

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

webinar series

### What's New With Flu

William Atkinson, MD, MPH August 17, 2017

#### **Disclosures**

- William Atkinson has worked as a consultant to Merck and as a speaker for Sanofi Pasteur educational programs
- The speaker will not discuss the off-label use any vaccine or a vaccine not approved by the Food and Drug Administration



# 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 Services, CDC, and the U.S. Public Health Service





#### **ACIP Recommendations**

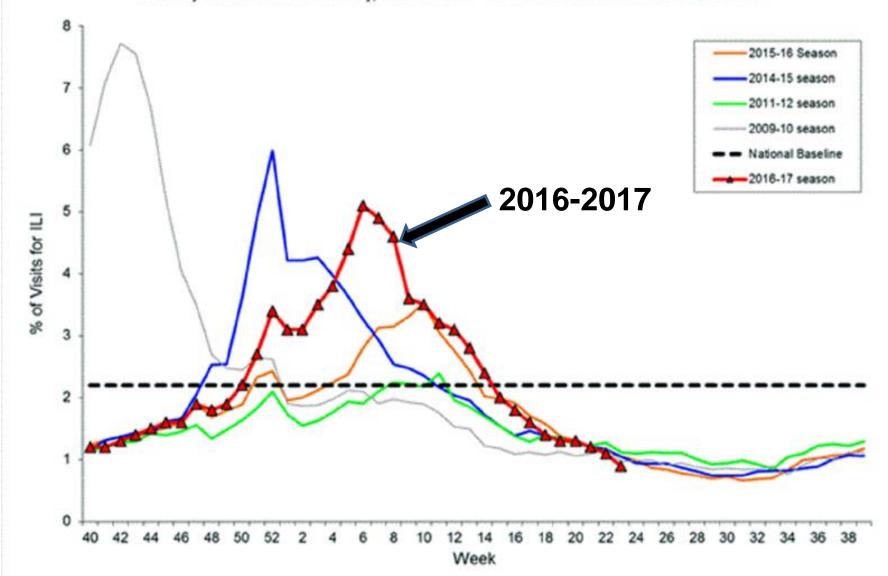
- Recommendations approved by the Committee are just the first step
- Recommendations do not become official policy until
  - approved by the CDC Director, and
  - published in *Morbidity and Mortality Weekly Report (MMWR)*



