



2014-2015 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. The viruses expected to circulate in 2014-15 are the same as 2013-14, and so no changes will be made to the vaccine formulations from last year. VAERS will monitor the safety of influenza vaccines during the 2014-15 season and communicate concerns if they arise. Please see <http://www.cdc.gov/flu/about/season/flu-season-2014-2015.htm> for more information about the influenza vaccine and upcoming influenza season.

- During the 2014-15 season, several kinds of influenza vaccine will be available.
 - The inactivated influenza vaccine, trivalent (IIV3) (flu shot) protects against three viruses [an A/California/7/2009 (H1N1)pdm09-like virus, an A/Texas/50/2012 (H3N2)-like virus, and a B/Massachusetts/2/2012-like virus]. It is available in both egg-based and cell culture-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[®] High-Dose has been available since the 2010-11 season for persons ages 65 and older. For more information, see http://www.cdc.gov/flu/protect/vaccine/qa_fluzone.htm
 - An intradermal trivalent egg-based influenza vaccine product (Fluzone[®] 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 cell culture-based flu vaccine, Flucelvax[®] (ccIIV3) has been available since the 2013-2014 season. Cell culture-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 Recombinant influenza vaccine trivalent, FluBlok[®] (RIV3) has been available since the 2013-2014 season. It is injected into the muscle and is



used for persons ages 18-49. For more information see http://www.cdc.gov/flu/protect/vaccine/qa_flublok-vaccine.htm

- The inactivated influenza vaccine (IIV4) quadrivalent (protects against four viruses [an A/California/7/2009 (H1N1)pdm09-like virus, an A/Texas/50/2012 (H3N2)-like virus, a B/Massachusetts/2/2012-like virus, and a B/Brisbane/60/2008-like virus]) has been available since the 2013-2014 season. It is injected (i.e., given as a shot) into the muscles. For more information see <http://www.cdc.gov/flu/protect/vaccine/quadrivalent.htm>
- The live, attenuated influenza vaccine (LAIV) is given by nasal spray and has been used since 2003. In previous years it was trivalent, but since the 2013-2014 season it has been quadrivalent (protect against four viruses [an A/California/7/2009 (H1N1)pdm09-like virus, an A/Texas/50/2012 (H3N2)-like virus, a B/Massachusetts/2/2012-like virus, and a B/Brisbane/60/2008-like virus]). It is used for persons ages 2-49. For more information, see <http://www.cdc.gov/flu/about/qa/nasalspray.htm>
- During the 2014-15 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 IIV or RIV, with additional safety measures. (See http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6332a3.htm?s_cid=mm6332a3_e) 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 2013-14 season.
- During the 2013-2014 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 IIV3 were not elevated (<http://www.cdc.gov/vaccines/acip/meetings/meetings-info.html>). 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 (IIV3) vaccination (flu shot) in children younger than 2 years of age. A further study confirmed that children aged 6-59 months had an increased 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 IIV3 was given together with the pneumococcal conjugate (PCV13) vaccine. The risk was less than 1 per 1,000 children vaccinated. An increase in reports 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. 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.
 - During the 2012-2013 and 2013-2014 seasons, no increase in reports of febrile seizures after influenza vaccine was seen in young children.
- Once influenza vaccines are available, CDC and FDA monitor VAERS data to look for adverse events that may be a vaccine safety concern or unexpected. These reports are reviewed by vaccine safety experts.
 - Please also see <http://www.cdc.gov/flu/about/season/flu-season-2014-2015.htm> for information related to the 2014-2015 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 or to view training on the use of VAERS WONDER, go to <http://www.youtube.com/watch?v=4bsuy7TsBe8>).

Instructions for using VAERS WONDER data search tool (See <http://www.youtube.com/watch?v=4bsuy7TsBe8>)

Go to <http://wonder.cdc.gov/vaers.html>

1. If you have a specific VAERS ID number that you want to view, click on the grey box entitled "VAERS Report Details, enter the VAERS ID number, and click on the gray box entitled "Event Details."
2. If you want to do a general search of the VAERS data, go back to the opening VAERS WONDER pages at <http://wonder.cdc.gov/vaers.html> and 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 see 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 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 vaccines.
 - The selected vaccines appear in the "Currently selected" box on the right.
 - In this section, you can also select a specific vaccine manufacturer, dose number or lot number to search.
8. In section 4 of the Request screen, labeled "Select location, age, gender" select the location(s), age(s) and gender you are interested in seeing.
9. In section 5 of the Request screen labeled "Select other event characteristics," select the specific characteristics you want to search.
10. In section 6 of the Request screen labeled "Select text fields," select the specific words or phrases from each section on the VAERS report that you want to search.
11. In section 7-11, select report completed dates, report received dates, vaccination dates, adverse event onset dates and death dates that you want to search.
12. Click any "Send" button on the right hand side of the screen. The results appear in the Results screen.