Vaccine Adverse Event Reporting System A National Program for Monitoring Vaccine Safety

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Vaccine Adverse Event Reporting System (VAERS)

The Vaccine Adverse Event Reporting System (VAERS) is a national program managed by the U.S. Centers for Disease Control and Prevention (CDC) and the U.S. Food and Drug Administration (FDA) to monitor the safety of all vaccines licensed in the United States. VAERS collects and analyzes information from reported adverse events that occur after vaccination. An "adverse event" is any health problem or "side effect" that happens after a vaccination. VAERS cannot determine if an adverse event was caused by a vaccine, but can help determine if further investigations are needed.



VAERS serves as an early-warning system to detect problems that may be related to vaccines. The system relies on reports from healthcare providers*, vaccine manufacturers, and the general public. Reporting gives CDC and FDA important and timely information to help identify health concerns and ensure vaccines are safe in order to protect the public's health.

VAERS staff evaluate adverse events of concern.

VAERS defines "serious adverse events" as those involving death, hospitalization, lifethreatening illness, persistent or significant disability/incapacity, or certain other medically important conditions. CDC and FDA evaluate individual reports and the reporting patterns to determine if in-depth reviews are needed before conducting additional studies. Once adverse events of concern are identified in VAERS they may be monitored in other immunization safety systems to evaluate if the event occurs more frequently after vaccination or to conduct more controlled scientific studies to confirm if a particular adverse event is related to a vaccination and identify any specific risk factors.

Anyone can report to VAERS.

Anyone can submit a report to VAERS, including patients, family members, healthcare providers, and vaccine manufacturers. CDC and FDA encourage anyone who experiences an adverse event after any vaccination to report to VAERS.

There are 3 ways to report.

- 1. Online at a secure Web site: https://secure.vaers.org/VaersDataEntryintro.htm.
- 2. Fax a completed VAERS form toll-free to 1-877-721-0366.
- 3. Mail the completed form to VAERS, P.O. Box 1100, Rockville, MD 20849-1100. You may download and print a VAERS form at http://vaers.hhs.gov/pdf/vaers_form.pdf, or you may get a form mailed to you by calling toll-free 1-800-822-7967, or by sending a faxed request to 1-877-721-0366.

VAERS data are available to the public.

VAERS data are made available on the VAERS Web site and can be searched for summaries on particular adverse events reported for specific vaccines. Personal identifying information (name, date of birth, address, etc.) is removed prior to posting the public data. The data is also screened to remove duplicate reports.

*Healthcare providers are required to report adverse events to VAERS including those found in the Reportable Events Table.







For more information about VAERS:

E-mail: info@vaers.org

Phone: 1-877-822-7967

Web site: www.vaers.hhs.gov