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

www.cdc.gov/vaccines/acip/
Human Influenza Viruses

Influenza A
- H3N2 subtypes
- H1N1

Influenza B
- Yamagata lineages
- Victoria

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
Influenza Positive Tests Reported to CDC by U.S. WHO/NREVSS Collaborating Laboratories, National Summary, 2014-15

The chart shows the number of positive specimens and the percent positive over several weeks from 2014 to 2015. The data is color-coded by subtype:
- Yellow: A (Subtyping not performed)
- Orange: 2009 H1N1
- Red: A (H3)
- Blue: H3N2
- Green: B

The y-axis represents the number of positive specimens, ranging from 0 to 16,000. The x-axis represents the weeks from 2014 to 2015.

The percent positive, ranging from 0 to 40%, is displayed on the right y-axis.

The chart indicates a peak in positive cases during the weeks from 2014 to 2015, with a significant drop in the following weeks.

The logo of "immunizations411" is visible at the bottom right corner of the image.
## Predominant Influenza Virus by Season

<table>
<thead>
<tr>
<th>Season</th>
<th>Early (Oct-Jan)</th>
<th>Late (Jan-May)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2009-2010</td>
<td>A/H1N1</td>
<td>A/H1N1</td>
</tr>
<tr>
<td>2010-2011</td>
<td>A/H3N2</td>
<td>A/H1N1, B</td>
</tr>
<tr>
<td>2011-2012</td>
<td>A/H3N2</td>
<td>B</td>
</tr>
<tr>
<td>2012-2013</td>
<td>A/H3N2</td>
<td>B</td>
</tr>
<tr>
<td>2013-2014</td>
<td>A/H1N1</td>
<td>B</td>
</tr>
<tr>
<td>2014-2015</td>
<td>A/H3N2</td>
<td>B</td>
</tr>
<tr>
<td>2015-2016</td>
<td>A/H1N1</td>
<td>B</td>
</tr>
</tbody>
</table>

[www.cdc.gov/flu/weekly/fluactivitysurv.htm](http://www.cdc.gov/flu/weekly/fluactivitysurv.htm)
Percentage of Visits for Influenza-like Illness (ILI) Reported by the U.S. Outpatient Influenza-like Illness Surveillance Network (ILINet), Weekly National Summary, 2015-2016 and Selected Previous Seasons

2015-2016
Pneumonia and Influenza Mortality for 122 U.S. Cities
Week Ending August 6, 2016

% of All Deaths Due to P&I

Epidemic Threshold
Seasonal Baseline

MMWR Week

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

2012-2013
Number of Deaths Reported = 171

2013-2014
Number of Deaths Reported = 111

2014-2015
Number of Deaths Reported = 148

2015-2016
Number of Deaths Reported = 85
Influenza-Associated Pediatric Deaths by Age Group

*Data from week 40, 2014 – week 21, 2015

Of 121 with known vaccination status, only 16 were fully vaccinated!

57% age 5 yrs or older

- 12-17 years
- 5-11 years
- 2-4 years
- 6-23 months
- 0-5 months

*2009-10*

- 94
  - 57% age 5 yrs or older
  - 30
  - 104

- 29
  - 24
  - 34

- 5
  - 2
  - 14

- 51
  - 21
  - 58

- 22
  - 29
  - 8

- 37
  - 22
  - 45
FLU SEASON IS HERE!
$79 STEAM CLEANING KILLS VIRUS
USE YOUR OWNER REWARDS
Prevention and Control of Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices, United States, 2015–16 Influenza Season

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.

MMWR 2015;64:818-25
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)

<table>
<thead>
<tr>
<th>Age group</th>
<th>Vaccines Approved for This Age Group</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 through 5 months</td>
<td>None</td>
</tr>
<tr>
<td>6 months and older</td>
<td>Fluzone IIV4 (not ID or HD)</td>
</tr>
<tr>
<td>2 through 49 years</td>
<td>FluMist IIV4</td>
</tr>
<tr>
<td>3 years and older</td>
<td>Fluarix IIV4, FluLaval IIV4*</td>
</tr>
<tr>
<td>4 years and older</td>
<td>Fluvirin IIV3, Flucelvax cclIV4</td>
</tr>
<tr>
<td>5 years and older</td>
<td>Afluria IIV3**</td>
</tr>
<tr>
<td>18 years and older</td>
<td>Flublok RIV3</td>
</tr>
<tr>
<td>18 through 64 years</td>
<td>Fluzone IIV4 intradermal</td>
</tr>
<tr>
<td>65 years and older</td>
<td>Fluzone IIV3 high dose, FLUAD IIV3</td>
</tr>
</tbody>
</table>

*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
CDC panel recommends against using FluMist vaccine

Flu vaccines are about to get more painful. A Centers for Disease Control and Prevention advisory committee recommended on Wednesday that FluMist, the nasal spray influenza vaccine, should not be used during the upcoming flu season.

