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

www.cdc.gov/vaccines/acip/
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)

www.cdc.gov/vaccines/acip/
2016-2017 Influenza Season Summary
Weekly Influenza Activity Estimates Reported by State & Territorial Epidemiologists*

Week ending February 18, 2017 - Week 7
Influenza Positive Tests Reported to CDC by U.S. Public Health Laboratories, National Summary, 2015-2016 Season

Number of Positive Specimens

Week
# Influenza Virus 2016-2017

<table>
<thead>
<tr>
<th>Virus</th>
<th>Circulating Virus</th>
<th>Vaccine Virus</th>
</tr>
</thead>
<tbody>
<tr>
<td>A/H1N1</td>
<td>A/California/7/2009 (100%)</td>
<td>A/California/7/2009</td>
</tr>
<tr>
<td>A/H3N2</td>
<td>A/Hong Kong 4801/2014 (97%)</td>
<td>A/Hong Kong 4801/2014</td>
</tr>
<tr>
<td>B/Victoria</td>
<td>B/Brisbane/60/2008 (91%)</td>
<td>B/Brisbane/60/2008</td>
</tr>
<tr>
<td>B/Yamagata</td>
<td>B/Phuket/3073/2013 (100%)</td>
<td>B/Phuket/3073/2013</td>
</tr>
</tbody>
</table>

www.cdc.gov/flu/weekly/index.htm, week ending June 10, 2017
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

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

*57% age 5 yrs or older

Of 121 with known vaccination status, only 16 were fully vaccinated!
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• Will not be published until at least mid-August 2017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

*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

*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

*provisional until published in MMWR
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)

*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)

<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), FluLaval IIV4*</td>
</tr>
<tr>
<td>2 through 49 years</td>
<td>FluMist IIV4 (may not be available)</td>
</tr>
<tr>
<td>3 years and older</td>
<td>Fluarix 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>Afluria IIV4, Flublok RIV4*</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 allIV3</td>
</tr>
</tbody>
</table>

*new for 2017-2018 season.

**Afluria is approved for persons 18 through 64 years when given by Stratis jet injector.
ACIP voted to rescind the recommendation to limit Afluria IIV3 to persons 9 years and older*

*provisional until published in MMWR
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.

“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)
LAIV Influenza Vaccine Updates
ACIP Meeting, June 2017

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

*provisional until published in MMWR
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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  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

MMWR 2015;64(No 30):818-25
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

*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)

*Fluzone High Dose Clinical Trials*

*Fluzone High Dose Clinical Trials*

*N Engl J Med* 2014;371:635-45

www.fda.gov/BiologicsBloodVaccines/ScienceResearch/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

Has the child received ≥2 total doses of trivalent or quadrivalent influenza vaccine before July 1, 2016? (Doses need not have been received during the same season or consecutive seasons.)

Yes

1 dose of 2016–17 influenza vaccine

No or don’t know

2 doses of 2016–17 influenza vaccine (administered ≥4 weeks apart)

MMWR 2016;65 (RR-5):28
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!

*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
## Influenza Vaccine Products for the 2016–2017 Influenza Season

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Trade Name (vaccine abbreviation)¹</th>
<th>How Supplied</th>
<th>Mercury Content (µg Hg/0.5mL)</th>
<th>Age Group</th>
<th>Vaccine Product Billing Code³</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<td>CPT</td>
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<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</td>
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<tr>
<td>GlaxoSmithKline</td>
<td>Fluarix (IIV4)</td>
<td>0.5 mL (single-dose syringe)</td>
<td>0</td>
<td>3 years &amp; older</td>
<td>90686</td>
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<tr>
<td>ID Biomedical Corp. of Quebec, a subsidiary of GlaxoSmithKline</td>
<td>FluLaval (IIV4)</td>
<td>0.5 mL (single-dose syringe)</td>
<td>0</td>
<td>6 months &amp; older</td>
<td>90686</td>
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<tr>
<td></td>
<td></td>
<td>5.0 mL (multi-dose vial)</td>
<td>&lt;25</td>
<td></td>
<td>90688</td>
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</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</td>
</tr>
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</tr>
<tr>
<td>Sanofi Pasteur, Inc.</td>
<td>Fluzone (IIV4)</td>
<td>0.25 mL (single-dose syringe)</td>
<td>0</td>
<td>6 through 35 months</td>
<td>90685</td>
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<tr>
<td></td>
<td></td>
<td>0.5 mL (single-dose syringe)</td>
<td>0</td>
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<td></td>
<td>0.5 mL (single-dose vial)</td>
<td>0</td>
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<td>90686</td>
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<tr>
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<td></td>
<td>5.0 mL (multi-dose vial)</td>
<td>25</td>
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<td>90687</td>
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<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</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</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; older¹²</td>
<td>90656</td>
</tr>
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<td></td>
<td></td>
<td>Q2035</td>
</tr>
<tr>
<td></td>
<td></td>
<td>5.0 mL (multi-dose vial)</td>
<td>24.5</td>
<td></td>
<td>90658</td>
</tr>
<tr>
<td></td>
<td>Afluria (IIV4)</td>
<td>0.5 mL (single-dose syringe)</td>
<td>0</td>
<td>18 years &amp; older¹²</td>
<td>90686</td>
</tr>
<tr>
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<td></td>
<td>90686</td>
</tr>
<tr>
<td></td>
<td></td>
<td>5.0 mL (multi-dose vial)</td>
<td>24.5</td>
<td></td>
<td>90688</td>
</tr>
<tr>
<td></td>
<td>Fluad (IIV3)</td>
<td>0.5 mL (single-dose syringe)</td>
<td>0</td>
<td>65 years &amp; older</td>
<td>90653</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>≤¹</td>
<td></td>
<td>90656</td>
</tr>
<tr>
<td></td>
<td>Fluvirin (IIV3)</td>
<td>0.5 mL (single-dose syringe)</td>
<td>25</td>
<td>4 years &amp; older</td>
<td>90656</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>90658</td>
</tr>
<tr>
<td></td>
<td>Flucelvax (ccIIV4)</td>
<td>0.5 mL (single-dose syringe)</td>
<td>0</td>
<td>4 years &amp; older</td>
<td>90674</td>
</tr>
</tbody>
</table>

³ Medicare common to both CPT and Medicare.
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

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 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*

*provisional until published in MMWR
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

*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 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

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/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/fluvoxview/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

### Influenza Vaccination Rates
(internet panel, Nov 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%)

www.cdc.gov/flu/fluvoxview/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

*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?