

hosted by the Missouri Department of Health and Senior Services' Bureau of Immunization Assessment and Assurance www.health.mo.gov/immunizations

webinar series

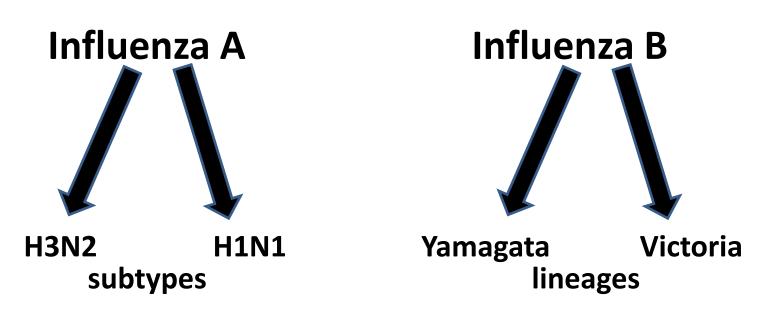
William Atkinson, MD, MPH Influenza Update August 18, 2016

Advisory Committee on Immunization Practices (ACIP)

- The recommendations to be discussed are primarily those of the ACIP
 - composed of 15 experts in clinical medicine and public health who are not government employees
 - provides guidance on the use of vaccines and other biologic products to the Department of Health and Human Resources, CDC, and the U.S. Public Health Service



Human Influenza Viruses



Example nomenclature

A/Texas/50/2012 (H3N2)

B/Brisbane/60/2008



Influenza Antigenic Changes

- Antigenic Shift
 - major change, new subtype
 - caused by exchange of gene segments
 - may result in pandemic
- Example of antigenic shift
 - H2N2 virus circulated in 1957-1967
 - H3N2 virus appeared in 1968 and completely replaced H2N2 virus
 - 2009 H1N1 pandemic was atypical

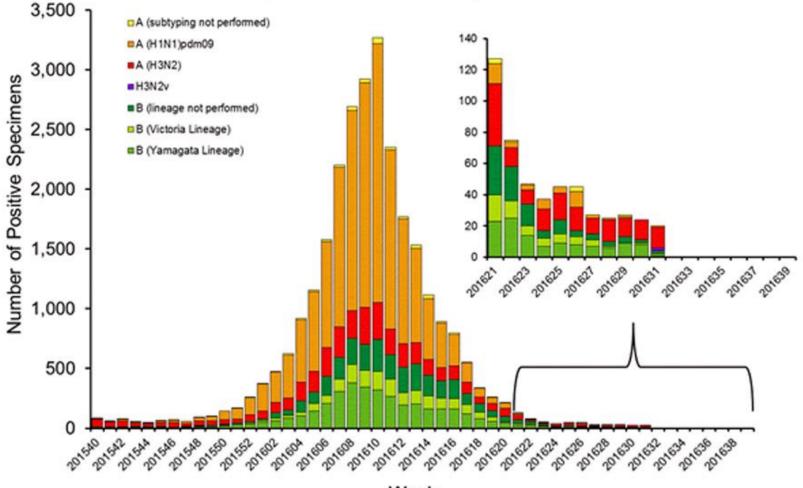


Influenza Antigenic Changes

- Antigenic Drift
 - Continuous, minor change, same subtype
 - caused by point mutations in gene
 - may result in epidemic
- Example of antigenic drift
 - in 2013-2014, A/Texas (H3N2) was dominant
 - In 2014-2015, A/Switzerland (H3N2) was dominant

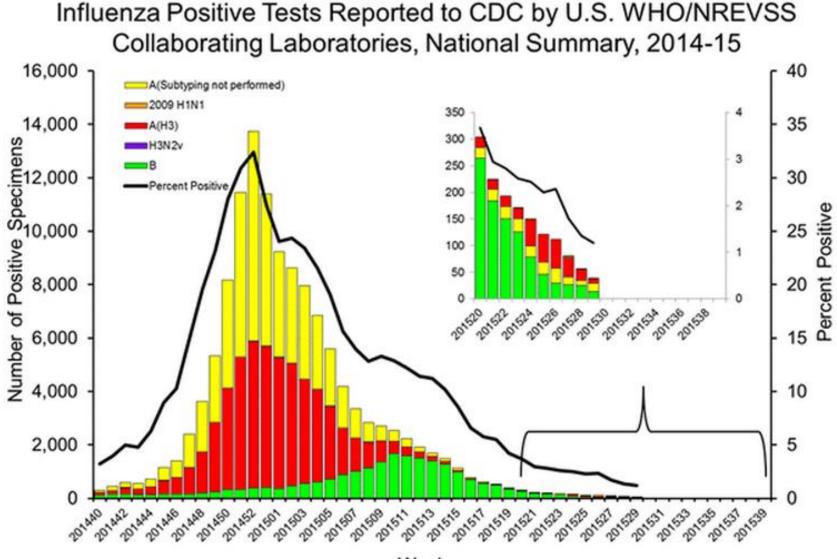


Influenza Positive Tests Reported to CDC by U.S. Public Health Laboratories, National Summary, 2015-2016 Season