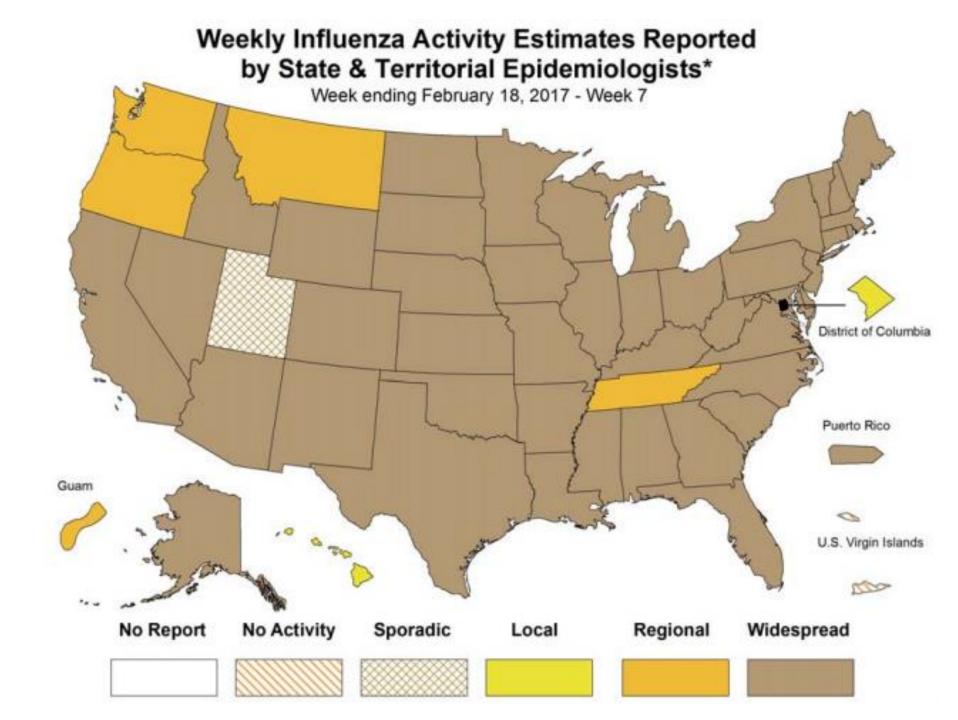
# 2016-2017 Influenza Season Summary



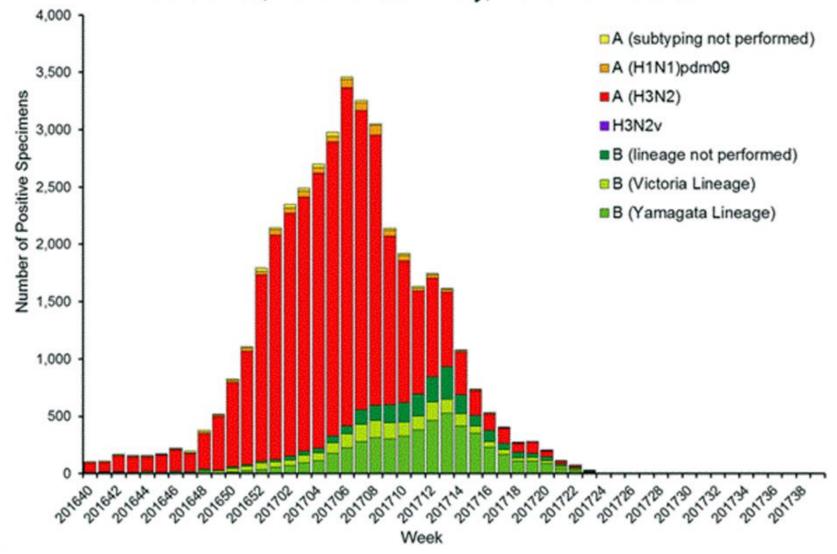
Percentage of Visits for Influenza-like Illness (ILI) Reported by the U.S. Outpatient Influenza-like Illness Surveillance Network (ILINet), Weekly National Summary, 2016-2017 and Selected Previous Seasons



