Related to Vaccine Administration (7 days) D. Vasovagal syncope (7 days) E. Any acute complications or sequelae (including death) of above events (interval - not applicable) F. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)
Measles, mumps and rubella in any combination: MMR, MMRV, MM	A. Anaphylaxis or anaphylactic shock (7 days) B. Encephalopathy or encephalitis (15 days) C. Shoulder Injury Related to Vaccine Administration (7 days) D. Vasovagal syncope (7 days) E. Any acute complications or sequelae (including death) of above events (interval - not applicable F. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)
Rubella in any combination: MMR, MMRV	A. Chronic arthritis (42 days) B. Any acute complications or sequelae (including death) of above event (interval - not applicable) C. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)
Measles in any combination: MMR, MMRV, MM	A. Thrombocytopenic purpura (7-30 days) B. Vaccine-strain measles viral infection in an immunodeficient recipient • Vaccine-strain virus identified (interval – not applicable) • If strain determination is not done or if laboratory testing is inconclusive (12 months) C. Any acute complications or sequelae (including death) of above events (interval - not applicable) D. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)
Oral Polio (OPV)	A. Paralytic polio • in a non-immunodeficient recipient (30 days) • in an immunodeficient recipient (6 months) • in a vaccine-associated community case (interval - not applicable) B. Vaccine-strain polio viral infection • in a non-immunodeficient recipient (30 days) • in an immunodeficient recipient (6 months) • in a vaccine-associated community case (interval - not applicable) C. Any acute complication or sequelae (including death) of above events (interval - not applicable) Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert) D. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)

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Vaccine/Toxoid	Event and Interval ** from Vaccination
Inactivated Polio in any combination: IPV, DTaP-IPV, DTaP-IPV/Hib, DTaP-HepB-IPV	A. Anaphylaxis or anaphylactic shock (7 days) B. Shoulder Injury Related to Vaccine Administration (7 days) C. Vasovagal syncope (7 days) D. Any acute complication or sequelae (including death) of above events (interval - not applicable) E. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)
Hepatitis B in any combination: HepB, HepA-HepB, DTaP-HepB-IPV, Hib-HepB	A. Anaphylaxis or anaphylactic shock (7 days) B. Shoulder Injury Related to Vaccine Administration (7 days) C. Vasovagal syncope (7 days) D. Any acute complications or sequelae (including death) of above events (interval - not applicable) E. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)
***Haemophilus influenzae* type b in any combination (conjugate): Hib, Hib-HepB, DTaP-IPV/Hib, Hib-MenCY**	A. Shoulder Injury Related to Vaccine Administration (7 days) B. Vasovagal syncope (7 days) C. Any acute complication or sequelae (including death) of above events (interval - not applicable) D. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)
Varicella in any combination: VAR, MMRV	A. Anaphylaxis or anaphylactic shock (7 days) B. Disseminated varicella vaccine-strain viral disease • Vaccine-strain virus identified (time interval unlimited) • If strain determination is not done or if laboratory testing is inconclusive (42 days) C. Varicella vaccine-strain viral reactivation (time interval unlimited) D. Shoulder Injury Related to Vaccine Administration (7 days) E. Vasovagal syncope (7 days) F. Any acute complication or sequelae (including death) of above events (interval - not applicable) G. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)
Rotavirus (monovalent or pentavalent) RV1, RV5	A. Intussusception (21 days) B. Any acute complication or sequelae (including death) of above events (interval - not applicable) C. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)
Pneumococcal conjugate (7-valent or 13-valent) PCV7, PCV13	A. Shoulder Injury Related to Vaccine Administration (7 days) B. Vasovagal syncope (7 days) C. Any acute complication or sequelae (including death) of above events (interval - not applicable) D. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)
Hepatitis A in any combination: HepA, HepA-HepB	A. Shoulder Injury Related to Vaccine Administration (7 days) B. Vasovagal syncope (7 days) C. Any acute complication or sequelae (including death) of above events (interval - not applicable) D. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)
Seasonal influenza (trivalent inactivated influenza, quadrivalent inactivated influenza, live attenuated influenza): IIV, IIV3, IIV4, RIV3, ccIIV3, LAIV4	A. Anaphylaxis or anaphylactic shock (7 days) B. Shoulder Injury Related to Vaccine Administration (7 days) C. Vasovagal syncope (7 days) D. Guillain-Barré Syndrome (42 days) E. Any acute complication or sequelae (including death) of above events (interval - not applicable) F. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)

Vaccine/Toxoid	Event and Interval ** from Vaccination
Meningococcal: MCV4, MPSV4, Hib-MenCY, MenACWY, MenB	A. Anaphylaxis or anaphylactic shock (7 days) B. Shoulder Injury Related to Vaccine Administration (7 days) C. Vasovagal syncope (7 days) D. Any acute complication or sequelae (including death) of above events (interval - not applicable) E. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)
Human Papillomavirus (quadrivalent, bivalent, or 9 valent): 9vHPV, 4vHPV, 2vHPV	A. Anaphylaxis or anaphylactic shock (7 days) B. Shoulder Injury Related to Vaccine Administration (7 days) C. Vasovagal syncope (7 days) D. Any acute complication or sequelae (including death) of above events (interval - not applicable) E. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)
Any new vaccine recommended by the Centers for Disease Control and Prevention for routine administration to children.	A. Shoulder Injury Related to Vaccine Administration (7 days) B. Vasovagal syncope (7 days) C. Any acute complication or sequelae (including death) of above events (interval - not applicable) D. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)

* 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/sites/default/files/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/sites/default/files/vaccinecompensation/vaccineinjurytable.pdf.