

## 2013-2014 Influenza Vaccine Data from the U.S. Vaccine Adverse Event Reporting System (VAERS)

Thank you for visiting the VAERS website. This site provides information about influenza vaccine safety.

Each year the formulation for the influenza vaccine is selected based on the virus strains that are expected to circulate. VAERS will monitor the safety of influenza vaccines during the 2013-14 season and communicate concerns if they arise. Please see <a href="http://www.cdc.gov/flu/about/season/flu-season-2013-2014.htm">http://www.cdc.gov/flu/about/season/flu-season-2013-2014.htm</a> for more information about the influenza vaccine and upcoming influenza season.

- During the 2013-14 season, several kinds of influenza vaccine will be available.
  - The inactivated influenza vaccine, trivalent (IIV3) (flu shot) (protects against three viruses [2 influenza A strains and 1 influenza B strain]). For more information on the strains, see <u>http://www.cdc.gov/flu/professionals/acip/2013-summary-</u> <u>recommendations.htm#primary-changes</u>. It is available in both egg-based and cell-based formulations:

- Several standard dose IIV3 products that are manufactured using eggs have been used for decades and are available. Most standard dose IIV3 products are injected into the muscle.

- In addition to the standard dose egg-based vaccine, a higher dose form of IIV3 called Fluzone<sup>®</sup> High-Dose is available for persons ages 65 and older. For more information, see

http://www.cdc.gov/flu/protect/vaccine/ga\_fluzone.htm

- An intradermal trivalent egg-based influenza vaccine product (Fluzone<sup>®</sup> Intradermal) has been available since the 2011-12 season. This vaccine is injected into the skin (dermis), rather than the muscle, and therefore uses a much smaller needle than the regular influenza vaccine. It is recommended in persons ages 18-64. For more information, see

http://www.cdc.gov/flu/protect/vaccine/qa\_intradermal-vaccine.htm

- In addition to the usual egg-based influenza vaccines, a new cellbased flu vaccine will be available this season. Cell-based influenza vaccines are grown in cultured cells of mammalian origin instead of in hens' eggs. For more information, see

http://www.cdc.gov/flu/protect/vaccine/cell-based.htm

- A new recombinant influenza vaccine trivalent (RIV3) will be available this season. It is injected into the muscle and is used for



persons ages 18-49. For more information see <a href="http://www.cdc.gov/flu/protect/vaccine/qa\_flublok-vaccine.htm">http://www.cdc.gov/flu/protect/vaccine/qa\_flublok-vaccine.htm</a>

- The inactivated influenza vaccine (IIV4) quadrivalent (protects against four viruses [2 influenza A strains and 2 influenza B strains]) will be available. It is injected (i.e., given as a shot) into the muscle.
- The live, attenuated influenza vaccine (LAIV) is given by nasal spray and has been used since 2003. In previous years it was trivalent, but this year it will be quadrivalent (protect against four viruses [2 influenza A strains and 2 influenza B strains]). It is used for persons ages 2-49. For more information, see <u>http://www.cdc.gov/flu/about/qa/nasalspray.htm</u>
- During the 2013-14 influenza season, the CDC's Advisory Committee on Immunization Practices (ACIP) recommended that persons with egg allergy who report only hives after egg exposure should receive TIV, with additional safety measures. These recommendations have been in place since the 2011-12 influenza season. VAERS data did not show any increased reporting for allergy or anaphylaxis after influenza vaccine during the 2012-13 season.
- During the 2012-2013 season, there was no increase in reporting in the VAERS data for febrile seizures after the influenza vaccine in young children. In addition CDC's Vaccine Safety Datalink showed that rates of seizure after TIV were not elevated (see ACIP meeting June 20, 2013 available at <a href="http://www.cdc.gov/vaccines/acip/meetings/meetings-info.html">http://www.cdc.gov/vaccines/acip/meetings/meetings-info.html</a>). VAERS and VSD will continue to monitor this season for increases in febrile seizures in children.
  - During the 2010-11 influenza season, FDA and CDC detected an increase in the number of reports to VAERS of febrile seizures following trivalent influenza vaccine (TIV) vaccination (flu shot) in children younger than 2 years of age. A further study confirmed that children aged 6-59 months had an increased for risk for febrile seizures on the day of vaccination and the next day. This study also found that the increased risk for febrile seizures peaked at age 16 months when TIV was given together with the pneumococcal conjugate (PCV13) vaccine. The risk was less than 1 per 1,000 children vaccinated. This increase was also observed in the VAERS data for 2011-2012 season and this was not unexpected since the formulation from 2010-11 was not changed for the 2011-12 season.
  - Recommendations were not changed for the 2012-2013 season since vaccination is the best way to prevent illness and serious complications from influenza and pneumococcal disease and nearly all children who have a febrile seizure recover quickly and have no long-term effects.



- VAERS will continue to monitor this season for increases in febrile seizures in children.
- Please also see <a href="http://www.cdc.gov/flu/">http://www.cdc.gov/flu/</a> for information related to the 2013-2014 influenza season.
- Archived material of VAERS influenza vaccine safety data from previous seasons is available at: <u>http://vaers.hhs.gov/resources/updates.</u>
- In addition, all VAERS data remain publicly available at the following sites:

Download at: <u>http://vaers.hhs.gov/data/index</u> from the VAERS website. Search at: <u>http://wonder.cdc.gov/vaers.html</u> on the VAERS WONDER tool (see instructions below or to view training on the use of VAERS WONDER, go to <u>http://www.youtube.com/watch?v=4bsuy7TsBe8</u>).

## Instructions for using VAERS WONDER data search tool

- 1. Go to http://wonder.cdc.gov/vaers.html .
- 2. Click on the grey box "VAERS Data Search."
- 3. In section 1 of the VAERS Request screen, labeled "Organize table layout", under "Group Results By" select the variables that you are interested in viewing. If you would like to read the adverse event description reported, select "VAERS ID" as the first choice in the "Group Results By" box and check "Adverse Event Description" in the next section below entitled "Optional Measures."
- 4. In section 2 of the Request screen, labeled "Select symptoms," click the "Search" tab above the Symptoms list.
- 5. Inside the Search form, type item you would like to search for (such as "ALLERGY") in the first entry field and then click the gray "Search" button at the bottom of the Search form.
- 6. Select the desired Symptom codes shown in the "Results of Search" form.
  - Press the "Ctrl" key while clicking on additional codes.
  - The currently selected items appear in the "Currently selected" box on the right.
- 7. In section 3 of the Request screen, labeled "Select vaccine products," select the desired vaccine products shown from the "Vaccine Product" list.
  - Press the "Ctrl" key while clicking on additional codes.
  - The currently selected items appear in the "Currently selected" box on the right.
- 8. In section 4, select event characteristics you are interested in viewing.



- 9. In section 5 of the Request screen, labeled "Select location, age, gender" select the locations(s) that you are interested in viewing. Select the age(s) and gender you are interested in seeing.
- 10. In section 6 of the "Select date vaccinated" if you are interested in the current influenza season, click on "2013" and the "open" tab at the bottom of the section. Then highlight "2013/07 push the shift key and highlight the rest of the months of the 2013-2014 season that you are interested in. (Note that influenza vaccine season lasts from July 2013-June of 2014.)
- 11. Click any "Send" button on the right hand side of the screen. The results appear in the Results screen.