Data as of June 10, 2017 (week 23). www.cdc.gov/flu/weekly/

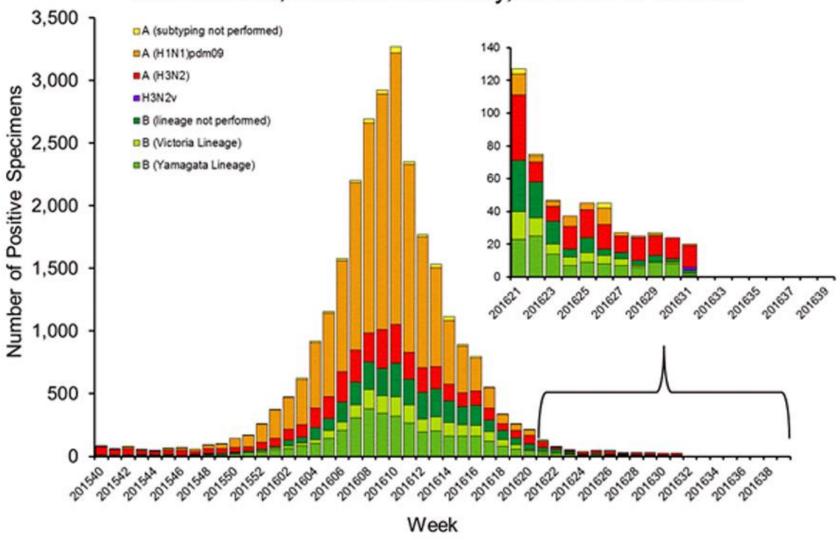


#### Influenza Positive Tests Reported to CDC by U.S. Public Health Laboratories, National Summary, 2016-2017 Season



Data as of June 10, 2017 (week 23). www.cdc.gov/flu/weekly/

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



### Influenza Virus 2016-2017

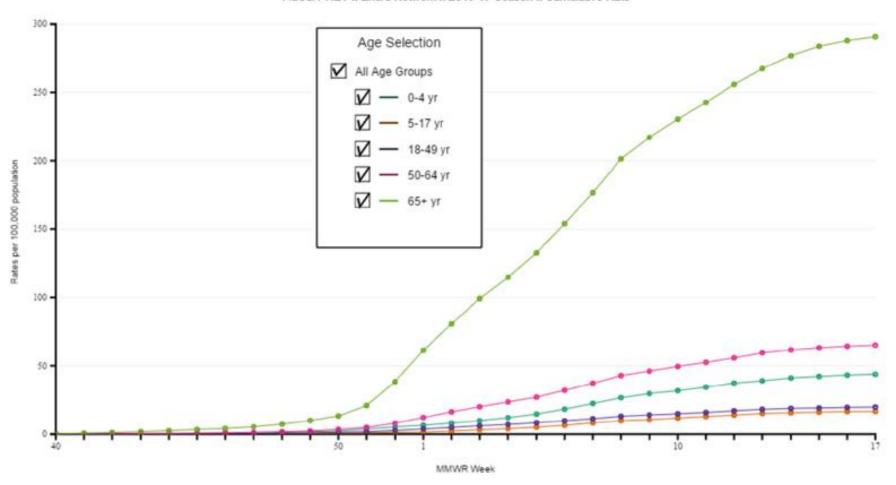
Virus	Circulating Virus	Vaccine Virus	
A/H1N1	A/California/7/2009 (100%)	A/California/7/2009	Match!
A/H3N2	A/Hong Kong 4801/2014 (97%)	A/Hong Kong 4801/2014	Match!
B/Victoria	B/Brisbane/60/2008 (91%)	B/Brisbane/60/2008	Match!
B/Yamagata	B/Phuket/3073/2013 (100%)	B/Phuket/3073/2013	Match!



#### Laboratory-Confirmed Influenza Hospitalizations

Preliminary cumulative rates as of Jun 10, 2017

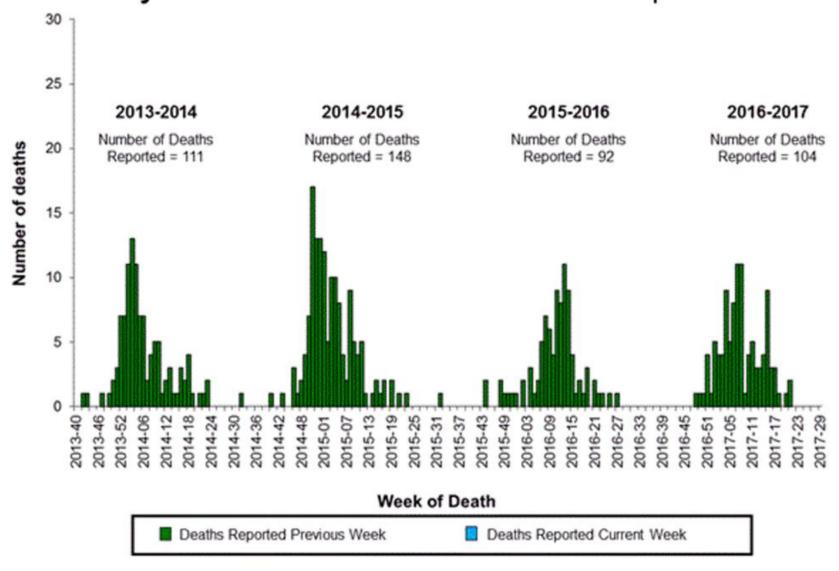
FluSury-NET :: Entire Network :: 2016-17 Season :: Cumulative Rate



