



Summary of 2010-2011 Trivalent Influenza Vaccine Data from the U.S. Vaccine Adverse Event Reporting System

Data through December 14, 2010

Please note: These summaries are posted monthly.

CDC and FDA provide monthly updates on our vaccine safety monitoring activities in an effort to put the data that are publicly available through the U. S. Vaccine Adverse Event Reporting System (VAERS; <http://vaers.hhs.gov>) and CDC's website, WONDER (<http://wonder.cdc.gov/vaers.html>) into context. The following information summarizes adverse event reports to VAERS after the administration of 2010-2011 trivalent influenza vaccine (either nasal spray or shot).

An adverse event is a health problem that is reported after someone gets a vaccine or medicine. Note that persons may experience adverse events shortly after vaccination which may or may not be caused by the vaccine. VAERS is primarily used to detect potential vaccine safety problems, also called signals that may require further investigation. VAERS is usually not able to determine if an adverse event was caused by a vaccination.

VAERS Summary:

- As of November 26, 2010, approximately 163 million doses of influenza vaccine have been distributed in U.S. although the precise number of vaccines administered is unknown.
- As of December 14, 2010, VAERS had received 6845 adverse event reports following 2010-2011 influenza vaccination.
- The vast majority (94%) of adverse events reported to VAERS after receiving the 2010-2011 influenza vaccine are classified as "non-serious" (e.g., adverse events did not require a hospitalization, was not life threatening, and/or did not result in permanent disability).
- Of the 6845 reports, 415 (6%) were reports that were classified as "serious" health events (defined as life threatening or resulting in death, major disability, birth defect, hospitalization, or extension of an existing hospitalization)*.
- The percentage of reports involving what would be considered serious health events is similar for 2010-2011 seasonal influenza vaccine and previous seasonal influenza vaccines. Among the 415 reports of serious health events, there were 18 reports of death.
- As with all reports of serious adverse events and deaths, the 18 VAERS reports that involve deaths are under review by CDC and FDA. Preliminary findings do not indicate a common cause or pattern (such as similarities in age, gender, geographic location, illness surrounding death, or underlying medical conditions) to suggest that these deaths were associated with the vaccine. These cases are under further review pending additional medical records (e.g., autopsy reports, medical files).



- VAERS has received 51 reports of Guillian-Barré syndrome (GBS). In the United States, about 80-160 cases of GBS are expected to occur each week, regardless of vaccination.
- FDA and CDC have recently detected an increase in the number of reports to VAERS of febrile seizures in children following vaccination with Fluzone (trivalent inactivated influenza vaccine or TIV, manufactured by Sanofi Pasteur, Inc.). Information on this is available at <http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/VaccineSafety/ucm240037.htm>. Analysis of febrile seizure data in VAERS is available at http://vaers.hhs.gov/resources/VAERSupdate_FebrileSeizures_Children.pdf.
- VAERS reports continue to be monitored as more vaccine is administered.

VAERS Limitations

- When reviewing data from VAERS, please keep in mind what the system is designed to do and what it is unable to do:
 - VAERS is a national reporting system, in which reports are mainly submitted voluntarily by people who think an adverse event occurred after vaccination. Healthcare providers are required by federal law to report certain adverse events after vaccination (http://vaers.hhs.gov/resources/VAERS_RET.pdf) and are encouraged to submit adverse events they think are clinically important. VAERS does not actively solicit reports in any systematic way from all people who have been vaccinated. Reports can be submitted by anyone, including healthcare providers, patients, or family members. Because of this feature, VAERS reports may and often do include incorrect and incomplete information. VAERS reports often lead to more complete follow-up and review of medical records.
 - VAERS staff follows up on all serious and other selected adverse event reports by obtaining additional medical, laboratory, and/or autopsy records when available. As a result of the follow-up/review process, coding terms (e.g., serious or non-serious) for individual VAERS reports may change based on the information received; these updated data are used by CDC and FDA VAERS staff. VAERS data in WONDER should be used with caution because numbers and conditions do not reflect data collected during follow-up. Events reported in VAERS should not be viewed as evidence that the vaccine directly caused the event. Data does not infer causality. Further investigation is warranted.
 - Underreporting, or failure to report events, is also one of the main limitations of VAERS. Serious medical events are more likely to be reported than minor events.
 - Most importantly, **VAERS cannot usually determine cause-and-effect**. VAERS accepts all reports without regard to whether or not the event was caused by the vaccine. The report of an adverse event to VAERS does not mean that a vaccine caused the event. It only indicates that the event occurred sometime after administration of the vaccine. Proof that the event was caused by the vaccine is NOT required in order for VAERS to accept the report.



- No reports are deleted from VAERS. Therefore, it is possible to have more than one VAERS report on an individual case (e.g., a physician and a patient may have filed separate reports for the same case).
- For all reports of serious adverse events, VAERS staff seeks associated medical records on each case and CDC and FDA medical officers review them closely to determine if any additional action may be needed.
- The most reliable information about vaccine side effects can be found in the manufacturers' vaccine package insert <http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm093830.htm>, vaccine information statements (VISs), or the Advisory Committee on Immunizations Practices' (ACIP's) statements on vaccines at <http://www.cdc.gov/vaccines/pubs/ACIP-list.htm>.

Actions taken by CDC and FDA

- CDC and FDA take every adverse event report seriously and individually review all reports of serious adverse events so that potential problems can be quickly evaluated.
- CDC, FDA and their partners are using many systems to monitor the safety of 2010-2011 seasonal influenza vaccine. Two primary systems that are in use are VAERS, which is jointly operated with FDA, and the Vaccine Safety Datalink (VSD) Project (<http://www.cdc.gov/vaccinesafety/Activities/VSD.html>).
- Additionally, CDC and FDA are collaborating with various agencies, departments (e.g., Departments of Defense and Veterans Affairs).
- These federal agencies and departments, in cooperation with state and local health departments, healthcare providers, and other partners work closely with CDC to monitor the safety of all vaccines licensed for use in the United States, including seasonal influenza vaccines.

Facts about VAERS

Healthcare providers are required by federal law to report certain adverse events after vaccination (http://vaers.hhs.gov/resources/VAERS_RET.pdf) and are encouraged to submit adverse events they think are clinically important. Anyone may report to VAERS, even if they are not certain that a vaccine caused the adverse event.

- This can be done online at <https://vaers.hhs.gov/esub/step1>, by regular mail to the following address: VAERS, P.O. Box 1100, Rockville, MD 20849-1100 or by fax to 877-721-0366
- A VAERS form may be downloaded from the VAERS website at http://vaers.hhs.gov/resources/vaers_form.pdf. Alternatively, you may request a VAERS form by sending an email to info@vaers.org, by calling toll-free 800-822-7967, or by sending a faxed request to 877-721-0366. For additional information on VAERS or vaccine safety, visit the VAERS Web site at www.vaers.hhs.gov or call 800-822-7967



*An adverse event, as defined by the Code of Federal Regulations, is considered serious if it is life threatening, or results in death, a persistent or significant disability or incapacity, congenital anomaly or birth defect, hospitalization, or prolongation of existing hospitalization.