

INFORMATION ON THE REPORTING OF ADVERSE EVENTS

The 2009 H1N1 influenza virus continues to circulate in New York State and pose the risk of illness and death. As a result, the New York State Department of Health (NYSDOH) is conducting a 2009 H1N1 influenza vaccination campaign this fall, in cooperation with the Centers for Disease Control and Prevention (CDC). It is extremely important that medical providers and the public be reassured that the vaccine is safe and that vaccine safety is being carefully monitored.

The CDC and the Food and Drug Administration (FDA) closely monitor the safety of influenza and other vaccines used in the US. The 2009 H1N1 influenza vaccine will be monitored using all routine practices, but, will also experience enhanced safety surveillance.

It is important to understand some key facts about how the 2009 H1N1 influenza vaccine is being made:

- 2009 H1N1 influenza vaccine will be made using the exact same methods that are used to make the seasonal influenza vaccine that is used every year;
- The 2009 H1N1 vaccine only represents a strain change. This happens every year when seasonal influenza vaccine is reformulated;
- Seasonal influenza vaccines are very safe and it is expected that 2009 H1N1 influenza vaccines will be also.
- Preliminary results of clinical studies on the 2009 H1N1 vaccine show that its safety profile is very similar to seasonal influenza vaccine.
- The 2009 H1N1 influenza vaccine is also made using chicken eggs and, therefore, those with a severe allergy to eggs should not receive this vaccine.

Adverse events following immunization may be coincidental or may be causally related to the vaccine. The following are objectives of the 2009 H1N1 monovalent vaccine safety monitoring response:

- Timely identification of clinically significant adverse events following receipt of 2009 H1N1 monovalent vaccine;
- Rapid evaluation of serious adverse events identified after 2009 H1N1 monovalent vaccine to determine the public health importance; and
- Evaluation of the risk of Guillain-Barré syndrome (GBS) associated with the 2009 H1N1 monovalent vaccine.

Vaccine Adverse Event Reporting System (VAERS)

VAERS will be the front-line monitoring system for collecting and analyzing reports of adverse events following 2009 H1N1 monovalent vaccination:

- VAERS is a vaccine safety surveillance system, co-managed by the CDC and FDA.
- VAERS collects reports of suspected vaccine adverse events, and reports are generated from this data. It is a passive surveillance system, and all reports both serious and non-serious are included.

- In general, VAERS cannot determine if an adverse event was caused by the vaccine but can highlight when an adverse event occurs and help determine if further investigations are needed.
- Healthcare providers are encouraged to report clinically significant adverse events after 2009 H1N1 monovalent vaccine or any other vaccine to VAERS. A report should be submitted even if the reporter is not certain that the vaccine caused the event.
- After a VAERS report is received, VAERS staff will collect additional information on reports of clinically serious adverse events by contacting the reporter and/or through other sources that may have relevant follow-up information. The VAERS data will then be analyzed to look for potential vaccine safety concerns.
- CDC will likely make adverse event reports accessible to the NYSDOH on a weekly basis
- VAERS data without identifiers may be accessed through the CDC Wide-ranging Online Data for Epidemiologic Research (WONDER) public database or for download at (<http://vaers.hhs.gov/scripts/data.cfm>) within about 6 weeks after CDC receives the VAERS report.

How to Report Adverse Events

- ANYONE, not just healthcare providers, can submit a VAERS report.
- Report forms can be downloaded online:<http://vaers.hhs.gov/>
http://www.vaers.org/pdf/vaers_form.pdf or can be obtained by calling: 1-800-822-7967. They may also be filed online (<https://secure.vaers.org/VaersDataEntryintro.htm>), by mail (VAERS PO Box 1100 Rockville, MD 20849-1100), or by fax (877-721-0366).

Other Vaccine Safety Monitoring Activities That Will be Used to Monitor the 2009 H1N1 Influenza Vaccine

- The Vaccine Safety Datalink (VSD) is a collaborative effort between CDC and eight managed care organizations representing approximately 3% of the U.S. population. The VSD is able to monitor specified adverse events in near real-time, using appropriate comparison groups.
- The Vaccine Analytic Unit (VAU) is a collaboration among the Department of Defense, CDC, and the FDA. It utilizes the Defense Medical Surveillance System, which has data on approximately 1.5 million active US military personnel.
- The Emerging Infections Program (EIP) is a population-based network of CDC and 10 state health departments (CA, CO, CT, GA, MD, MN, NM, NY, OR, TN), working in collaboration with multiple providers, labs, and institutions that will be used to perform active surveillance and case-finding for Guillain-Barré syndrome (GBS) after vaccination.
- The CDC has also established collaboration with the American Academy of Neurology to enhance VAERS reporting of neurological events, including GBS.

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New York State Department of Health
Bureau of Immunization

- The Clinical Immunization Safety Assessment (CISA), a collaboration between CDC and six academic centers with expertise in immunization safety, will provide clinical expertise and consultation in the evaluation of serious adverse events after 2009 H1N1 monovalent vaccine.