Data as of June 10, 2017 (week 23). www.cdc.gov/flu/weekly/

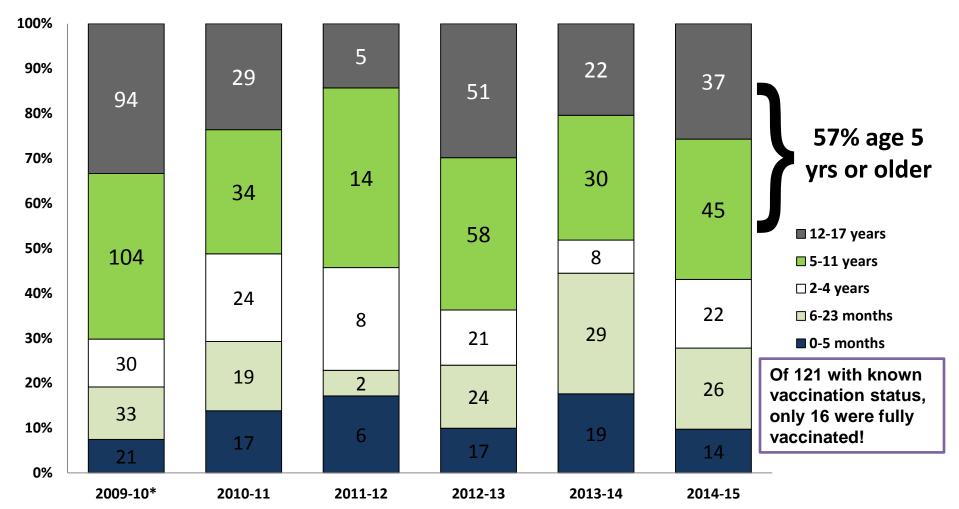


#### Number of Influenza-Associated Pediatric Deaths by Week of Death: 2013-2014 season to present



Data as of August 5, 2017 (week 31). www.cdc.gov/flu/weekly/

# Influenza-Associated Pediatric Deaths by Age Group





<sup>\*</sup>Data from week 40, 2014 – week 21, 2015

# 2017-2018 Influenza ACIP Recommendations

- Will not be published until at least mid-August 2017
- ACIP discussed the 2017-2018 recommendations at their June 2017 meeting
- Although recommendations have been voted upon by ACIP they do not become "official" until they are published in MMWR



### What's New for Influenza 2017-2018\*

- H1N1 strain change
- Changes in vaccines
- Revision of recommendation for Afluria for children 5 through 8 years of age
- Slight revision of recommendation for vaccination during pregnancy
- Live attenuated influenza vaccine



<sup>\*</sup>based upon discussion at ACIP meeting June 21, 2017

## Influenza Vaccine Recommendations, 2017-2018\*

- 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

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<sup>\*</sup>provisional until published in MMWR

### Influenza Vaccine Timing, 2017-2018\*

- 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

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# Influenza Vaccine Virus Strains 2017-2018

- Trivalent vaccines will contain:
  - an A/Michigan/45/2015 (H1N1)pdm09-like\*
  - 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)

<sup>\*</sup>new for the 2017-2017 season VRBPAC meeting minutes March 9, 2017. Available at www.fda.gov

# Influenza Vaccines by FDA-Approved Age Group, 2017-2018 (as of July 2017)

Age group	Vaccines Approved for This Age Group			
0 through 5 months	None			
6 months and older	Fluzone IIV4 (not ID or HD), FluLaval IIV4*			
2 through 49 years	FluMist IIV4 (may not be available)			
3 years and older	Fluarix IIV4			
4 years and older	Fluvirin IIV3, Flucelvax ccIIV4			
5 years and older	Afluria IIV3**			
18 years and older	Afluria IIV4, Flublok RIV4*			
18 through 64 years	Fluzone IIV4 intradermal			
65 years and older	Fluzone IIV3 high dose, Fluad alIV3			

<sup>\*</sup>new for 2017-2018 season.

<sup>\*\*</sup>Afluria is approved for persons 18 through 64 years when given by Stratis jet injector

## 2017-18 ACIP Influenza Recommendations— Proposed Recommendation for Afluria (IIV3) (1)

- Afluria is licensed by FDA for persons aged ≥5 years.
- Since 2010-11, ACIP has recommended Afluria for persons aged ≥9 years, following reports of febrile seizures and reactions in association with the 2010 Southern Hemisphere formulation
- February 2017: ACIP heard presentation from Seqirus summarizing investigation into root cause of reactions and manufacturing changes

# **ACIP** voted to rescind the recommendation to limit Afluria IIV3 to persons 9 years and older\*







poorly compared to the injectable vaccine," said Dr. William Schaffner, an infectious disease specialist.

An alternative to the standard flu shot, FluMist had been approved for people between the ages of 2 and 49 years old by the Food and Drug Administration.

The CDC committee, which includes 15 immunization experts, reviewed data from

#### **AAP News**

June 22, 2016

#### AAP backs new ACIP recommendation on influenza vaccine

AAP News staff

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.

