What’s New for the 2016-2017 Flu Season:
Recommendations for Children

Clinician Outreach and Communication Activity (COCA) Call
October 27, 2016
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Objectives

At the conclusion of this session, the participant will be able to:

- Describe strategies to prepare for the 2016-2017 influenza season
- Identify key recommendations in the AAP influenza policy statement
- Discuss vaccine effectiveness
- Clarify recommendations related to live attenuated influenza vaccine
- Explain the importance of antiviral medications in the control of influenza
- Discuss flu vaccine and egg allergic children
Today’s First Presenter

Lisa Grohskopf, MD, MPH
Medical Officer
National Center for Immunization and Respiratory Diseases – Influenza Division
Centers for Disease Control and Prevention
Today’s Second Presenter

Henry (Hank) Bernstein, DO, MHCM, FAAP
Professor of Pediatrics
Influenza Division
Hofstra Northwell - LIJ School of Medicine
2016-17 ACIP Influenza Vaccination Recommendations Update

Lisa Grohskopf
Influenza Division, CDC

October 27, 2016
2016-17 ACIP Influenza Statement--Overview

- Published in MMWR August 26, 2016

- Principal changes
  - LAIV not recommended during the 2016-17 season
  - New/recent vaccine licensures
    - Flud
    - Flucelvax Quadrivalent
  - Changes to egg allergy recommendations

- Some new product licensures since publication
  - Afluria Quadrivalent
  - Flublok Quadrivalent
Change in LAIV Recommendations--Language

“In light of concerns regarding low effectiveness against influenza A(H1N1)pdm09 in the United States during the 2013–14 and 2015–16 seasons, for the 2016–17 season, ACIP makes the interim recommendation that live attenuated influenza vaccine (LAIV4) should not be used.”
Change in LAIV Recommendations—History (1)

- LAIV licensed in 2003
- Early randomized comparative trials of LAIV vs. IIV
  - Conducted pre-pandemic (2002-03 and 2004-05 seasons) demonstrated superior efficacy of LAIV among young children
  - Lead to ACIP preference for LAIV for healthy 2 through 8 year olds for 2014-15
- Analysis of complete US Flu VE Network data for 2013-14 revealed no effectiveness of LAIV against H1N1pdm09
  - First H1N1-predominant season since 2009 pandemic
  - IIV was effective against H1N1pdm09
- LAIV no more effective than IIV against drifted H3N2 during 2014-15 season
- ACIP did not renew preferential recommendation for LAIV for 2015-16 season
In June 2016, ACIP reviewed LAIV VE data for children 2 through 17 years of age, for the 2015-16 season, from three U.S. observational studies.

VE against all influenza A and B
- US Flu VE Network: 3%, not statistically significant
- MedImmune: 46%, statistically significant
- US Department of Defense: 53%, statistically significant

VE against influenza A(H1N1)pdm09
- US Flu VE Network: -21%, not statistically significant
- MedImmune: 50%, not statistically significant
- US Department of Defense: 15%, not statistically significant

Concerns regarding low VE against H1N1pdm09 lead ACIP to recommend LAIV not be used during the 2016-17 season.
LAIV and IIV vaccine effectiveness ages 2–17 years, by influenza type/subtype, 2015-16

- Any influenza: LAIV4 3, IIV3/4 63
- H1N1pdm09: LAIV4 65, IIV3/4 -21
- B/Yamagata: LAIV4 64
- B/Victoria: LAIV4 56

Total, Flu +: 324, 367, 156, 174, 59, 63, 100, 121
Vaccinated, Flu +: 38, 81, 23, 41, 8, 12, 7, 28
LAIV and IIV vaccine effectiveness ages 2–8 years, by influenza type/subtype, 2015-16