Week





Week

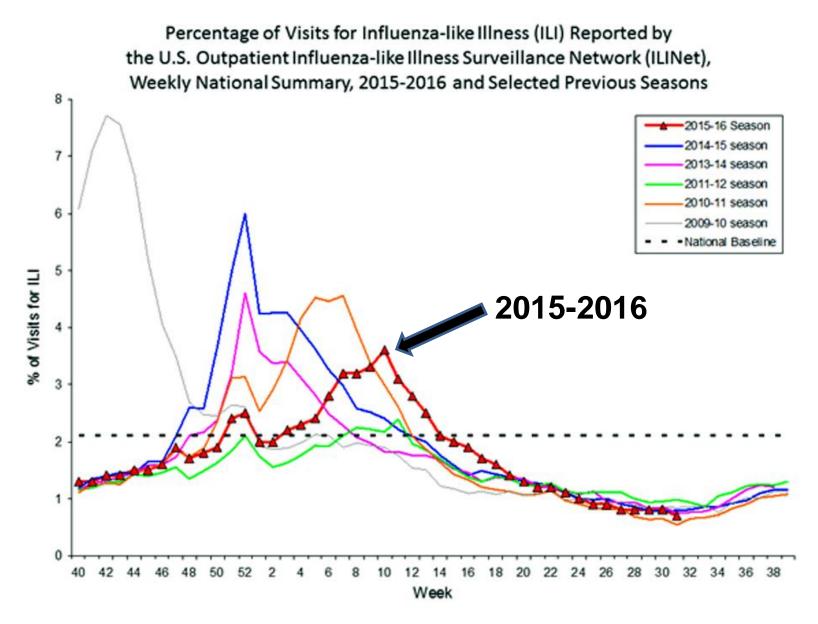


Predominant Influenza Virus by Season

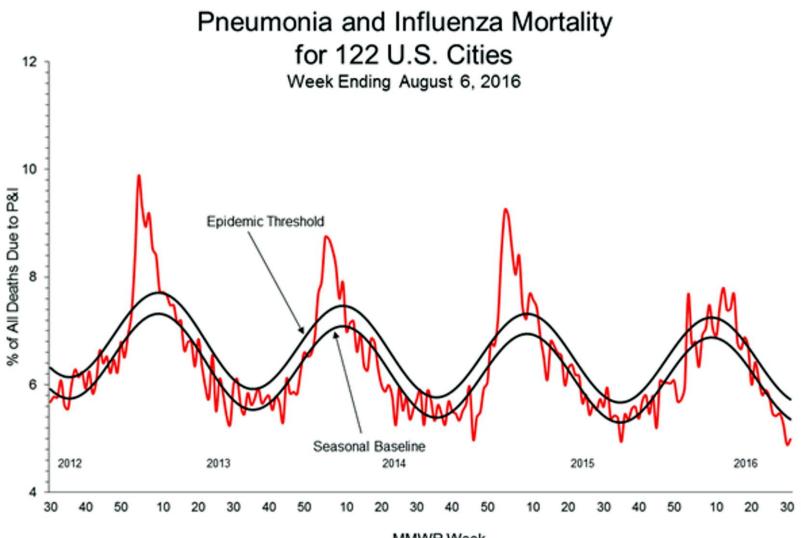
| Season | Early (Oct-Jan) | Late (Jan-May) | |
|-----------|-----------------|----------------|--|
| 2009-2010 | A/H1N1 | A/H1N1 | |
| 2010-2011 | A/H3N2 | A/H1N1, B | |
| 2011-2012 | A/H3N2 | В | |
| 2012-2013 | A/H3N2 | В | |
| 2013-2014 | A/H1N1 | В | |
| 2014-2015 | A/H3N2 | В | |
| 2015-2016 | A/H1N1 | В | |