## Live Attenuated Influenza Vaccine 2016-2017 Season

- On June 22, 2016 ACIP voted to recommend that LAIV not be used in any setting in the U.S. during the 2016-2017 influenza vaccination season\*
- AAP concured with the recommendation
- This was done because CDC studies indicated that LAIV was not effective during the previous 3 influenza seasons



# LAIV Influenza Vaccine Updates ACIP Meeting, June 2017

 ACIP voted to extend the recommendation not to use LAIV for the 2017-2018 season\*



### **Quick Quiz**

- What was the impact of the lack of availability of LAIV on influenza vaccination coverage among children for the 2016-2017 season?
  - a) Coverage went down
  - b) Coverage went up
  - c) Coverage did not change

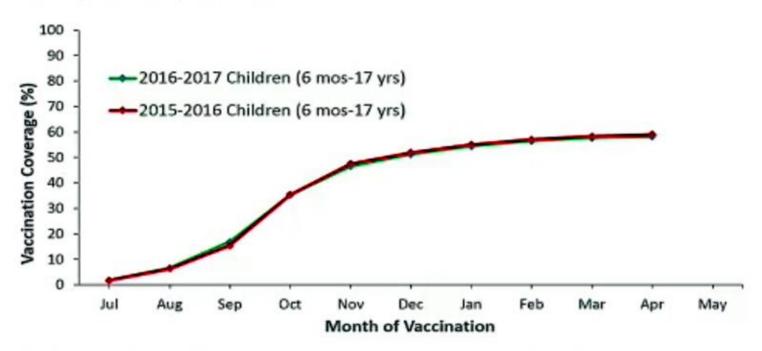


### **Quick Quiz**

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  - c) Coverage did not change



#### Preliminary Influenza Vaccination Coverage for the 2016-17 Season Compared with 2015-16 Final Season Estimates, Children, NIS-Flu, United States\*



Preliminary child results from NIS-Flu interviews conducted October through May for 2016-17 season,
 Final child results from NIS-Flu interviews conducted October through June for 2015-16 season.



#### 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 adjuvanted vs standard dose



### Fluad (Seqirus) 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 times the 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



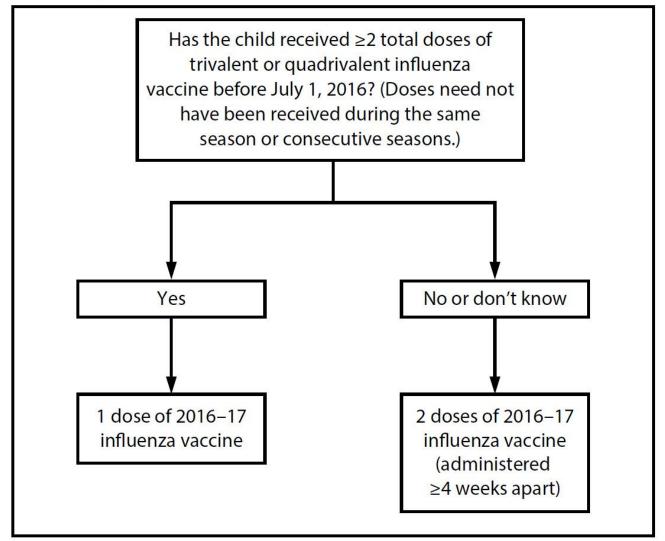
### Fluzone High Dose Clinical Trials

- 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
  - 36% reduction in risk of death during H3N2 season (2012-2013)

N Engl J Med 2014;371:635-45 www.fda.gov/BiologicsBloodVaccines/Scie nceResearch/ucm562601.htm



FIGURE. Influenza vaccine dosing algorithm for children aged 6 months through 8 years — Advisory Committee on Immunization Practices, United States, 2016–17 influenza season





# Influenza Vaccination of Children 6 Through 35 Months of Age

- Only Fluzone and FluLaval IIVs are approved for children younger than 36 months\*
- Doses are different
  - Fluzone dose is 0.25 mL
  - FluLaval dose is 0.5 mL
- Be careful!