<table>
<thead>
<tr>
<th></th>
<th>Any influenza</th>
<th>H1N1pdm09</th>
<th>B</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>LAIV4</td>
<td>IIV3/4</td>
<td>LAIV4</td>
</tr>
<tr>
<td>Adjusted Vaccine Effectiveness (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Any influenza</td>
<td>58</td>
<td>62</td>
<td>72</td>
</tr>
<tr>
<td>H1N1pdm09</td>
<td>-3</td>
<td>-48</td>
<td>-12</td>
</tr>
<tr>
<td>B</td>
<td>36</td>
<td>47</td>
<td>21</td>
</tr>
</tbody>
</table>

Total, Flu +  183  213  113  126  66  83
Vaccinated, Flu +  28  58  20  33  8  25
LAIV and IIV vaccine effectiveness ages 9–17 years, by influenza type/subtype, 2015-16

<table>
<thead>
<tr>
<th></th>
<th>Any influenza</th>
<th>H1N1pdm09</th>
<th>B</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adjusted Vaccine Effectiveness (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LAIV4</td>
<td>20</td>
<td>33</td>
<td>17</td>
</tr>
<tr>
<td>IIV3/4</td>
<td>71</td>
<td>66</td>
<td>69</td>
</tr>
<tr>
<td>Total, Flu +</td>
<td>141</td>
<td>43</td>
<td>92</td>
</tr>
<tr>
<td>Vaccinated, Flu +</td>
<td>10</td>
<td>3</td>
<td>7</td>
</tr>
<tr>
<td></td>
<td>154</td>
<td>48</td>
<td>100</td>
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<tr>
<td></td>
<td>23</td>
<td>8</td>
<td>15</td>
</tr>
</tbody>
</table>
U.S. Flu VE Network: LAIV and IIV VE age 2-17 yrs

Any Influenza A or B

Adjusted Vaccine Effectiveness (%)

<table>
<thead>
<tr>
<th>Year</th>
<th>LAIV3</th>
<th>IIV3</th>
<th>LAIV3</th>
<th>IIV3</th>
<th>LAIV3</th>
<th>IIV3</th>
<th>LAIV3</th>
<th>IIV3</th>
<th>LAIV3</th>
<th>IIV3</th>
<th>LAIV3</th>
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</thead>
<tbody>
<tr>
<td>2010-11</td>
<td>71</td>
<td>71</td>
<td>267</td>
<td>314</td>
<td>225</td>
<td>264</td>
<td>722</td>
<td>859</td>
<td>220</td>
<td>222</td>
<td>588</td>
</tr>
<tr>
<td>2011-12</td>
<td>67</td>
<td>55</td>
<td>12</td>
<td>51</td>
<td>61</td>
<td>198</td>
<td>34</td>
<td>36</td>
<td>106</td>
<td>180</td>
<td>324</td>
</tr>
<tr>
<td>2012-13</td>
<td>46</td>
<td>45</td>
<td>60</td>
<td>15</td>
<td>3</td>
<td>3</td>
<td>63</td>
<td>3</td>
<td>3</td>
<td>81</td>
<td>367</td>
</tr>
</tbody>
</table>

Total, Flu +

- 267
- 314
- 225
- 264
- 722
- 859
- 220
- 222
- 588
- 562
- 324
- 367

Vaccinated, Flu +

- 21
- 66
- 12
- 51
- 61
- 198
- 34
- 36
- 106
- 180
- 38
- 81
New Vaccines for 2016-17

- **Fluad**
  - MF59-adjuvanted trivalent IIV
  - Indicated for persons aged 65 years and older
  - Immunogenically non-inferior to licensed comparator IIV3 in preclinical studies
  - Canadian observational study noted 60% relative effectiveness compared with unadjuvanted IIV3 among adults 65 years and older

- **Flucelvax Quadrivalent**
  - Will replace trivalent Flucelvax for 2016-17
  - Licensed for persons aged 4 years and older
  - Vaccine viruses propagated in Madin-Darby canine kidney cells instead of eggs
  - Immunogenically noninferior to trivalent formulation
Other Recent Licensures

