Centers for Disease Control and Prevention

How to Report Adverse Events to VAERS

There are 2 ways to submit a report to the Vaccine Adverse Event Reporting System (VAERS)

Reporting adverse events to VAERS helps scientist at CDC and FDA keep vaccines safe.

Option 1: Submit a VAERS Report online (Preferred)
The online VAERS Report must be completed and submitted in the same session; it cannot be saved and edited at a later time. Note: sessions time out after 20 minutes of inactivity; no information is saved.

Option 2: Download a Writable PDF Form and upload when ready
The Writable PDF Form can be downloaded and completed electronically on your own time. When ready, return to the VAERS Writable PDF web page (use link above) and follow **Step 2** instructions to upload the form.

More information on reporting an adverse event to VAERS. If you need further assistance, please email info@VAERS.org or call 1-800-822-7967.

What to Report to VAERS

Reporting possible health problems (adverse events) after vaccination to VAERS provides valuable information. These reports help CDC and FDA detect new or unusual adverse events that could indicate a problem with a vaccine. If it looks as though a vaccine might be causing a problem, FDA and CDC will investigate further and take action if needed.

Everyone is encouraged to report possible adverse events after vaccination to VAERS, even if they are not sure whether the vaccine caused the problem. In general, **you should report any side effect or health problem after vaccination that is concerning to you.**

Under the National Childhood Vaccine Injury Act (NCVIA), healthcare providers are **required by law** to report to VAERS:

- Any adverse event listed in the VAERS Table of Reportable Events Following Vaccination [PDF – 5 Pages] that occurs within the specified time period after vaccinations
- An adverse event listed by the vaccine manufacturer as a contraindication to further doses of the vaccine

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

- 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

Vaccine manufacturers are required to report to VAERS all adverse events that come to their attention.

VAERS Reporting Requirements for COVID-19 Vaccines (Updated 3/13/2023)

As of August 2022, there are four vaccines available to protect against COVID-19 disease:

- Pfizer-BioNTech COVID-19 Vaccine (Comirnaty®)
- Moderna COVID-19 Vaccine (Spikevax®)
- Johnson & Johnson's Janssen COVID-19 Vaccine
- Novavax COVID-19 Vaccine, Adjuvanted

The Vaccine Adverse Event Reporting System (VAERS) is a national early warning system to detect possible safety problems in vaccines used in the United States. VAERS accepts and analyzes reports of adverse events (AEs) after a person has received a vaccination. Anyone can report an adverse event to VAERS. Healthcare professionals are required to report certain adverse events and vaccine manufacturers are required to report all adverse events that come to their attention.

The reporting requirements for COVID-19 vaccines are the same for those authorized under emergency use (EUA) or approved under a Biologics License Application (BLA).

Healthcare providers who administer COVID-19 vaccines are required to report the following to VAERS:

- Vaccine administration errors whether or not associated with an adverse event (AE).
  - If the incorrect mRNA COVID-19 vaccine product was inadvertently administered for a second dose in a 2-dose series, **VAERS reporting is required.**
  - If a different product from the primary series is inadvertently administered for the additional or booster (third dose), **VAERS reporting is required.**
  - **VAERS reporting is not required for the following situations:**
    - If a mixed series is given intentionally (e.g., due to hypersensitivity to a vaccine ingredient)
    - Mixing and matching of booster doses intentionally (as of October 21, 2021, mixing and matching of booster doses is allowed)

- Serious AEs regardless of causality. Serious AEs per FDA are defined as:
  1. Death
  2. A life-threatening AE
  3. Inpatient hospitalization or prolongation of existing hospitalization
  4. A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions
  5. A congenital anomaly/birth defect
  6. An important medical event that based on appropriate medical judgement may jeopardize the individual and may require medical or surgical intervention to prevent one of the outcomes listed above
- Cases of myocarditis after a Pfizer-BioNTech, Moderna, Novavax, or Janssen COVID-19 vaccine
- Cases of pericarditis after a Pfizer-BioNTech, Moderna, Novavax, or Janssen COVID-19 vaccine
- Cases of Multisystem Inflammatory Syndrome in children and adults
- Cases of COVID-19 that result in hospitalization or death