<sup>\*</sup>Live attenuated influenza vaccine (LAIV) is approved for children as young as 2 years but is not recommended for use in the United States



# CDC Guidance on Influenza Vaccine Dosage Errors

- A person age 36 months or older is given a 0.25 mL dose of Fluzone
  - if the error is discovered on the same day the error occurred give the other "half" of the dose
  - if the error is discovered the next day or later give a full 0.5 mL repeat dose
- If a child younger than 36 months is given a 0.5 mL dose\* of Fluzone the dose can be counted as valid

\*A 0.5 mL dose is recommended for FluLaval regardless of age www.cdc.gov/flu/about/qa/vaxadmin.htm immunizations

### **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 or FluLaval
- Fluzone HD and Fluad are approved only for people 65 years and older



#### Influenza Vaccine Products for the 2016-2017 Influenza Season

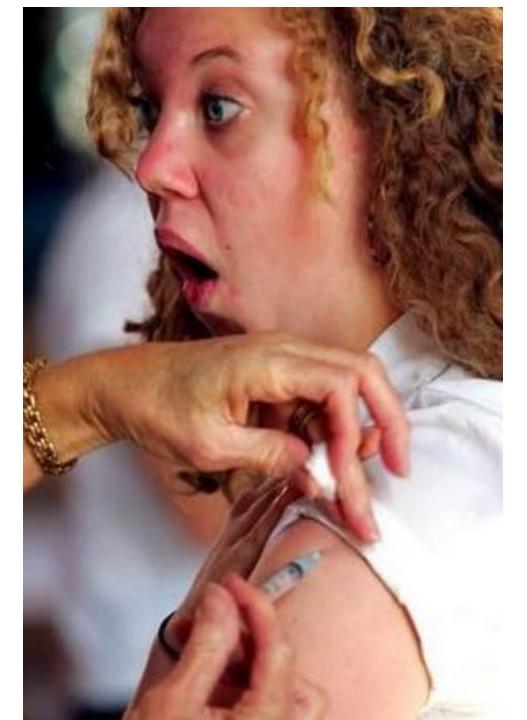
Manufacturer	Trade Name (vaccine abbreviation) <sup>1</sup>	How Supplied	Mercury Content (µg Hg/0.5mL)	Age Group	Vaccine Product Billing Code <sup>2</sup>	
					СРТ	Medicare <sup>3</sup>
AstraZeneca	FluMist <sup>4</sup> (LAIV4)	0.2 mL (single-use nasal spray)	0	2 through 49 years	90672	90672
GlaxoSmithKline	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	6 months & older	90686	90686
		5.0 mL (multi-dose vial)	<25	6 months & older	90688	90688
Protein Sciences Corp.	Flublok (RIV3)	0.5 mL (single-dose vial)	0	18 years & older	90673	90673
Sanofi Pasteur, Inc.	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 <sup>5,6</sup>	90656	90656
		5.0 mL (multi-dose vial)	24.5		90658	Q2035
	Afluria (IIV4)	0.5 mL (single-dose syringe)	0	18 years & older <sup>6</sup>	90686	90686
		5.0 mL (multi-dose vial)	24.5		90688	90688
	Fluad (alIV3)	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
		5.0 mL (multi-dose vial)	25		90658	Q2037
	Flucelvax (ccIIV4)	0.5 mL (single-dose syringe)	0	4 years & older	90674	90674



www.immunize.org/catg.d/p4072.pdf



This is wrong!
Be certain of your anatomic landmarks before giving an intramuscular injection!





Correct locations for intramuscular vaccine injections (gloves not required)

### CDC Guidance on Influenza Vaccine Route Errors

Should I repeat a dose of influenza vaccine administered by an incorrect route (such as intradermal)?

- Yes, if a formulation labeled for intramuscular injection is given by the subcutaneous or intradermal route, it should be repeated
- The dose may be administered as soon as possible
- There is no minimum interval required between the invalid dose (by subcutaneous or intradermal route) and the repeat dose



### Influenza Vaccine Administration

- The first shipment of influenza vaccine each season should be administered to you and your staff
- Use this opportunity to have each staff member who will be administering influenza vaccine demonstrate proper technique



### 2017-18 ACIP Influenza Recommendations—

#### Proposed Recommendation for Vaccination of Pregnant Women

#### 2016-17:

"Because pregnant and postpartum women are at higher risk for severe illness and complications from influenza than women who are not pregnant, the ACIP recommends that all women who are pregnant or who might be pregnant in the upcoming influenza season receive IIV. Influenza vaccination can be administered at any time during pregnancy, before and during the influenza season."