www.cdc.gov/flu/weekly/fluactivitysurv.htm





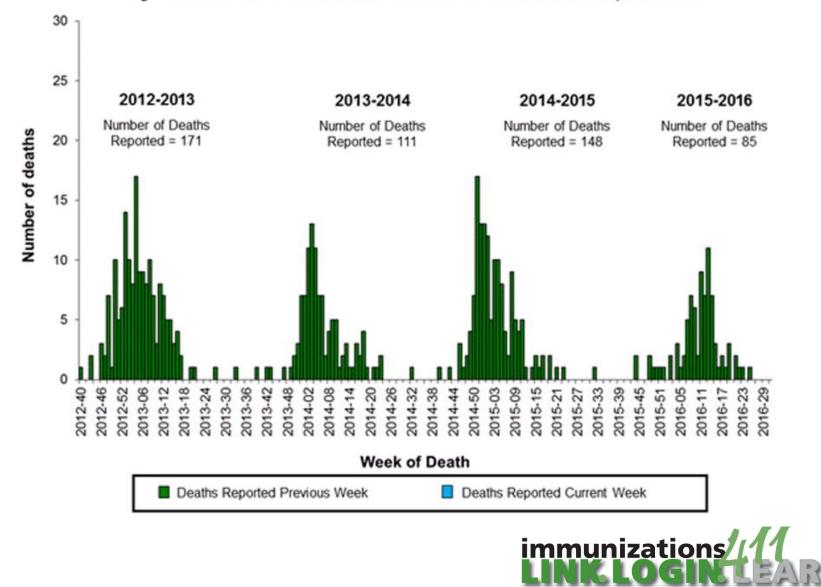




MMWR Week



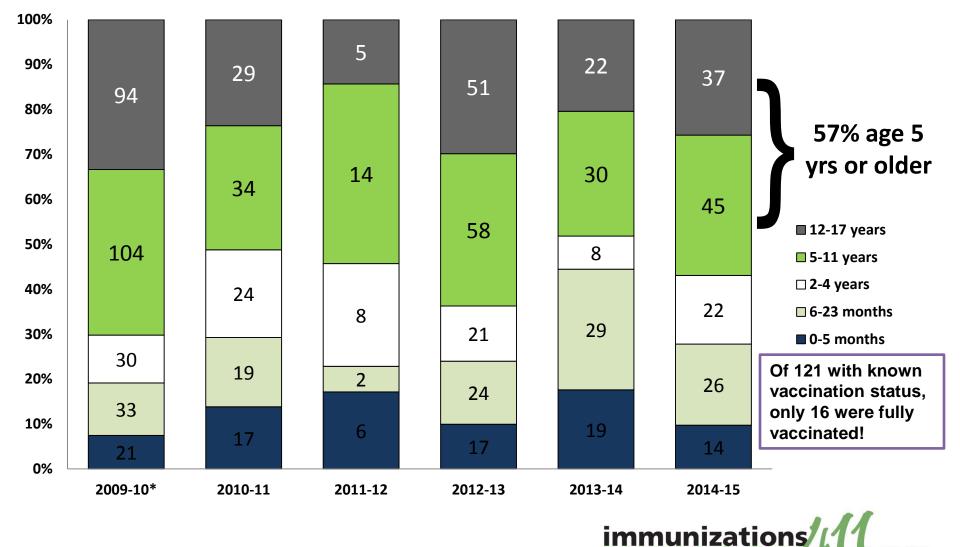
Number of Influenza-Associated Pediatric Deaths by Week of Death: 2012-2013 season to present



webinar series

www.health.mo.gow/immunizatio

Influenza-Associated Pediatric Deaths by Age Group



webinar series





Morbidity and Mortality Weekly Report August 7, 2015

Prevention and Control of Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices, United States, 2015–16 Influenza Season

Lisa A. Grohskopf, MD¹; Leslie Z. Sokolow, MSc, MPH^{1,2}; Sonja J. Olsen, PhD¹; Joseph S. Bresee, MD¹; Karen R. Broder, MD³; Ruth A. Karron, MD⁴

This report updates the 2014 recommendations of the Advisory Committee on Immunization Practices (ACIP) regarding the use of seasonal influenza vaccines (1). Updated information for the 2015-16 season includes 1) antigenic composition of U.S. seasonal influenza vaccines; 2) information on influenza vaccine products expected to be available for the 2015–16 season; 3) an updated algorithm for determining the appropriate number of doses for children aged 6 months through 8 years; and 4) recommendations for the use of live attenuated influenza vaccine (LAIV) and inactivated influenza vaccine (IIV) when either is available, including removal of the 2014-15 preferential recommendation for LAIV for healthy children aged 2 through 8 years. Information regarding topics related to influenza vaccination that are not addressed in this report is available in the 2013 ACIP seasonal influenza recommendations (2).

Information in this report reflects discussions during public meetings of ACIP held on February 26 and June 24, 2015. Subsequent modifications were made during CDC clearance review to update information and clarify wording. Meeting minutes, information on ACIP membership, and information on conflicts of interest are available at http://www.cdc.gov/ vaccines/acip/committee/members.html. Any updates will be posted at http://www.cdc.gov/flu.

Groups Recommended for Vaccination and Timing of Vaccination

Routine annual influenza vaccination is recommended for all persons aged ≥ 6 months who do not have contraindications. Optimally, vaccination should occur before onset of influenza activity in the community. Health care providers should offer vaccination by October, if possible. Vaccination

Influenza Vaccine Recommendations, 2016-2017

- Routine annual influenza vaccination is recommended for all persons age 6 months and older who do not have a contraindication
- Special effort should be made to vaccinate
 - infants and young children and their contacts
 - persons age 65 years and older and their contacts
 - persons with underlying medical conditions (including pregnancy) and their contacts
 - healthcare providers

*as of August 15 this recommendation has not been published



Influenza Vaccine Timing, 2015-2016

- To avoid missed opportunities for vaccination, providers should offer influenza vaccine during routine health care visits and hospitalizations when vaccine is available
- Children age 6 months through 8 years who require 2 doses should receive their first dose as soon as possible after vaccine becomes available, and the second dose at least 4 weeks later
- Healthcare providers should offer vaccine by October, if possible



What's New for Influenza 2016-2017*

- H3N2 strain changed
- New vaccine for persons 65 years and older
- Reduction in emphasis on egg allergy
- Live attenuated influenza vaccine

*based upon discussion at ACIP meeting, February and June 2016. As of August 13 the 2016-2017 ACIP influenza recommendations have not yet be published.



