



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

Data through November 9th, 2009

CDC and FDA will be providing weekly updates on our vaccine safety monitoring activities in an effort to better characterize data that are being viewed publicly 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 to the Vaccine Adverse Event Reporting System after the administration of 2009 H1N1 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 can not determine if an adverse event was caused by vaccination.

VAERS Summary:

- As of November 10, 2009, 33.7 million doses of 2009 H1N1 vaccine had been shipped to healthcare providers in the United States.
- A total of 1922 adverse events following 2009 H1N1 flu vaccination have been reported to VAERS through November 9, 2009.
- The vast majority (96%) of adverse events reported to VAERS after receiving the 2009 H1N1 vaccine have not been serious. An adverse event is considered serious* if it is life threatening, or results in death, permanent disability, abnormal conditions at birth, hospitalization, or prolonged hospitalization.
- Of the 1922 reports of adverse events, 84 (4% of all reports) described serious adverse events, including 6 reports of death.
- The 6 death reports are under review by CDC, FDA and the states. Follow-up investigations are underway; however, 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 4 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.
 - 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.
 - 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 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 and its partners are using many systems to monitor the safety of 2009 H1N1 influenza vaccine. Two primary systems that are in use are the Vaccine Adverse Event Reporting System (VAERS), which is jointly operated with FDA, and the Vaccine Safety Datalink (VSD) Project (<http://www.cdc.gov/vaccinesafety/Activities/VSD.html>).
- Additionally, CDC is 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).

- CDC and FDA, in cooperation with state and local health departments, health care 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, health care 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 vaccine safety monitoring systems (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 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 www.flu.gov.

Facts about VAERS

- VAERS is a program that is jointly administered by CDC's Immunization Safety Office and FDA. VAERS receives information from individuals (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.
- All 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 coincidentally* 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.