#### Proposed New:

"Because pregnant and postpartum women are at higher risk for severe illness and complications from influenza than women who are not pregnant, the ACIP recommends that all women who are pregnant or who might be pregnant in the upcoming influenza season receive influenza vaccine. Any licensed, recommended, and age-appropriate, trivalent or quadrivalent IIV or RIV may be used. Influenza vaccination can be administered at any time during pregnancy, before and during the influenza season"

# ACIP voted to simplify the wording to "any age-appropriate IIV. LAIV should not be administered to pregnant women."\*

\*provisional until published in MMWR



# Influenza Vaccination for Persons with Egg Allergy

 No change from 2016-2017 recommendations\*



## ACIP Recommendations for Influenza Vaccination of Persons with Egg Allergy

- A previous severe allergic reaction to influenza vaccine, regardless of the component suspected of being responsible for the reaction, is a contraindication to future receipt of the vaccine
- Providers should consider observing all patients for 15 minutes after vaccination to decrease the risk for injury should they experience syncope

MMWR 2016;65(RR-5): 29-30



### FluBlok (RIV4) (Protein Sciences)

- Approved for persons 18 years and older
- Quadrivalent formulation approved in 2016
- 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



### 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



#### 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:

- · keep you from getting flu.
- · make flu less severe if you do get it, and
- keep you from spreading flu to your family and other people.

#### 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 seas vaccine doesn't exactly match it provide some protection.

Flu vaccine cannot prevent:

- flu that is caused by a virus no or
- · illnesses that look like flu but

It takes about 2 weeks for protevaccination, and protection last-

### 3 Some people s

Tell the person who is giving y

- If you have any severe, lifest If you ever had a life-threaten after a dose of flu vaccine, or any part of this vaccine, your get vaccinated. Most, but not, contain a small amount of egg
- If you ever had Guillain-Ba called GBS).

Some people with a history of vaccine. This should be discur

 If you are not feeling well.
 It is usually okay to get flu vu a mild illness, but you might i when you feel better

#### VACCINE INFORMATION STATEMENT

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

Many Vaccine Information Statements are available in Spanish and other languages. See work-menunism org/vis Bojan de Información subre vacunamentin.

Mojas de información subte vacuras-estar disposibles en español y en muchos-otros áliomas. Visite wave immunice.org/vis

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

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· keep you from getting flu.

· make flu less severe if you do get it, and

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

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, or
- · 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 this vaccine

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 breething problems, or are a child who wheezing episodes.

ald or adolescent who is receiving aspirin or containing products.

weakened immune system.

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

#### 2 Inactivated and recombinant flu vaccines

A dose of flu vaccine is recom Children 6 months through 8 y doses during the same flu seas only one dose each flu season.

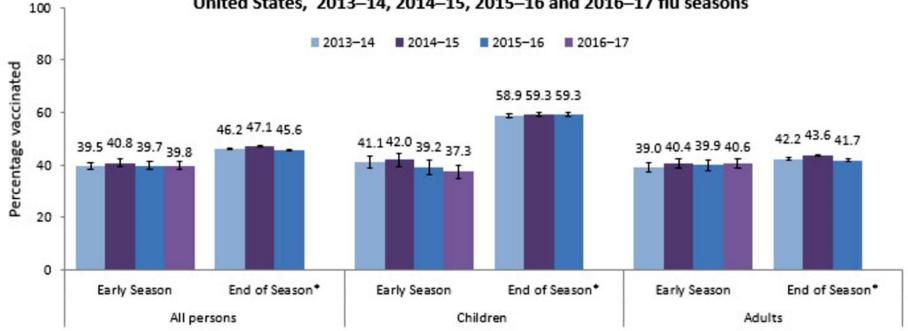
Some inactivated flu vaccines amount of a mercury-based por thimerosal. Studies have not s vaccines to be harmful, but flu contain thimerosal are availab

# 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 some time as other vaccines.



Early season and end of season flu vaccination coverage estimates, National Immunization Survey-Flu, Behavioral Risk Factor Surveillance System, and National Internet Flu Survey, United States, 2013–14, 2014–15, 2015–16 and 2016–17 flu seasons



\*Early season, November 2016 www.cdc.gov/flu/fluvaxview/nifs-estimates-nov2016.htm