- **Afluria Quadrivalent**
  - Standard-dose quadrivalent IIV
  - Indicated for persons aged 18 years and older
  - Immunogenically noninferior to trivalent formulation
  - Will be available alongside trivalent formulation of Afluria this season
    - **Note:** trivalent licensed for 5 years and older; but recommended by ACIP only for 9 years and older due to febrile reactions with 2010 Southern Hemisphere formulation

- **Flublok Quadrivalent**
  - Recombinant quadrivalent influenza vaccine
  - Indicated for persons aged 18 years and older
  - Hemagglutinin produced in insect cell line using a viral vector
  - Immunogenically noninferior to trivalent formulation
  - Currently not anticipated to be available for 2016-17
Changes to Egg Allergy Language

- Removal of the 30-minute post-vaccination observation period
- Egg allergic persons can receive any licensed, recommended vaccine that is otherwise appropriate (IIV or RIV—however, RIV not licensed for persons under 18 years of age)
- One additional measure remains for persons with a history of severe allergic reaction to egg (i.e., any symptom other than hives)
  - “The selected vaccine should be administered in an inpatient or outpatient medical setting (including but not necessarily limited to hospitals, clinics, health departments, and physician offices). Vaccine administration should be supervised by a health care provider who is able to recognize and manage severe allergic conditions.”
Egg Allergy Algorithm

- No longer printed in the MMWR
Acknowledgements

ACIP Influenza Work Group
Joe Bresee
Lynette Brammer
Lenee Blanton
Brendan Flannery
Alicia Fry
Jessie Clippard
Thank You!
Questions?

For more information please contact Centers for Disease Control and Prevention

1600 Clifton Road NE, Atlanta, GA 30333
Telephone, 1-800-CDC-INFO [232-4636]/TTY: 1-888-232-6348
E-mail: cdcinfo@cdc.gov     Web: www.cdc.gov
Intranasal Flu MISSED
Its Target: Influenza Prevention and Treatment for 2016-2017

Henry (Hank) Bernstein, DO, MHCM, FAAP
Red Book Online Associate Editor
Ex Officio, Committee on Infectious Diseases
American Academy of Pediatrics
Professor of Pediatrics
Hofstra Northwell School of Medicine
Percent Reduction in Outcomes for HCP Receiving Influenza Vaccine

All values statistically significant when compared with those for unvaccinated control healthcare workers (P < .05)

HCP Flu Vaccine Coverage
United States, 2015-2016

Influenza Disease Burden in the US in an Average Year

- Infections and illnesses: 50–60 million
- Hospitalizations: 117,000–816,000
- Deaths\(^a\): 3,349–48,614
- Physician visits: ~25 million


\(^b\) All-cause hospitalization and mortality associated with influenza virus infection.

50% of hospitalized children were HEALTHY.

Top chronic medical conditions in children:
1. Asthma (21%)
2. Neurologic Disorder (16%)
3. Cardiovascular Disease (9%)
Influenza Vaccination Rates for Adults 2015-2016 (trends from 2014-2015 season)

- **Adults 18-64 years:** 36%
- **Adults ≥ 65 years:** 63%
- **Pregnant Women:** 50%
- **Health Care Personnel:** 79%

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[a](http://www.cdc.gov/flu/fluuvaxview/coverage-1516estimates.htm)
[b] CDC Internet Panel Surveys. [http://www.cdc.gov/mmwr/volumes/65/wr/mm6538a2.htm](http://www.cdc.gov/mmwr/volumes/65/wr/mm6538a2.htm)
# Pediatric Deaths and Hospitalizations by Season and Predominant Strain