“To everyone’s surprise and increasing consternation, this vaccine has performed quite 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, 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

MMWR 2011;60:1128-32
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 laboratory-confirmed 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

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Trade Name (vaccine abbreviation)</th>
<th>How Supplied</th>
<th>Mercury Content (µg Hg/0.5mL)</th>
<th>Age Group</th>
<th>Vaccine Product Billing Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>AstraZeneca</td>
<td>FluMist® (LAIV4)</td>
<td>0.2 mL (single-use nasal spray)</td>
<td>0</td>
<td>2 through 49 years</td>
<td>90672, 90672</td>
</tr>
<tr>
<td>GlaxoSmithKline</td>
<td>Fluarix (IIIV4)</td>
<td>0.5 mL (single-dose syringe)</td>
<td>0</td>
<td>3 years &amp; older</td>
<td>90686, 90686</td>
</tr>
<tr>
<td>ID Biomedical Corp., of Quebec, a</td>
<td>FluLaval (IIIV4)</td>
<td>0.5 mL (single-dose syringe)</td>
<td>0</td>
<td>3 years &amp; older</td>
<td>90688, 90688</td>
</tr>
<tr>
<td>subsidiary of GlaxoSmithKline</td>
<td></td>
<td>5.0 mL (multi-dose vial)</td>
<td>&lt;25</td>
<td>3 years &amp; older</td>
<td>90688, 90688</td>
</tr>
<tr>
<td>Protein Sciences Corp.</td>
<td>Flublok (RIV3)</td>
<td>0.5 mL (single-dose vial)</td>
<td>0</td>
<td>18 years &amp; older</td>
<td>90673, 90673</td>
</tr>
<tr>
<td>Sanofi Pasteur, Inc.</td>
<td>Fluzone (IIIV4)</td>
<td>0.25 mL (single-dose syringe)</td>
<td>0</td>
<td>6 through 35 months</td>
<td>90685, 90685</td>
</tr>
<tr>
<td></td>
<td></td>
<td>0.5 mL (single-dose syringe)</td>
<td>0</td>
<td>3 years &amp; older</td>
<td>90686, 90686</td>
</tr>
<tr>
<td></td>
<td></td>
<td>0.5 mL (single-dose vial)</td>
<td>0</td>
<td>3 years &amp; older</td>
<td>90686, 90686</td>
</tr>
<tr>
<td></td>
<td></td>
<td>5.0 mL (multi-dose vial)</td>
<td>25</td>
<td>6 through 35 months</td>
<td>90687, 90687</td>
</tr>
<tr>
<td></td>
<td></td>
<td>5.0 mL (multi-dose vial)</td>
<td>25</td>
<td>3 years &amp; older</td>
<td>90688, 90688</td>
</tr>
<tr>
<td></td>
<td>Fluzone High-Dose (IIV3-HD)</td>
<td>0.5 mL (single-dose syringe)</td>
<td>0</td>
<td>65 years &amp; older</td>
<td>90662, 90662</td>
</tr>
<tr>
<td></td>
<td>Fluzone Intradermal (IIV4-ID)</td>
<td>0.1 mL (single-dose microinjection system)</td>
<td>0</td>
<td>18 through 64 years</td>
<td>90630, 90630</td>
</tr>
<tr>
<td>Seqirus (formerly Novartis influenza vaccines and bioCSL)</td>
<td>Afluria (IIV3)</td>
<td>0.5 mL (single-dose syringe)</td>
<td>0</td>
<td>9 years &amp; older</td>
<td>90656, 90656</td>
</tr>
<tr>
<td></td>
<td></td>
<td>5.0 mL (multi-dose vial)</td>
<td>24.5</td>
<td>65 years &amp; older</td>
<td>90658, Q2015</td>
</tr>
<tr>
<td></td>
<td>FluidflurA (IIV3)</td>
<td>0.5 mL (single-dose syringe)</td>
<td>0</td>
<td>65 years &amp; older</td>
<td>90653, 90653</td>
</tr>
<tr>
<td></td>
<td>Fluorine (IIV3)</td>
<td>0.5 mL (single-dose syringe)</td>
<td>≤1</td>
<td>4 years &amp; older</td>
<td>90656, 90656</td>
</tr>
</tbody>
</table>

Compensation Growing for Botched Vaccine Administration

Meghan Ross, Associate Editor
Published Online: Thursday, September 10, 2015

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The US Department of Health and Human Services (HHS) is making it easier for patients with shoulder injury related to vaccine administration (SIRVA) to be compensated for their pain.

HHS recently made revisions to its vaccine injury table, which lists and explains potential injuries presumed to be caused by vaccines.

Citing scientific evidence demonstrating a causal relationship between a vaccine injection and deltoid bursitis, HHS Secretary Sylvia Mathews Burwell suggested adding “a more expansive injury of SIRVA” to the table.

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

- Has the child received ≥2 total doses of trivalent or quadrivalent influenza vaccine before July 1, 2015*

  - Yes
    - 1 dose of 2015–16 influenza vaccine
  - No or don’t know
    - 2 doses† of 2015–16 influenza vaccine

* The two doses need not have been received during the same season or consecutive seasons.
† Doses should be administered ≥4 weeks apart.
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
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

*MMWR 2013;62(RR-7)*
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”
Influenza VISs now available and now good indefinitely!
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
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

- Offered: 58.8%
- Recommended but not offered: 20.1%
- No recommendation: 7.1%
Health Care Personnel and Influenza Vaccination, U.S., 2015

Influenza Vaccination Rates (internet panel, Nov 2015)

<table>
<thead>
<tr>
<th>Occupation</th>
<th>Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physicians</td>
<td>88%</td>
</tr>
<tr>
<td>NP/PA</td>
<td>82%</td>
</tr>
<tr>
<td>Nurses</td>
<td>77%</td>
</tr>
<tr>
<td>Pharmacists</td>
<td>77%</td>
</tr>
</tbody>
</table>

2020 Healthy People Goal is 90%

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

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?