Influenza Vaccine Virus Strains 2016-2017

- Trivalent vaccines contain:
 - an A/California/7/2009 (H1N1)-like virus
 - an A/Hong Kong/4801/2014 (H3N2)-like* virus
 - a B/Brisbane/60/2008-like virus (Victoria lineage)
- Quadrivalent vaccines also contain: – a B/Phuket/3073/2013-like virus
 - (Yamagata lineage)

*new for the 2016-2017 season. MMWR 2016;65:567-75



Influenza Vaccines by FDA-Approved Age Group, 2016-2017 (as of August 2016)

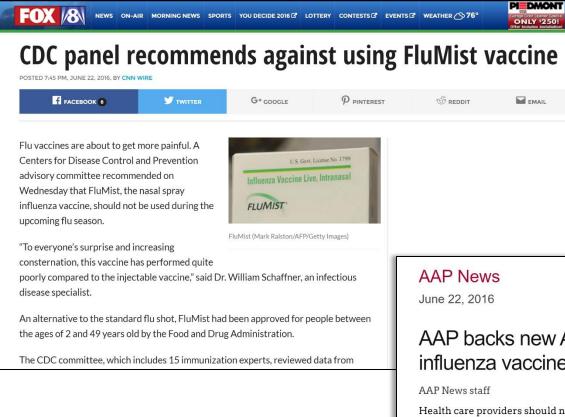
| Age group | Vaccines Approved for This Age Group |
|---------------------|--------------------------------------|
| 0 through 5 months | None |
| 6 months and older | Fluzone IIV4 (not ID or HD) |
| 2 through 49 years | FluMist IIV4 |
| 3 years and older | Fluarix IIV4, FluLaval IIV4* |
| 4 years and older | Fluvirin IIV3, Flucelvax ccIIV4 |
| 5 years and older | Afluria IIV3** |
| 18 years and older | Flublok RIV3 |
| 18 through 64 years | Fluzone IIV4 intradermal |
| 65 years and older | Fluzone IIV3 high dose, FLUAD IIV3 |

*FluLaval is expected to be approved for children as young as 6 months in late 2016 **Afluria IIV3 is approved by FDA for persons 5 years and older but recommended by ACIP for persons 9 years and older. Afluria is approved for persons 18 through 64 years when given by Stratis jet injector

Choice of Influenza Vaccine

- Where more than one type of vaccine is appropriate and available, ACIP has no preferential recommendation for use of any influenza vaccine product over another
 - quadrivalent vs trivalent
 - high-dose vs standard dose





AAP backs new ACIP recommendation on influenza vaccine

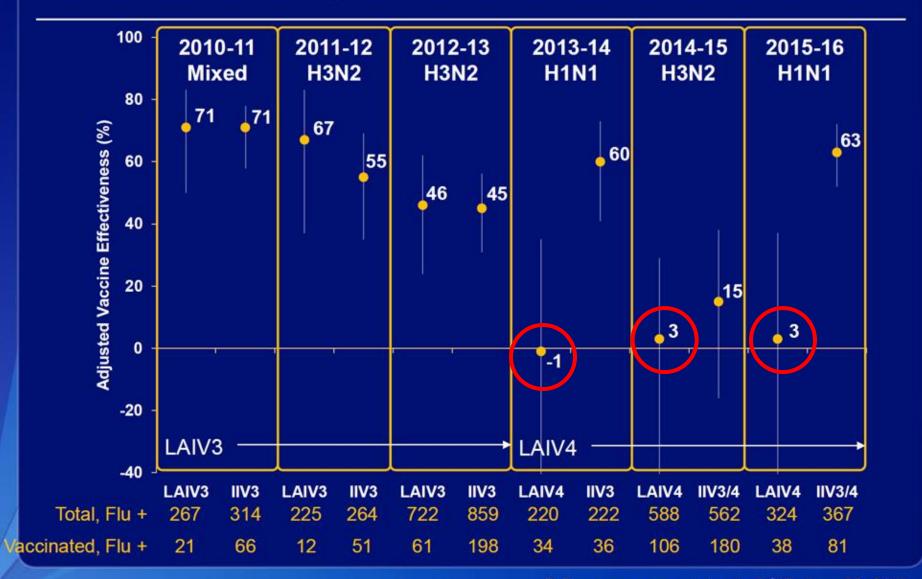
Health care providers should not use live attenuated influenza vaccine (LAIV) in the upcoming 2016-'17 season due to poor effectiveness, a Centers for Disease Control and Prevention (CDC) committee said Wednesday.

Academy leaders say they support the interim recommendation by the CDC's Advisory Committee on Immunization Practices (ACIP).

"We agree with ACIP's decision today to recommend health care providers and parents use only the inactivated vaccine for this influenza season," said AAP President Benard Dreyer, M.D., FAAP.

The AAP recommends children ages 6 months and older be immunized against influenza every year. Previously, the CDC and AAP had recommended either form of flu vaccine – the inactivated influenza vaccine (IIV) that is given by injection and is approved for all patients older than 6 months, or LAIV which is given by intranasal spray and is approved for healthy patients ages 2 through 49 years.

