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

Data through December 23, 2009

CDC and FDA provide weekly updates on our vaccine safety monitoring activities in an effort to put the 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) in context. The following information summarizes adverse event reports 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 is primarily used to detect signals that may require further investigation, but is not able to determine if an adverse event was caused by vaccination.

VAERS Summary:

- As of December 23, 2009, 92.6 million doses of 2009 H1N1 vaccine had been shipped to vaccination providers in the United States, although the precise number of vaccines administered is unknown.
- As of December 23, 2009, VAERS had received 6945 adverse event reports following 2009 monovalent H1N1 vaccination.
- The vast majority (94.1%) of adverse events reported to VAERS after receiving the 2009 monovalent H1N1 vaccine are classified as "non serious" (e.g., soreness at the vaccine injection site).
- Of the 6945 reports, 410 (5.9%) were reports that were classified as "serious" health events (defined as life threatening or resulting in death, major disability, abnormal conditions at birth, hospitalization, or extension of an existing hospitalization)*.
- The percentage of reports involving what would be considered serious health events is not different between 2009 H1N1 and seasonal influenza vaccines. Additionally, no new or unusual events or pattern of adverse events have emerged.
- VAERS reports continue to be monitored as more vaccine is administered.
- Among the 410 reports of serious health events, there were 29 reports of death.
- As with all reports of serious adverse events and deaths, the 29 VAERS reports that involve deaths are under review by CDC, FDA and the states where the reported deaths occurred. 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 32 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 what the system is designed to do and what it is unable to do:
    - VAERS is a national reporting system, in which reports are submitted voluntarily by people who think an adverse event occurred after vaccination. VAERS does not 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 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 or non-serious) for individual VAERS reports may change based on the information received. These changes are reflected in the weekly updates of VAERS data in the 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**. 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 follow-up medical records on each case and medical officers review them closely to determine if any additional action or studies 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 2009 monovalent 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 FDA are collaborating with various agencies, departments (e.g., Departments of Defense and Veterans Affairs), and other partners (e.g., professional organizations, academic institutions) to conduct surveillance of adverse events (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 work closely with CDC to monitor the safety of all vaccines licensed for use in the United States, including 2009 H1N1 and seasonal influenza vaccines.
- In an effort to be able to provide accurate and timely data on the safety of the 2009 monovalent 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).
- The National Vaccine Advisory Committee (NVAC) created the H1N1 Vaccine Safety Risk Assessment Working Group to review 2009 H1N1 vaccine safety data http://www.hhs.gov/nvpo/nvac/subgroups/h1n1risk.html. 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.

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 or* 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 monovalent 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.