



## Summary of 2009 Monovalent H1N1 Influenza Vaccine Data – Vaccine Adverse Event Reporting System

Data through November 13, 2009

CDC and FDA will be providing weekly updates on our vaccine safety monitoring activities in an effort to better characterize data that are publicly available through the Vaccine Adverse Event Reporting System (VAERS; <http://vaers.hhs.gov>) and CDC's website, WONDER (<http://wonder.cdc.gov/vaers.html>). The following information summarizes adverse event reports submitted to VAERS after the administration of 2009 H1N1 monovalent 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. While VAERS is an important system for helping to find potential signs, VAERS cannot determine if an adverse event was caused by vaccination.

### VAERS Summary:

- As of November 13, 2009, 36.8 million doses of 2009 H1N1 influenza vaccine had been shipped to healthcare providers in the United States.
- As of November 13, 2009, VAERS had received 2365 reports related to 2009 H1N1 influenza vaccination.
- The vast majority (95%) of adverse events reported to VAERS after receiving the 2009 H1N1 influenza vaccine have not involved serious health problems or outcomes (e.g., they encompass things like soreness at the vaccine injection site).
- Of the 2365 reports, 116 (5%) were reports that involved what would be considered serious health events.
- The number of reports involving what would be considered serious health events (i.e., life threatening or results in death, major disability, abnormal conditions at birth, hospitalization, or extension of an existing hospitalization)\* is similar to those historically seen after distribution of a similar number of seasonal flu vaccine doses.
- Among the 2365 reports of adverse events, there were 8 reports of death.
- The 8 VAERS reports that involve deaths are under review by CDC, FDA and the states where the reported deaths occurred. Preliminary findings indicate that there does not appear to be 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 6 reports of Guillian-Barré syndrome (GBS), for which follow-up assessments are underway. In the United States, about 80-160 cases of GBS are expected to occur each week, regardless of vaccination.



## VAERS Limitations

- When reviewing data from VAERS, please keep in mind the following limitations:
  - VAERS is a passive reporting system, meaning that reports about adverse events can be submitted voluntarily 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 follow-up on all serious and other selected adverse event reports and obtain additional medical, laboratory, and/or autopsy records when available. As a result of the follow-up/review process, coding terms (e.g., serious, non-serious) for individual VAERS reports may change based on the information received. These changes are reflected in the weekly updates of VAERS data on WONDER database. VAERS data in WONDER should be used with caution because numbers and conditions are often updated. 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 determine cause-and-effect**. The report of an adverse event to VAERS does not confirm 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. VAERS accepts all reports without regard as to whether or not the event was caused by the vaccine.
  - 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 collects follow-up records on each case and medical officers review them closely to determine if any additional action or studies are 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, FDA, and Other Federal Agencies and Departments

- 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 2009 H1N1 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 other federal agencies and departments, including the Departments of Defense and Veterans Affairs are conducting surveillance of adverse events through partnerships with other federal agencies, state agencies, professional organizations, and academic institutions ([http://www.flu.gov/professional/federal/monitor\\_immunization\\_safety.html](http://www.flu.gov/professional/federal/monitor_immunization_safety.html)).
- These federal agencies and departments, in cooperation with state and local health departments, healthcare providers, and other partners, closely monitor the safety of all vaccines licensed for use in the United States, including 2009 H1N1 and seasonal influenza vaccines, in cooperation with state and local health departments, healthcare providers, and other partners.
- In an effort to be able to provide accurate and timely data on the safety of the 2009 H1N1 influenza vaccine, the federal government, along with local, professional, and academic partners, has enhanced the existing vaccine safety monitoring systems ([http://www.flu.gov/professional/federal/monitor\\_immunization\\_safety.html](http://www.flu.gov/professional/federal/monitor_immunization_safety.html)).
- The National Vaccine Advisory Committee (NVAC) created the H1N1 Vaccine Safety Risk Assessment Working Group to review 2009 H1N1 influenza vaccine safety data. This working group of outside experts will conduct regular, rapid reviews of available data from the federal safety monitoring systems and present them to NVAC and federal leadership for appropriate policy action and follow up.
- A summary of the *Federal Plans to Monitor Immunization Safety for the Pandemic 2009 H1N1 Influenza Vaccination Program* is available at [http://www.flu.gov/professional/federal/monitor\\_immunization\\_safety.html](http://www.flu.gov/professional/federal/monitor_immunization_safety.html).

## Facts about VAERS

- VAERS is a program that is jointly administered by CDC's Immunization Safety Office and FDA. VAERS receives information from different sources (vaccine recipients, parents, other family members, doctors, other healthcare workers, and the vaccine manufacturer) across the United States who choose to report an adverse event occurring after vaccination. VAERS is designed to identify potential adverse events that warrant additional study.
- Serious adverse event and other selected reports are reviewed by medical officers, nurses, and trained staff at both FDA and CDC. VAERS receives reports of many events that occur following immunization. It serves as an early warning system that can detect patterns in reports and determine whether further investigation is necessary.
- An adverse event is a health problem that is reported after someone gets a vaccine or medicine. It *may* or *may not* have been caused by the vaccine or medicine. Some of these events *may occur by chance* during the period following vaccination, while others may actually be caused by vaccination.
- Anyone who thinks that they may have had an adverse event after receiving 2009 H1N1 influenza vaccine (or any vaccine) should file a VAERS report. This can be done [online](#), by [regular mail](#), or by [fax](#).

\*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.