US Flu VE Network: LAIV and IIV VE age 2-17 yrs Any Influenza A or B



B Flannery, presentation to ACIP, June 22, 2016

Live Attenuated Influenza Vaccine 2016-2017 Season

- On June 22, ACIP voted to recommend that LAIV not be used in any setting in the U.S. during the 2016-2017 influenza vaccination season*
- AAP concurs with the recommendation
- This was done because CDC studies indicated that LAIV was not effective during the last 3 influenza seasons
- Conflicting data from the manufacturer, a European study and a Canadian study

*as of August 15 this recommendation has not been published



Live Attenuated Influenza Vaccine 2016-2017 Season

- FDA approved the 2016-2017 formulation of LAIV on July 1, 2016
- It appears that Astra Zeneca will distribute LAIV
 - at least 5 lots of LAIV have been released by FDA
- Tentative CDC recommendation is to count doses of LAIV administered during the 2016-2017 season*

*as of August 15 this recommendation has not been published



FLUAD (Novartis) IIV3

- Approved by FDA on November 24, 2015 based on demonstration of noninferiority to licensed trivalent inactivated vaccine
- Approved only for persons 65 years and older
- First U.S. influenza vaccine that contains an adjuvant (MF59)
- Used in Europe since 1997
- Approved in 38 other countries

www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/VaccineSafety/ucm473989.htm



Fluzone High-Dose

- Available since December 2009
- Trivalent formulation only
- Contains 4 X amount of influenza antigen than regular Fluzone
- Approved only for persons 65 years and older
- Produces higher antibody levels
- Local reactions more frequent than with standard dose vaccine



Fluzone High Dose Clinical Trial

- Multi-center randomized clinical trial
- 32,000 persons 65 years or older
- Compared to standard Fluzone
 - –24.2% reduction in laboratoryconfirmed influenza
 - –effective against both influenza A and B
 - reduction in risk of pneumonia and hospitalization



Influenza Vaccine Administration Errors

- Clinicians should not administer influenza vaccine to persons outside the licensed age range for the vaccine they are using
- If influenza vaccine is given outside the licensed age ranges it is not necessary to repeat the dose* unless a 0.25 mL dose was administered to a person 3 years or older

*except Fluzone Intradermal in some circumstances



Avoiding Mistakes with Influenza Vaccine

- Be certain of the approved ages for the vaccine(s) you stock
- Children 6 through 35 months of age can receive only Fluzone*
- Fluzone HD and FLUAD are approved only for people 65 years and older

*FluLaval is expected to be approved for children as young as 6 months in late 2016



Listing of Influenza Vaccines Available in the United States for the 2016-2017 Season

Influenza Vaccine Products for the 2016–2017 Influenza Season

| Manufacturer | Trade Name (vaccine abbreviation) ¹ | How Supplied | Mercury Content (µg Hg/0.5mL) | Age Group | Vaccine Product Billing Code | |
|---|---|--|-------------------------------------|--------------------------------|------------------------------|-----------------------|
| | | | | | CPT ³ | Medicare ⁴ |
| AstraZeneca | FluMist ^s (LAIV4) | 0.2 mL (single-use nasal spray) | 0 | 2 through 49 years | 90672 | 90672 |
| GlaxoSmithKline | Fluarix (IIV4) | 0.5 mL (single-dose syringe) | 0 | 3 years & older | 90686 | 90686 |
| ID Biomedical Corp. of Quebec, a subsidiary of GlaxoSmithKline | FluLaval (IIV4) | 0.5 mL (single-dose syringe) | 0 | 3 years & older | 90686 | 90686 |
| | | 5.0 mL (multi-dose vial) | <25 | 3 years & older | 90688 | 90688 |
| Protein Sciences Corp. | Flublok (RIV3) | 0.5 mL (single-dose vial) | 0 | 18 years & older | 90673 | 90673 |
| Sanofi Pasteur, Inc. Flu | Fluzone (IIV4) | 0.25 mL (single-dose syringe) | 0 | 6 through 35 months | 90685 | 90685 |
| | | 0.5 mL (single-dose syringe) | 0 | 3 years & older | 90686 | 90686 |
| | | 0.5 mL (single-dose vial) | 0 | 3 years & older | 90686 | 90686 |
| | | 5.0 mL (multi-dose vial) | 25 | 6 through 35 months | 90687 | 90687 |
| | | 5.0 mL (multi-dose vial) | 25 | 3 years & older | 90688 | 90688 |
| | Fluzone High-Dose (IIV3-HD) | 0.5 mL (single-dose syringe) | 0 | 65 years & older | 90662 | 90662 |
| | Fluzone Intradermal (IIV4-ID) | 0.1 mL (single-dose microinjection system) | 0 | 18 through 64 years | 90630 | 90630 |
| Seqirus (formerly Novartis influenza vaccines and bioCSL) | Afluria (IIV3) | 0.5 mL (single-dose syringe) | 0 | 9 years & older ^{6,7} | 90656 | 90656 |
| | | 5.0 mL (multi-dose vial) | 24.5 | | 90658 | Q2035 |
| | Fluad ⁸ (IIV3) | 0.5 mL (single-dose syringe) | 0 | 65 years & older | 90653 | 90653 |
| | Fluvirin (IIV3) | 0.5 mL (single-dose syringe) | ا≥ | 4 years & older | 90656 | 90656 |