<table>
<thead>
<tr>
<th>Influenza Season</th>
<th>Predominant Strain</th>
<th>Pediatric Deaths</th>
<th>Hospitalizations (0-4 years old) per 100,000</th>
<th>Hospitalizations (5-17 years old) per 100,000</th>
</tr>
</thead>
<tbody>
<tr>
<td>2015-2016</td>
<td>pH1N1</td>
<td>85</td>
<td>42.5</td>
<td>9.6</td>
</tr>
<tr>
<td>2014-2015*</td>
<td>H3N2</td>
<td>148</td>
<td>57.3</td>
<td>16.6</td>
</tr>
<tr>
<td>2013-2014</td>
<td>pH1N1</td>
<td>111</td>
<td>47.3</td>
<td>9.4</td>
</tr>
<tr>
<td>2012-2013</td>
<td>H3N2</td>
<td>171</td>
<td>67</td>
<td>14.6</td>
</tr>
<tr>
<td>2011-2012*</td>
<td>H3N2</td>
<td>37</td>
<td>16</td>
<td>4</td>
</tr>
<tr>
<td>2010-2011</td>
<td>H3N2</td>
<td>123</td>
<td>49.5</td>
<td>9.1</td>
</tr>
<tr>
<td>2009-2010</td>
<td>pH1N1</td>
<td>288</td>
<td>77.4</td>
<td>27.2</td>
</tr>
<tr>
<td>2008-2009</td>
<td>H1N1</td>
<td>137</td>
<td>28</td>
<td>5</td>
</tr>
<tr>
<td>2007-2008</td>
<td>H3N2</td>
<td>88</td>
<td>40.3</td>
<td>5.5</td>
</tr>
<tr>
<td>2006-2007</td>
<td>H1N1</td>
<td>77</td>
<td>34.6</td>
<td>2.3</td>
</tr>
</tbody>
</table>
2016-2017 Seasonal Influenza Vaccine Strains

**Trivalent**
- A/California/7/2009 (H1N1)-like virus
- A/Hong Kong/4801/2014 (H3N2)-like virus
- B/Brisbane/60/2008-like virus (B/Victoria lineage)

**Quadrivalent**
- Adds B/Phuket/3073/2013-like virus (B/Yamagata lineage)

Strains that changed from last season

* B strains in quadrivalent formulation are the same as 2015-16 vaccine
LAIV4 should NOT be used in any setting during the 2016-2017 season
LAIV3 had consistently fewer episodes of culture-confirmed illness in 2003 as compared with TIV.
Figure 1. Kaplan–Meier Curves for the Time to the First Culture-Confirmed Report of Influenza in the Two Vaccine Groups.
LAIV 3 vs LAIV 4
Hypotheses for why LAIV4 wasn’t effective vs H1N1pdm09

- Increased susceptibility to thermal degradation
- Viral interference with adding 4\textsuperscript{th} strain
- Pre-existing immunity due to more years of annual influenza vaccination or natural infection
- Poor antigenic match between vaccine and circulating strains
- Waning protection during season
- Manufacturing problem
## Overall Vaccine Effectiveness LAIV4 vs. IIV
### Ages 2-17 Years By Season

<table>
<thead>
<tr>
<th>Season (Predominant Strain)</th>
<th>Age Range (yrs)</th>
<th>Adjusted VE (95% CI)</th>
<th>LAIV4</th>
<th>IIV3/IIV4</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>2013-2014 (H1N1pdm09)</strong></td>
<td>2-17</td>
<td>2% (-53 to 37)</td>
<td>61% (42 to 74)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>2-8</td>
<td>-39% (-156 to 25)</td>
<td>60% (32 to 76)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>9-17</td>
<td>36% (-31 to 69)</td>
<td>62% (30 to 80)</td>
<td></td>
</tr>
<tr>
<td><strong>2014-2015 (H3N2)</strong></td>
<td>2-17</td>
<td>9% (-18 to 29)</td>
<td>31% (16 to 44)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>2-8</td>
<td>9% (-28 to 35)</td>
<td>26% (2 to 44)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>9-17</td>
<td>17% (-27 to 46)</td>
<td>33% (9 to 51)</td>
<td></td>
</tr>
<tr>
<td><strong>2015-2016 (H1N1pdm09)</strong></td>
<td>2-17</td>
<td>3% (-49 to 37)</td>
<td>63% (52 to 72)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>2-8</td>
<td>-3% (-76 to 40)</td>
<td>58% (40 to 70)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>9-17</td>
<td>20% (-78 to 64)</td>
<td>71% (52 to 82)</td>
<td></td>
</tr>
</tbody>
</table>

