

The Vaccine Adverse Event Reporting System (VAERS)

The Vaccine Adverse Event Reporting System (**VAERS**) is a national early warning system to detect possible safety problems in U.S.-licensed vaccines. **VAERS** was established in 1990 and is co-managed by the Centers for Disease Control and Prevention (CDC) and the U.S. Food and Drug Administration (FDA). The VAERS database contains information on unverified reports of adverse events (illnesses, health problems, or symptoms) following immunization with US-licensed vaccines. Reports are accepted from anyone and can be submitted electronically at www.vaers.hhs.gov.

Why is reporting to VAERS important?

The purpose of VAERS is to detect possible signs of adverse reactions associated with vaccines.

What is an adverse reaction to a vaccine?

- An adverse reaction is an undesirable side effect that occurs after a vaccination. Vaccine adverse reactions are classified as 1) local, 2) systemic, or 3) allergic. Local reactions (e.g., **redness**) are usually the least severe and most frequently reported.
- Any new vaccine recommended by the CDC for routine administration is monitored for:
 - Shoulder Injury Related to Vaccine Administration (7 days post-vaccination)
 - Vasovagal syncope (Fainting) (7 days post-vaccination)
 - Any acute complication or sequelae (an aftereffect of a disease, condition, or injury, including death) of the above events (at any time)
 - Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval may vary)

How to Report Adverse Reactions to VAERS

There are two ways to submit a report to VAERS:

Option 1: Submit a VAERS report online. (Preferred) <https://vaers.hhs.gov/esub/index.jsp>

The online VAERS Report must be completed and submitted in the same session; it cannot be saved and edited later. Sessions time out after 20 minutes of inactivity; no information is saved.

Option 2: Download a Writable PDF form and upload when ready

<https://vaers.hhs.gov/uploadFile/index.jsp>

The Writable PDF Form can be downloaded and completed electronically on your own time. Return to the VAERS Writable PDF web page (use link above) and follow **Step 2** instructions to upload the form.

Understanding VAERS: <https://www.cdc.gov/vaccines/hcp/patient-ed/conversations/downloads/vacsafe-vaers-color-office.pdf>

More information on reporting an adverse event: <https://vaers.hhs.gov/reportevent.html> If you need further assistance, please email info@VAERS.org or call 1-800-822-7967.