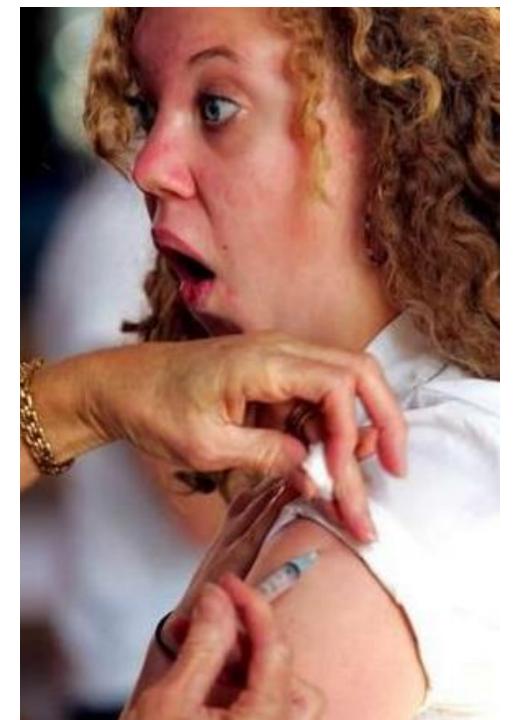






There is also evidence of patients experiencing shoulder pain after getting vaccinated against tendonitis, impingement syndrome, frozen shoulder syndrome, and adhesive capsulitis, HHS noted. "In order to capture the broader array of potential injuries, the Secretary proposes to add SIRVA for all tetanus toxoid-containing vaccines that are administered intramuscularly through percutaneous injection into the upper arm," the agency stated.

With these changes, patients diagnosed with SIRVA may receive compensation 12 to 18 months faster, according to a report published in *Wired*. This is wrong! Be certain of your anatomic landmarks before giving an intramuscular injection!





Correct locations for intramuscular vaccine injections (gloves not required)

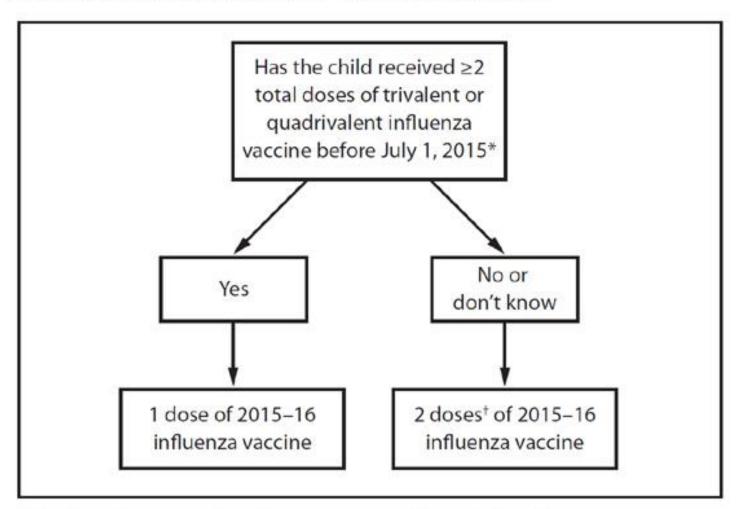
Influenza Vaccine for Children 6 Months Through 8 Years

- Two doses this season if
 - -first season they are vaccinated, or
 - did not receive a total of at least two doses of trivalent or quadrivalent influenza vaccine before July 1, 2015*, or
 - child's vaccination history is unknown
- Otherwise 1 dose this season

* The two doses need not have been received during the same season or consecutive seasons *MMWR* 2015;64:818-25



FIGURE 1. Influenza vaccine dosing algorithm for children aged 6 months through 8 years — Advisory Committee on Immunization Practices, United States, 2015–16 influenza season



* The two doses need not have been received during the same season or consecutive seasons.

[†] Doses should be administered ≥4 weeks apart. MMWR 2015;64:818-25

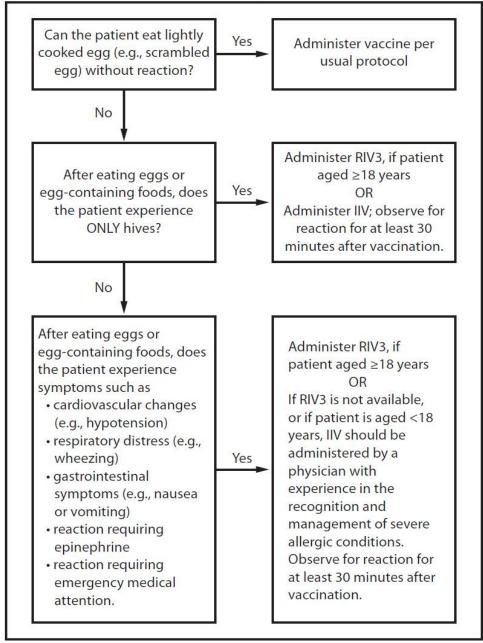
Influenza Vaccination for Persons with Egg Allergy

