

## Information from CDC – 10-19-09

### **(NEW) Recent Adverse Event Reports in the Media**

This week, a very rare adverse event following seasonal influenza vaccine was reported to VAERS and received attention by the media.

- CDC can confirm this case was reported to the Vaccine Adverse Event Reporting System (VAERS). VAERS is a useful early warning public health system that helps CDC and FDA detect possible adverse events, or side effects, following vaccination.
- Dystonia is a rare neurological condition that can be brought on by infections, brain trauma or reaction to medication. It causes body jerks and abnormal or repetitive movements.
- VAERS data, which dates back to 1991, contains 5 reports of dystonia after the administration of almost one billion doses of flu vaccine (nasal and injectable). A total of 50 cases have been reported for ALL vaccines.
- 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, VAERS data may and often does include incorrect and incomplete information.
  - 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 ones.
  - 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 confirms that the event occurred sometime after vaccine receipt. No proof that the event was caused by the vaccine is required in order for VAERS to accept the report.
  - VAERS accepts all reports without judging whether or not the event was caused by the vaccine. No reports are deleted out of the VAERS system. Therefore, it is possible to have more than one report on an individual case.
  - As with all serious reports of adverse events, VAERS staff collect follow-up records on each case and medical officers review them closely to determine if in-depth reviews are needed before conducting additional studies.

- VAERS defines "serious adverse events" as those involving death, hospitalization, life-threatening illness, persistent or significant disability/incapacity, or certain other medically-important conditions.
- The most reliable information about vaccine side effects can be found in the manufacturer's vaccine package insert, vaccine information statements (VISs), or the ACIP's statements on vaccines at <http://www.cdc.gov/vaccines/pubs/ACIP-list.htm>.

## **2009 H1N1 Influenza Vaccine Safety**

### *General H1N1 Vaccine Safety*

- **(NEW)** The 2009 H1N1 influenza vaccines have not been associated with any unexpected adverse events (or possible side effects). In addition, the 2009-2010 seasonal influenza vaccines also have not been associated with any unexpected adverse events (or possible side effects).
- The 2009 H1N1 influenza vaccine have a similar safety profile as seasonal flu vaccines, which have very good safety track records.
- CDC expects that any serious side effects following vaccination with the 2009 H1N1 influenza vaccine would be rare.
- The types and frequencies of side effects from the 2009 H1N1 vaccine will likely be similar to those experienced following seasonal influenza vaccines which are mild, localized reactions.

### *Vaccine Safety Monitoring*

- **(UPDATED)** CDC and its partners are using several 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.
- **(UPDATED)** Additionally, CDC is conducting surveillance of adverse events through partnerships with other federal agencies, professional organizations, and academic institutions.
- **(UPDATED)** CDC and FDA closely monitor the safety of all vaccines licensed for use in the United States, including seasonal influenza vaccines, in cooperation with state and local health departments, health care providers, and other partners. Additional special monitoring of the 2009 H1N1 vaccine is occurring to assure that any rare side effects are detected as soon as possible.

- Vaccine safety monitoring is a complex process that uses both active and passive surveillance.
- Vaccine safety monitoring includes reviewing adverse events reported by providers, manufacturers, people who were vaccinated or their caregivers, and comparing the rate of these adverse events to the background rates (the rates at which they normally occur in the population).
  - An adverse event following immunization is a medical incident that occurs after someone receives an immunization.
  - Adverse events may be coincidental (meaning occurring around the same time but not related to vaccination) or caused by vaccination.
  - Adverse events can be reported by providers, manufacturers, people who were vaccinated or their caregivers.
- The purpose of vaccine safety monitoring is timely identification of any clinically significant adverse events following immunization, as well as to provide timely information to the public, vaccine providers, public health officials, and policy makers.
- **(NEW)** As with all vaccines licensed for use in the United States, any problems detected with this vaccine will be reported to health officials, health care providers, and the public, and needed action will be taken to ensure the public's health and safety.

### Adjuvants

- Some vaccines contain “adjuvants,” which are ingredients that help boost the vaccine’s potency. As a result, a smaller amount of vaccine is needed per person, and therefore, the vaccine supply can be used to reach more people.
- **(UPDATED)** Only unadjuvanted influenza (flu) vaccines will be used in the United States during the 2009-10 flu season.
- This includes all of the 2009 H1N1 and seasonal influenza vaccines that will be available for children and adults in both the injectable (flu shot) and nasal spray formulations. None of these influenza vaccines that will be used in the U.S. during the 2009-10 season will contain adjuvants.
- Studies of 2009 H1N1 influenza vaccines with adjuvants are being conducted to determine if 2009 H1N1 influenza vaccines with adjuvants meet safety and efficacy requirements for use in the United States.

### Thimerosal

- Thimerosal is a mercury-based preservative that is used in some influenza vaccines to keep them free from contamination of microorganisms.
- The 2009 H1N1 influenza vaccine is being manufactured in several formulations.
  - Several vaccine manufacturers will be producing some of the 2009 H1N1 influenza vaccine in single-dose units, which will not require the use of thimerosal as a preservative.
  - The live-attenuated version of the vaccine, which is administered intranasally (through the nose), is produced in single-units and will not contain thimerosal.
  - Some vaccine will come in multi-dose vials and will contain thimerosal as a preservative, as is the case with seasonal influenza vaccines in multi-dose vials.
- Multi-dose vials of seasonal influenza vaccine contain thimerosal to prevent potential contamination after the vial is opened. Seasonal flu vaccines that do not contain thimerosal also are available.

#### Guillain-Barré syndrome (GBS) (Updated)

- Guillain-Barré syndrome (GBS) is a medical condition in which the body damages its own nerve cells, causing muscle weakness and sometimes paralysis.
- It is not fully understood why some people develop GBS, but it often occurs following infection. It is believed that stimulation of the body's immune system may play a role in its development.
- The infection that most commonly precedes GBS is caused by a bacterium called *Campylobacter jejuni*. Influenza virus infection has also been associated with GBS.
- Most people who develop GBS fully recover, but in some cases, death can result, usually from difficulty breathing.
- In 1976, there was a small risk of GBS following influenza (swine flu) vaccination (approximately 1 additional case per 100,000 people who received the swine flu vaccine). That number of GBS cases was slightly higher than the background rate for GBS. Since then, numerous studies have been done to evaluate if other flu vaccines were associated with GBS. In most studies, no association was found, but two studies suggested that approximately 1 additional person out of 1 million vaccinated people may be at risk for GBS associated with the seasonal influenza vaccine.

- FDA and CDC and several partners will be closely monitoring reports of serious vaccine adverse events, including GBS, following the 2009 H1N1 influenza vaccination.

*Syncope (Updated)*

- Syncope, or fainting, has been reported after vaccination with any vaccine, and is common among adolescent patients. Falls, as a result of fainting after vaccination, can sometimes result in serious injuries.
- Such injuries can be prevented by assuring that the vaccinated person is sitting in a chair or lying down and is observed for 15 minutes following vaccination.