> Healthcare providers are encouraged to report to VAERS any additional clinically significant AEs following vaccination, even if unsure whether the vaccine caused the event.
>
> Also report any additional selected AEs and/or any revised safety reporting requirements per FDA's conditions of authorized use of vaccine(s) throughout the duration of any COVID-19 vaccine's Emergency Use Authorization (EUA) or as outlined in the Fact Sheet for Healthcare Providers for any approved COVID-19 vaccine.

VAERS Reporting Requirements for Monkeypox vaccines

> The vaccination provider must report all serious* adverse events following administration of JYNNEOS or ACAM2000 vaccine and vaccine administration errors to the Vaccine Adverse Event Reporting System (VAERS) by submitting online at https://vaers.hhs.gov/reportevent.html .
>
> The vaccination provider is responsible for mandatory reporting of the following listed events following JYNNEOS or ACAM2000 vaccination to VAERS:
>
> - Vaccine administration errors, whether or not associated with an adverse event
> - Serious* adverse events (irrespective of attribution to vaccination)
> - Cases of cardiac events, including myocarditis and pericarditis
> - Cases of thromboembolic events and neurovascular events
>
> *Serious adverse events are defined as:
>
> - Death
> - A life-threatening adverse event
> - Inpatient hospitalization or prolongation of existing hospitalization
> - A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions
> - A congenital anomaly/birth defect
> - An important medical event that based on appropriate medical judgement may jeopardize the individual and may require medical or surgical intervention to prevent one of the outcomes listed above
>
> Providers are encouraged to also report to VAERS any additional clinically significant AEs following vaccination, even if they are not sure if vaccination caused the event.
>
> As of August 9, 2022, FDA issued an Emergency Use Authorization (EUA) for JYNNEOS monkeypox vaccine. It authorizes the vaccine to be administered in one of two ways:
>
> 1. Intradermally (between the layers of the skin) on the inner aspect of the forearm, and
> 2. Subcutaneously (under the skin) in the upper arm above the elbow.
>
> These are considered routes of vaccination. When submitting a VAERS report, ensure that you document the **Route** in **Section 17** of the VAERS form, by choosing "intradermal" or "subcutaneous" from the selection menu.

Who can report to VAERS

CDC and FDA encourage anyone who experiences (or is made aware) of an adverse event after vaccination to report it to VAERS, even if they are not sure the vaccine caused the problem:

- Patients
- Parents/family member
- Caregivers
- Those who administer vaccines
- Healthcare providers
- Vaccine manufacturers

Reporting to VAERS helps CDC and FDA scientists keep vaccines safe.

What happens after a report is submitted

Which adverse events are considered "serious"?

By the Code of Federal Regulations (CFR) Title 21, an adverse event is defined as serious if it involves any of the following outcomes:

- Death
- A life-threatening adverse event
- A persistent or significant disability or incapacity
- A congenital anomaly or birth defect
- Hospitalization, or prolongation of existing hospitalization

Learn more about adverse events.

Each VAERS report is assigned a VAERS identification number. This number can be used to provide additional information about the report to VAERS, if necessary. VAERS will send the identification number to the reporting individual in a confirmation letter (electronically or by mail, depending on communications preferences listed on the original report).

Other than the confirmation letter, **VAERS will only reach out to the reporting individual for additional information if "essential fields" of the VAERS form are not filled out. VAERS will not contact the reporting individual by phone for follow-up.** Additional information requests are sent electronically or by mail and will explain what information is missing from the report and how the reporter can update it.

The VAERS program follows up on reports classified as serious by attempting to obtain medical records to better understand the event. These requests for medical records are made directly to health institutions or public health authorities that create and maintain medical records. The medical records are added to the permanent record under the VAERS ID, compliant with privacy standards.

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