LAIV4 Confidence intervals all cross zero.
LAIV4 has struck Out
LAIV Timeline

**LAIV3**
- **2003**
  - **LAIV3** licensed ages 5-49
  - FDA

**LAIV4**
- **Feb 2007**
  - Belshe et al.
  - The New England Journal of Medicine

**Feb 2012**
- **LAIV4** licensed ages 2-49
  - FDA

**Feb 2015**
- Rescind preferential recommendation
  - CDC

**Feb 2012**
- **LAIV4** licensed ages 2-49
  - FDA

**Sept 2007**
- Expand use to ages 2-4
  - Ashkenazi et al.
  - The Pediatric Infectious Disease Journal

**June 2014**
- Preferential recommendation
  - CDC

**June 2016**
- “LAIV4 should not be used in any setting during the 2016-2017 season.”
  - American Academy of Pediatrics
  - CDC

**What’s next for LAIV4?**
Everyone 6 months and older should get a flu shot this year.
Offer Vaccine Throughout Year

Start as soon as available  
(ideally no later than Oct.)

Continue into late spring  
(season ends June 30)
Special Populations to Reach

Children

Health Care Personnel

Pregnant Women

Household Contacts of High Risk Children and All Children <5
Effectiveness of Maternal Influenza Immunization in Mothers and Infants

Zaman et al.
One Dose

Two Dose
Number of Seasonal Influenza Doses for Children 6 Months – 8 Years

Has child received 2 or more total doses* of any trivalent or quadrivalent vaccine† prior to July 1, 2016?

Yes

1 Dose

No/Don’t know

2 Doses
(Interval is 4 weeks)

* 2 doses need not have been received during the same season or consecutive seasons
† Receipt of LAIV4 in the past is still expected to have primed a child’s immune system, despite recent evidence for poor effectiveness. There currently are no data that suggest otherwise.
Evidence-Based Practice

- **28** studies
- **4315** egg-allergic subjects (656 with severe allergies)
- **No** serious allergic reactions (respiratory distress or hypotension) after receiving the influenza vaccine

Onset Time of Vaccine-Triggered Anaphylaxis (n=33)

- < 30 min: Not documented
- 30 min-2 hr: Not documented
- 2-4 hr: Not documented
- 4-8 hr: Not documented
- > 24 hr: Not documented

AAP Policy Recommendation

All children with egg allergies can receive the influenza vaccine with no special precautions than those recommended for routine vaccines.

Recommendations for Prevention and Control of Influenza in Children, 2016–2017. COMMITTEE ON INFECTIOUS DISEASES. Pediatrics Sep
<table>
<thead>
<tr>
<th>2015–2016 Viruses</th>
<th>Adamantanes (Amantadine/Rimantadine)</th>
<th>Oseltamivir (Tamiflu)</th>
<th>Zanamivir (Relenza)</th>
<th>Peramivir (Rapivab)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Influenza A (H1N1) (derived from 2009 pandemic)</td>
<td>Resistant</td>
<td>Susceptible</td>
<td>Susceptible</td>
<td>Susceptible</td>
</tr>
<tr>
<td>Influenza A (H3N2)</td>
<td>Resistant</td>
<td>Susceptible</td>
<td>Susceptible</td>
<td>Susceptible</td>
</tr>
<tr>
<td>Influenza B (both lineages)</td>
<td>Resistant</td>
<td>Susceptible</td>
<td>Susceptible</td>
<td>Susceptible</td>
</tr>
</tbody>
</table>

AAP 2016-17 Seasonal Influenza Policy
OFFER treatment ASAP to children

• Hospitalized for:
  o presumed influenza
  o severe, complicated, or progressive illness attributable to influenza

• With influenza (any severity) at high risk of complications

AAP 2016-17 Seasonal Influenza Policy
CONSIDER treatment for clinical influenza if...

