Influenza and Pneumococcal Vaccine Update

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GenerateHealth STL
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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

www.cdc.gov/vaccines/acip/
Influenza

• Circulates in the Northern Hemisphere every year

• Not possible to predict when it will start, peak or end
  – typically peaks in January or February

• Vaccine viruses are chosen in February so that vaccine can be available by September

www.cdc.gov/flu/
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/
Data as of August 5, 2017 (week 31). www.cdc.gov/flu/weekly/
Prevention and Control of Seasonal Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices — United States, 2017–18 Influenza Season

www.cdc.gov/mmwr/volumes/66/rr/rr6602a1.htm
What’s New for Influenza 2017-2018

• H1N1 strain change
• Changes in some vaccine composition and labeling
• Slight revision of recommendation for vaccination during pregnancy
• Live attenuated influenza vaccine

*MMWR* 2017;66(RR-2):1-20
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

*MMWR* 2017;66(RR-2):1-20
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.

*MMWR* 2017;66(RR-2):1-20
# Influenza Vaccines by FDA-Approved Age Group, 2017-2018 (as of September 2017)

<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><strong>Fluzone IIIV4</strong> (not ID or HD), <strong>FluLaval IIIV4</strong></td>
</tr>
<tr>
<td>2 through 49 years</td>
<td><strong>FluMist IIIV4</strong> (may not be available)</td>
</tr>
<tr>
<td>3 years and older</td>
<td><strong>Fluarix IIIV4</strong></td>
</tr>
<tr>
<td>4 years and older</td>
<td><strong>Fluvirin IIIV3</strong>, <strong>Flucelvax cclIIIV4</strong></td>
</tr>
<tr>
<td>5 years and older</td>
<td><strong>Afluria IIIV3</strong>, <strong>Afluria IIIV4</strong></td>
</tr>
<tr>
<td>18 years and older</td>
<td><strong>Flublok RIV4</strong></td>
</tr>
<tr>
<td>18 through 64 years</td>
<td><strong>Fluzone IIIV4 intradermal</strong></td>
</tr>
<tr>
<td>65 years and older</td>
<td><strong>Fluzone IIIV3 high dose, Fluad allIV3</strong></td>
</tr>
</tbody>
</table>

*new for 2017-2018 season.

**Afluria is approved for persons 18 through 64 years when given by Stratis jet injector**
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, 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 concurred with the recommendation

• This was done because CDC studies indicated that LAIV was not effective during the previous 3 influenza seasons

*MMWR 2016;65(RR-5)
ACIP Influenza Recommendations 2017-2018
Live Attenuated Influenza Vaccine

• ACIP recommends that LAIV not be used during the 2017-2018 season
• LAIV is scheduled to be discussed again at the October 2017 ACIP meeting so a change in ACIP recommendation is possible

MMWR 2017;66(RR-2):1-20
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
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 for persons 65 years and older

*MMWR* 2017;66(RR-2):1-20
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 (Sanofi) IIV3

• Available since December 2009
• 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

MMWR 2011;60:1128-32
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 laboratory-confirmed 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/ScienceResearch/ucm562601.htm
ACIP Recommendations for Adults 65 Years and Older

- May receive any age-appropriate IIV (standard- or high-dose, trivalent or quadrivalent, adjuvanted or unadjuvanted) or RIV

- High-dose IIV3 exhibited superior efficacy over comparator standard-dose IIV3 in a large randomized trial, and may provide better protection than standard dose IIV3 for this age group

- However, vaccination should not be delayed to find a particular product if an appropriate one is available

*MMWR* 2017;66(RR-2):1-20
FIGURE. Influenza vaccine dosing algorithm for children aged 6 months through 8 years — Advisory Committee on Immunization Practices, United States, 2017–18 influenza season

Has the child received ≥2 total doses of trivalent or quadrivalent influenza vaccine before July 1, 2017? (Doses need not have been received during the same season or consecutive seasons.)

No or don't know

2 doses of 2017–18 influenza vaccine (administered ≥4 weeks apart)

Yes

1 dose of 2017–18 influenza vaccine

No change in algorithm compared to 2016-2017

MMWR 2017;66(RR-2):1-20
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 - NEW

• Be careful!

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

[www.cdc.gov/flu/about/qa/vaxadmin.htm](http://www.cdc.gov/flu/about/qa/vaxadmin.htm)
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
ACIP Influenza Recommendations 2017-2018
Pregnant Women

• All women who are pregnant or might be pregnant in the influenza season should receive inactivated influenza vaccine

• Influenza vaccine can be administered at any time during pregnancy, before and during influenza season
Influenza Vaccination for Persons with Egg Allergy

• No change from 2016-2017 recommendations

• Persons with egg allergy can receive either IIV or RIV

MMWR 2017;66(RR-2):1-20
ACIP Recommendations
Allergic Reactions and Syncope

• 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 2017;66(RR-2):1-20*
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 2017;66(RR-2):1-20*
Influenza VISs now available and now good indefinitely!
*Early season, November 2016
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

www.cdc.gov/flu/fluvoxview/pregnant-women-nov2016.htm
Influenza Vaccination of Pregnant Women, 2016

