

## Disclaimer

VAERS accepts reports of adverse events that occur following vaccination. **Anyone, including healthcare providers, vaccine manufacturers, and the public, can submit reports to the system. While very important in monitoring vaccine safety, VAERS reports alone cannot be used to determine if a vaccine caused or contributed to an adverse event or illness.** Vaccine providers are encouraged to report any clinically significant health problem following vaccination to VAERS even if they are not sure if the vaccine was the cause. In some situations, reporting to VAERS is required of healthcare providers and vaccine manufacturers.

**VAERS reports may contain information that is incomplete, inaccurate, coincidental, or unverifiable.** Reports to VAERS can also be biased. As a result, there are limitations on how the data can be used scientifically. Data from VAERS reports should always be interpreted with these limitations in mind.

The strengths of VAERS are that it is national in scope and can often quickly detect an early hint or warning of a safety problem with a vaccine. VAERS is one component of CDC's and FDA's multifaceted approach to monitoring safety after vaccines are licensed or authorized for use. There are multiple, complementary systems that CDC and FDA use to capture and validate data from different sources. VAERS is designed to rapidly detect unusual or unexpected patterns of adverse events, also referred to as "safety signals." If a possible safety signal is found in VAERS, further analysis is performed with other safety systems, such as the CDC's Vaccine Safety Datalink (VSD) and Clinical Immunization Safety Assessment (CISA) Project, or in the FDA BEST (Biologics Effectiveness and Safety) system. These systems are less impacted by the limitations of spontaneous and voluntary reporting in VAERS and can better assess possible links between vaccination and adverse events. Additionally, CDC and FDA cannot provide individual medical advice regarding any report to VAERS.

Key considerations and limitations of VAERS data:

- **The number of reports alone cannot be interpreted as evidence of a causal association between a vaccine and an adverse event,** or as evidence about the existence, severity, frequency, or rates of problems associated with vaccines.
- Reports may include incomplete, inaccurate, coincidental, and unverified information.
- VAERS does not obtain follow up records on every report. If a report is classified as serious, VAERS requests additional information, such as health records, to further evaluate the report.
- VAERS data are limited to vaccine adverse event reports received between 1990 and the most recent date for which data are available.
- VAERS data do not represent all known safety information for a vaccine and should be interpreted in the context of other scientific information.

**VAERS data available to the public include only the initial report data to VAERS. Updated data which contains data from medical records and corrections reported during follow up are used by the government for analysis. However, for numerous reasons including data consistency, these amended data are not available to the public.**