- Residual egg protein in influenza vaccine is a very rare cause of allergic reaction even in severely allergic people
- ACIP is going to relax restrictions on vaccination of egg-allergic people including elimination of the 30-minute observation period*
- Exact wording pending

*as of August 15 this recommendation has not been published



FIGURE 2. Recommendations regarding influenza vaccination of persons who report allergy to eggs^{*†} — Advisory Committee on Immunization Practices, United States, 2015–16 influenza season



This algorithm may be eliminated

FluBlok (RIV3) (Protein Sciences)

- Approved for persons 18 years and older
- Vaccine contains recombinant influenza virus hemagglutinin
 - protein is produced in insect cell line
 - no eggs or influenza viruses used in production
- Available in 0.5mL single-dose vials for IM injection
- Egg-free



MMWR 2015;64:818-25

Influenza Vaccine Revaccination

- ACIP recommends only 1 dose of influenza vaccine per season except for certain children younger than 9 years
- IIV4 is not recommended if IIV3 has already been given
- Fluzone High Dose/FLUAD is not recommended if standard IIV has already been given



Influenza Vaccine Cannot Cause Influenza

- Influenza-like illness following influenza vaccination is usually due to
 - influenza infection AFTER vaccination (influenza virus incubation period is 2-3 days immunity after vaccination takes a week to develop)
 - infection with a respiratory virus other than influenza (influenza vaccine won't prevent this)
 - coincidental illness interpreted by the patient to be "the flu"



VACCINE INFORMATION STATEMENT

Influenza (Flu) Vaccine (Inactivated or Recombinant): What you need to know

1 Why get vaccinated?

Influenza ("flu") is a contagious disease that spreads around the United States every year, usually between October and May.

Flu is caused by influenza viruses, and is spread mainly by coughing, sneezing, and close contact.

Anyone can get flu. Flu strikes suddenly and can last several days. Symptoms vary by age, but can include: · fever/chills

- · sore throat
- · muscle aches · fatigue
- · cough
- headache
- · runny or stuffy nose

Flu can also lead to pneumonia and blood infections, and cause diarrhea and seizures in children. If you have a medical condition, such as heart or lung disease, flu can make it worse.

Flu is more dangerous for some people. Infants and young children, people 65 years of age and older. pregnant women, and people with certain health conditions or a weakened immune system are at greatest risk.

Each year thousands of people in the United States die from flu, and many more are hospitalized.

Flu vaccine can:

2

- · keep you from getting flu.
- · make flu less severe if you do get it, and

flu vaccines

A dose of flu vaccine is recon

Children 6 months through 8

doses during the same flu sea

only one dose each flu seasor

Some inactivated flu vaccines

amount of a mercury-based pr

thimerosal. Studies have not s vaccines to be harmful, but fl contain thimerosal are availab

· keep you from spreading flu to your family and other people.

Inactivated and recombinant

There is no live flu virus in flu the flu.

There are many flu viruses, and changing. Each year a new flux against three or four viruses the disease in the upcoming flu sea vaccine doesn't exactly match t provide some protection

Flu vaccine cannot prevent: · flu that is caused by a virus n

- 01
- · illnesses that look like flu bu

It takes about 2 weeks for prote vaccination, and protection last

Some people s 3 this vaccine

- Tell the person who is giving y If you have any severe, life-t If you ever had a life-threater after a dose of flu vaccine, or any part of this vaccine, you get vaccinated. Most, but not contain a small amount of ea
- · If you ever had Guillain-Ba called GBS). Some people with a history of vaccine. This should be disci
- · If you are not feeling well, It is usually okay to get flu va a mild illness, but you might

VACCINE INFORMATION STATEMENT

Influenza (Flu) Vaccine (Live, Intranasal): What You Need to Know

Why get vaccinated?

Influenza ("flu") is a contagious disease that spreads around the United States every year, usually between October and May.

Flu is caused by influenza viruses, and is spread mainly by coughing, sneezing, and close contact.

Anyone can get flu. Flu strikes suddenly and can last several days. Symptoms vary by age, but can include:

· fever/chills · sore throat

1

- · muscle aches
- · fatigue
- cough
- headache
- · runny or staffy nose

Flu can also lead to pneumonia and blood infections, and cause diarrhea and seizures in children. If you have a medical condition, such as heart or lung disease, flu can make it worse.

Flu is more dangerous for some people. Infants and young children, people 65 years of age and older. pregnant women, and people with certain health conditions or a weakened immune system are at greatest risk.

Each year thousands of people in the United States die from flu, and many more are hospitalized.