# 2016 Influenza Vaccination Coverage (preliminary results)

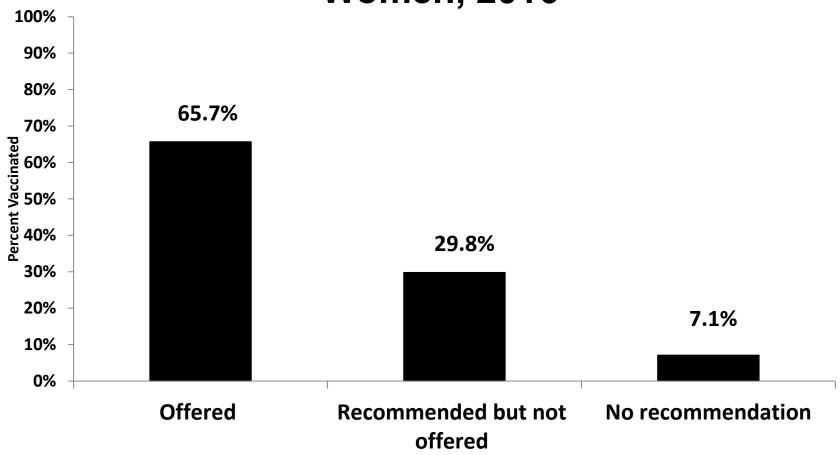
- Pregnant Women (HP 2020 goal of 80%)
  - as of early November 2016, influenza vaccination coverage among pregnant women before and during pregnancy was 46.6%, approximately 6 percentage points higher compared with 2015–16 early-season vaccination coverage (40.2%)
  - in the previous two flu seasons, vaccination coverage increased by approximately 7–10 percentage points from the early season to the end of the season

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.

www.cdc.gov/flu/fluvaxview/preg nant-women-nov2016.htm



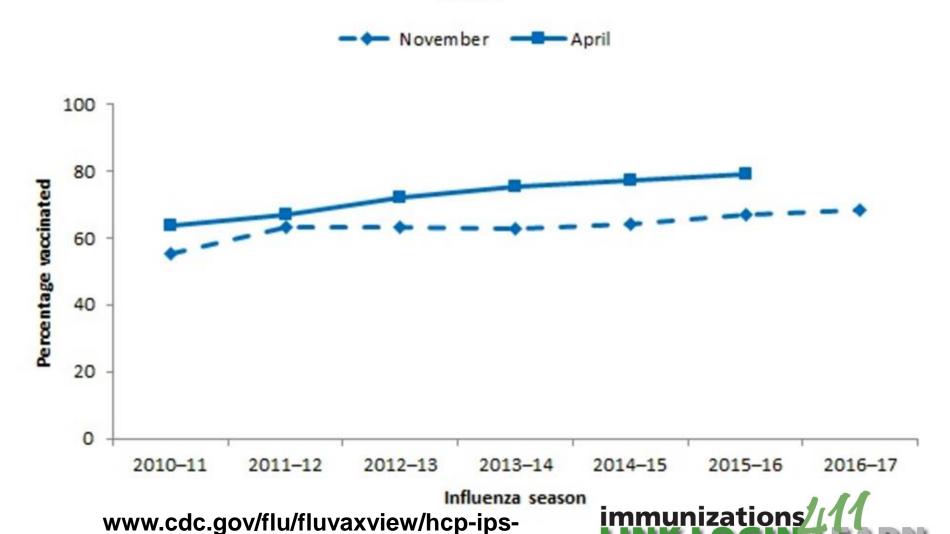
### Influenza Vaccination of Pregnant Women, 2016



www.cdc.gov/flu/fluvaxview/pregnant-women-nov2016.htm



Flu vaccination coverage among health care personnel vaccinated by November and by April for 2010–11 through 2015–16 flu seasons, and by November for 2016–17 flu season, Internet panel survey, United States



nov2016.htm

# Health Care Personnel and Influenza Vaccination, U.S., 2016

# Influenza Vaccination Rates (internet panel, Nov 2016)

Occupation	Rate
Physicians	83%
NP/PA	83%
Nurses	81%
Pharmacists	81%

2020 Healthy People Goal is 90%

Lowest among administrative/non-clinical support staff (65%) and assistants/aides (57%)

www.cdc.gov/flu/fluvaxview/hcp-ips-nov2016.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



<sup>\*</sup>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/



# Thank you. Questions?