The VAERS Project

Survey Answers

Are you aware of the Vaccine Adverse Event Reporting System (VAERS)?

VAERS is a passive national database to collect information about adverse events after vaccination. The system is reliant on independent widespread reporting by healthcare providers for any occurrence out of the normal for the patient. The purpose of VAERS is to detect early warning signals for side effects that were not observed during trials.

Does your employer provide education on VAERS?

We are finding most employers do not provide education on VAERS. If you would like to initiate education in your area, please text **EDUCATE** to **(317) 799-0988** or sign up for emails at **thevaersproject.com.** We will provide resources to those interested in building the culture of safety & understanding our patients deserve.

Do you know who is responsible for reporting to VAERS at your facility?

Anyone witnessing an adverse event should report to VAERS. Discuss the report with the patient. Only one report per incident should be submitted.

Adverse Events following which vaccines are to be reported via VAERS?

All vaccines. VAERS is an important part of post market surveillance monitoring for signals of potential safety concerns, whether the vaccine is fully approved or under Emergency Use Authorization (EUA).

Who can report to VAERS?

Anyone can report to VAERS; all medical professionals, patients, family members and caregivers.[1] However, only one report should be submitted per Adverse Event. It is imperative for healthcare personnel to complete the report, educate patients about the importance of VAERS and dispel myths related to reporting.

Note: Adverse Event reporting is not proof of causation, rather part of Federally driven data collection, which contributes to the integrity of vaccine safety science.

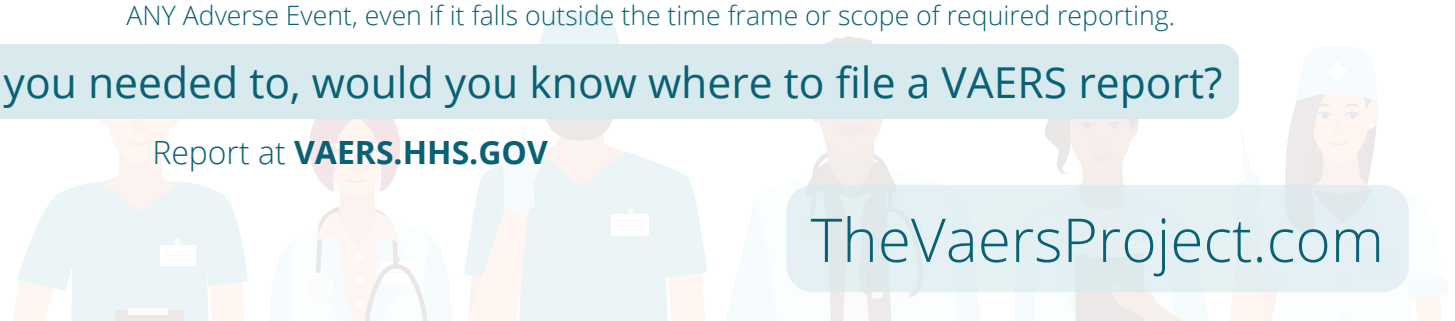
What does the CDC **encourage**, but not require, providers to report?

- **Any Adverse Event** that occurs after the administration of a vaccine in the United States, **whether or not it is clear that a vaccine caused the Adverse Event.**[2]
- Vaccine **administration errors.**[2]

Note: You will read about legally required reporting on the next page. However, the CDC values your contribution of critical thinking and clinical observations to vaccine science, thus encourages reporting ANY Adverse Event, even if it falls outside the time frame or scope of required reporting.

If you needed to, would you know where to file a VAERS report?

Report at **VAERS.HHS.GOV**



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Are healthcare providers **legally required** to report adverse events to VAERS?

Yes. **The Act of 1986 requires Healthcare Providers* & pharmaceutical manufactures to report adverse** events including:[3, 5]

- Any Adverse Event listed in the **VAERS Table of Reportable Events Following Vaccination**, that occurs within the specified time period after vaccination.[4]
- Any Adverse Event **listed by the vaccine manufacturer as a contraindication** to further doses of the vaccine.[5]

***'Health care provider'** means **any** *licensed health care professional*, *organization*, or *institution*, under whose authority a vaccine on the Vaccine Injury Table is administered.[3]

COVID-19 Vaccinations require additional guidelines:[6]

- Administration errors, whether or not associated with an Adverse Event (AE)
- Cases of Multisystem Inflammatory syndrome
- Cases of COVID-19 that result in hospitalization or death
- Serious AE per FDA including:
  - 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 judgment, may jeopardize the individual and may require medical or surgical intervention to prevent one of the outcomes listed above

VAERS collects approximately what percent of adverse events?

This is a difficult answer to find. It is widely accepted that Adverse Events are significantly under reported to VAERS. The term "significantly under reported" is vague and subjective. In previous years, I was able to find **estimates on FDA & CDC sites claiming between 1-10%** of adverse events were reported to VAERS.[7, 8]

Unfortunately, it has been difficult to locate any information on the rates from the agency websites in more recent searches. A CDC commissioned study claimed <1% of adverse events are reported to VAERS.[9] It is difficult to identify why these data points were removed. Lack of information may be due to the increased attention to VAERS reporting due to COVID vaccines. Searching online you may find citations in line with the above, however, there are arguments as to why they may not be accurate. Please review, discuss with your peers, and discern. This is a topic that should be widely discussed and examined for the sake of vaccine science & safety. If you have further information on VAERS effectiveness, please forward it to us at **info@thevaersproject.com**. We strive for comprehensive and up to date information.

1. https://vaers.hhs.gov/
2. https://www.cdc.gov/vaccinesafety/hcproviders/reportingadverseevents.html
3. https://www.ncbi.nlm.nih.gov/books/NBK220067/
4. https://vaers.hhs.gov/docs/VAERS_Table_of_Reportable_Events_Following_Vaccination.pdf
5. https://www.cdc.gov/vaccinesafety/hcproviders/reportingadverseevents.html
6. https://vaers.hhs.gov/faq.html
7. https://doi.org/10.1016/0163-8343(94)90051-5
8. https://www.bmj.com/rapid-response/2011/10/30/adverse-reactions-varicella-vaccination-are-grossly-under-reported
9. https://digital.ahrq.gov/sites/default/files/docs/publication/r18hs017045-lazarus-final-report-2011.pdf