Flu vaccine can:

- · keep you from getting flu
- · make flu less severe if you do get it, and

disponibles en español y en muchos strut sitionas. Visite www.immunite.org/vis LAIV is sprayed into the nose. LAIV does not contain thimerosal or other preservatives. It is made from weakened flu virus and does not cause flu

Many Vaccine Information Statements are

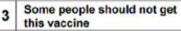
available in Spanish and other languages. See work immunities org/vis

Bojas de información subst vacunas estás

There are many flu viruses, and they are always changing. Each year LAIV is made to protect against four viruses that are likely to cause disease in the upcoming flu season. But even when the vaccine doesn't exactly match these viruses, it may still provide some protection.

- Flu vaccine cannot prevent:
- · flu that is caused by a virus not covered by the vaccine. OF.
- · illnesses that look like flu but are not.

It takes about 2 weeks for protection to develop after vaccination, and protection lasts through the flu season.



Some people should not get LAIV because of age, health conditions, or other reasons. Most of these people should get an injected flu vaccine instead. Your healthcare provider can help you decide.

Tell the provider if you or the person being vaccinated:

- · have any allergies, including an allergy to eggs, or have ever had an allergic reaction to an influenza. vaccine.
- have ever had Guillain-Barré Syndrome (also called GBS)
- · have any long-term heart, breathing, kidney, liver, or nervous system problems.

thma or breathing problems, or are a child who wheezing episodes.

tnant.

ild or adolescent who is receiving aspirin or containing products.

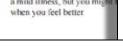
weakened immune system.

visiting or taking care of someone, within the fays, who requires a protected environment (for , following a bone marrow transplant)



Influenza VISs now available and now good indefinitely!

may be given to healthy, non-pregnant people 2 through 49 years of age. It may safely be given at the same time as other vaccines.



2015-2016 Influenza Vaccination Coverage (preliminary results)*

- 39.7% of those 6 months of age and older vaccinated (40.3% in November 2014)
- 39.2% of those 6 months-17 years of age vaccinated (42.0% in November 2014)
- 39.9% of adults 18 years of age and older vaccinated (39.7 in November 2014)
 - Only 60.2% of those 65 years of age and older vaccinated (61.3% in November 2014, but 66% in 2005)
 - 31.8% of adults 18-64 years of age with at least one high-risk medical condition vaccinated (31.7% in November 2014)

*Early season, November 2015 www.cdc.gov/flu/fluvaxview/nifs-estimates-42nov2015.htm



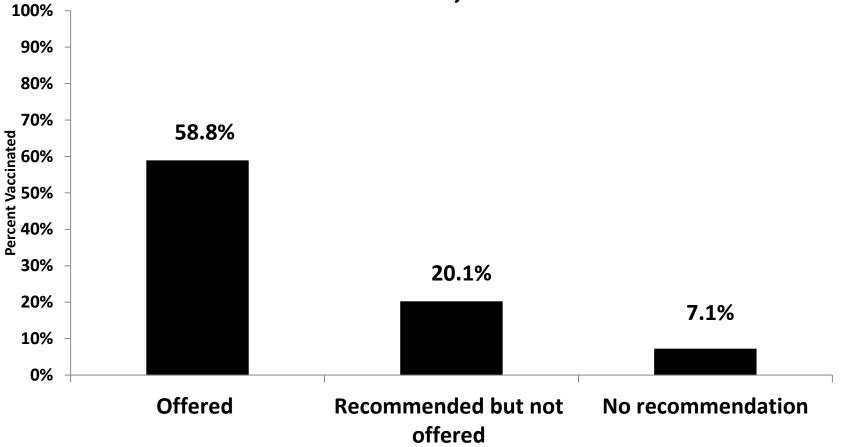
2015 Influenza Vaccination Coverage (preliminary results)

- Pregnant Women (HP 2020 goal of 80%)
 - as of early November 2015, vaccination coverage before and during pregnancy among pregnant women was 40.2%, similar to 2013-14 early season vaccination coverage (43.5%)

Influenza vaccination (inactivated vaccine only) was first recommended for women who were in the second or third trimester of pregnancy during the influenza season in 1997; recommended regardless of trimester in 2004.



Influenza Vaccination of Pregnant Women, 2015





Health Care Personnel and Influenza Vaccination, U.S., 2015

Influenza Vaccination Rates (internet panel, Nov 2015)

| Occupation | Rate |
|-------------|------|
| Physicians | 88% |
| NP/PA | 82% |
| Nurses | 77% |
| Pharmacists | 77% |

2020 Healthy People Goal is 90%

Lowest among administrative/non-clinical support staff (63%) and assistants/aides (55%)

www.cdc.gov/flu/fluvaxview/hcp-ipsnov2015.htm



How To Improve Influenza Vaccination Coverage in Your Practice

- Give a strong, unequivocal recommendation for the vaccine
- Be a role model* and be vaccinated yourself
- Make the vaccine available
- Publicize that you have vaccine available
- Consider the use of standing orders to "automate" the vaccination process
 - standing orders for influenza and all other vaccines available from IAC at www.immunize.org

*and protect yourself, your patients and your family!



Resources

- CDC Influenza Website –www.cdc.gov/flu/index.htm
- Immunization Action Coalition –www.immunize.org
- National Adult and Influenza Immunization Summit (NAIIS) –www.izsummitpartners.org/

Questions?