- Offered: 65.7%
- Recommended but not offered: 29.8%
- No recommendation: 7.1%

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

<table>
<thead>
<tr>
<th>Occupation</th>
<th>Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physicians</td>
<td>83%</td>
</tr>
<tr>
<td>NP/PA</td>
<td>83%</td>
</tr>
<tr>
<td>Nurses</td>
<td>81%</td>
</tr>
<tr>
<td>Pharmacists</td>
<td>81%</td>
</tr>
</tbody>
</table>

2020 Healthy People Goal is 90%

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

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!
# Pneumococcal Vaccines

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>23-valent Pneumococcal Polysaccharide Vaccine (PPSV23)</th>
<th>13-Valent Pneumococcal Conjugate Vaccine (PCV13)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Components</strong></td>
<td>Purified polysaccharide</td>
<td>Purified polysaccharide covalently bound to carrier protein</td>
</tr>
<tr>
<td><strong>Ages</strong></td>
<td>2 years and older</td>
<td>6 weeks and older</td>
</tr>
<tr>
<td><strong>Number of serotypes</strong></td>
<td>23</td>
<td>13</td>
</tr>
<tr>
<td><strong>Route</strong></td>
<td>Subcut or IM injection</td>
<td>IM injection</td>
</tr>
</tbody>
</table>

*MMWR* 2012;61(40):816-19
Administering Pneumococcal Vaccines to Adults

• Adult PCV13 schedule:
  – administer 1 dose at age 65 years to adults who have no history of PCV13 vaccine
  – if PCV13 was administered before age 65, no additional doses are indicated at 65 years of age and older

• Adult PPSV23 schedule:
  – no more than 2 doses of PPSV23 are recommended before age 65 and 1 dose on or after age 65 years
  – separate doses of PPSV23 by at least 5 years

_citation:
MMWR 2015;64(34):944-47_
Administering Pneumococcal Vaccines to Adults

- Administer PCV13 before PPSV23 whenever possible
- PCV13 and PPSV23 should not be administered during the same clinic visit
  - either vaccine may be administered with other vaccines

*MMWR* 2015;64(34):944-47
Pneumococcal Vaccination and Adults

- PCV13 and PPSV23 adult vaccination recommendations are divided between 2 age groups. Persons who are:
  - 19 through 64 years of age
  - 65 years of age and older

- Immunization recommendations for persons 19 through 64 years of age are based on risk, including those at:
  - High risk
  - Higher risk
  - Highest risk
High Risk for IPD

• Adults 19 through 64 years of age at high risk for IPD include:
  – persons with chronic conditions, including:
    • pulmonary disease (including asthma)
    • cardiac disease (excluding hypertension)
    • liver disease (including cirrhosis)
    • diabetes
    • alcoholism
  – smokers
  – residents of a long-term care facility

• Administer 1 dose of PPSV23

MMWR 2015;64(34):944-47
Higher Risk for IPD

• Adults 19 through 64 years of age at higher risk for IPD, including those with:
  – CSF leak
  – Cochlear implant

• Administer PCV13 followed by PPSV23 vaccine

*MMWR 2015;64(34):944-47*
Highest Risk for IPD

• Adults 19 through 64 years of age at highest risk for IPD, including those who:
  – are immunocompromised (including HIV infection)
  – have chronic renal failure or nephrotic syndrome
  – are asplenic

• Administer PCV13 and 2 doses of PPSV23

*MMWR* 2015;64(34):944-47
Persons Age 65 Years and Older

• No history of pneumococcal vaccine

• Immunization history of PPSV23 at age 65 or older

*8 weeks if at higher or highest risk

MMWR 2015;64(34):944-47
Persons Age 65 Years and Older

• Received PPSV23 before age 65 years

Separate doses of PPSV23 by at least 5 years

*8 weeks if at higher or highest risk

MMWR 2015;64(34):944-47
Administration of PCV13 and PPSV23

• PCV13 should be administered before PPSV23 if possible
  – 8 week interval if high risk condition
  – 1 year interval for routine vaccination of persons age 65 years and older

• If PCV13 and PPSV23 are administered at intervals shorter than recommended (including on the same day) CDC does not recommend repeating either vaccine

www.immunize.org/askexperts/experts_pneumococcal_vaccines.asp#scheduling
Pneumococcal Vaccines and Medicare

• Effective September 19, 2014 Medicare will cover
  – an initial pneumococcal vaccine to all Medicare beneficiaries who have never received the vaccine under Medicare Part B; and
  – a different, second pneumococcal vaccine one year after the first vaccine was administered (that is, 11 full months have passed following the month in which the last pneumococcal vaccine was administered)

www.cms.gov
Pneumococcal Vaccine Job Aids

Immunization Action Coalition
Pneumococcal Recommendation Summary

CDC Pneumococcal Vaccine Timing
Influenza 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?