

2012-2013 Trivalent 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 which strains of viruses are expected to circulate. Two of the three virus strains in this year's influenza vaccine were changed from strains used in the 2011-12 vaccine. Despite annual changes in formulation, the safety profile of the influenza vaccine is usually similar from year to year. VAERS will monitor the safety of influenza vaccines during the 2012-13 season and communicate concerns if they arise. Please see http://www.cdc.gov/flu/protect/keyfacts.htm for more information about the influenza vaccine.

- During the 2012-13 season, three forms of influenza vaccine will be available.
 - The trivalent inactivated influenza vaccine (TIV) (flu shot) is injected into the muscle, and has been used for many years. In addition to the standard dose vaccine, a higher dose form of TIV called Fluzone High Dose is available for persons ages 65 and older. For more information, see http://www.cdc.gov/flu/protect/vaccine/ga_fluzone.htm
 - The live, attenuated influenza vaccine (LAIV) is given by nasal spray and has been used since 2003. For more information, see http://www.cdc.gov/flu/about/qa/nasalspray.htm.
 - An intradermal influenza vaccine product 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, For more information, see http://www.cdc.gov/flu/protect/vaccine/qa intradermal-vaccine.htm
- During the 2010-11 influenza season, FDA and CDC detected an increase in the number of reports to VAERS of febrile seizures following 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.
 - Febrile seizures can be frightening for the child's parents/caregivers;
 however, nearly all children who have a febrile seizure recover quickly and have no long-term effects.



 No changes in vaccine recommendations were made for TIV or PCV13; vaccination is the best way to prevent illness and serious complications from influenza and pneumococcal disease. For more information on this issue, see

http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/VaccineSafety/ucm240037.htm and

http://www.cdc.gov/vaccinesafety/concerns/FebrileSeizures.html.

 During the 2011-12 influenza season, 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 remain in place for the 2012-13 season. VAERS data did not show any increased reporting for allergy or anaphylaxis after influenza vaccine during the 2011-12 season as compared to the previous season. For more information on this issue, see

http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6132a3.htm?s_cid=mm6132a3_w

- Please also see http://www.cdc.gov/flu/ for information related to the 2012-2013 influenza season.
- Archived material of VAERS influenza vaccine safety data from previous seasons is available at: http://vaers.hhs.gov/resources/updates.
- In addition, all VAERS data remain publicly available at the following sites:

Download at: http://vaers.hhs.gov/data/index from the VAERS website. Search at: http://wonder.cdc.gov/vaers.html on the VAERS WONDER tool (see instructions below).

Instructions for using VAERS WONDER data search tool

- 1. Go to http://wonder.cdc.gov/vaers.html
- 2. 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.
- 3. In section 2 of the Request screen, labeled "Select symptoms," click the "Search" tab above the Symptoms list.
- 4. 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.
- 5. 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.
- 6. 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.
- 7. In section 4, select event characteristics you are interested in viewing.
- 8. 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.
- 9. In section 6 of the "Select date vaccinated" if you are interested in the current influenza season, click on "2012" and the "open" tab at the bottom of the section. Then highlight "2012/07 push the shift key and highlight the rest of the months of the 2012-2013 season that you are interested in. (Note that influenza vaccine season lasts from July 2012-June of 2013)
- 10. Click any "Send" button on the right hand side of the screen. The results appear in the Results screen.