- Any healthy child with presumed influenza
- Siblings at home:
  - < 6 months old
  - with underlying medical conditions that predispose to flu complications

AAP 2016-17 Seasonal Influenza Policy
Oseltamivir Treatment Evidence

<48 hrs after onset

Prospective, controlled study in outpatient setting\(^a\)

>48 hrs after onset

Retrospective, uncontrolled studies of hospitalized patients\(^b,c,d,e,f\)

Reduced morbidity and mortality


**Antiviral Treatment Clinical Efficacy**

- **Placebo**
- **Oseltamivir 2 mg/kg BID**

*Difference = 36 hours*

*P < .001*

*Difference = 44 hours*

*P < .001*

**Placebo (n=182)**

**Zanamivir (n=164)**

*Difference = 1.25 days*

*P < 0.001*

**Time to Resolution of Symptoms**

- **Placebo (n=182)**: 5.25 days
- **Zanamivir (n=164)**: 4 days


NAIs and Mortality in Children
California Surveillance Data (n=784)

Early treatment → decreased mortality
Test for Trend P=0.0002

* P=0.04

Early treatment

<table>
<thead>
<tr>
<th>Days from symptom onset to antiviral treatment</th>
<th>Proportion that died</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-48 Hours</td>
<td>9/255 3.5%</td>
</tr>
<tr>
<td>Days 3-7</td>
<td>13/247 5.3%</td>
</tr>
<tr>
<td>Days 8-14</td>
<td>6/66 9.1%</td>
</tr>
<tr>
<td>After Day 14</td>
<td>6/23 26.1%</td>
</tr>
<tr>
<td>Never Treated</td>
<td>11/131 8.4%*</td>
</tr>
</tbody>
</table>

Neuraminidase inhibitors for preventing and treating influenza in healthy adults and children

First published: 10 April 2014
**Randomized, Controlled Trial**

Population

- Selected population

- Randomization

- Vaccine

- Control

- Exposure to influenza

Efficacy (\%) = \left(1 - \frac{\text{Cumulative incidence among vaccinated persons}}{\text{Cumulative incidence among controls}}\right) \times 100

**Observational Cohort Analysis**

- Vaccinated?

- Exposure to influenza

- Vaccinated

- Not Vaccinated

**Test-Negative Case-Control Approach**

- Exposure to influenza

- Illness cohort

- Positive test result

- Negative test result

- Ascertain vaccine history

Efficacy (\%) = \left(1 - \frac{\text{Odds of vaccination in positive test result}}{\text{Odds of vaccination in negative test result}}\right) \times 100

Commentary and IDSA Support for Influenza Antiviral Treatment

• No placebo-controlled RCTs available for NAI treatment of hospitalized influenza patients

• Challenging to undertake RCTs with mortality and severe morbidity as outcomes

• Observational studies consistently report clinically meaningful benefits of NAI treatment that creates large body of evidence for benefit

Nguyen-Van-Tam et al., Commentary in The Lancet IDSA Statement
THANK YOU!
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  - “Click” the Q&A tab at the top left of the webinar tool bar
  - “Click” in the white space
  - “Type” your question
  - “Click” ask

- **On the Phone**
  - Press Star (*) 1 to enter the queue
  - State your name
  - Listen for the operator to call your name
  - State your organization and then ask your question
Thank you for joining!
Please email us questions at coca@cdc.gov

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Upcoming COCA Call:

Zika Update: Required Knowledge for Emergency Providers

- Date: Tuesday, November 1, 2016
- Time: 2:00 – 3:00 pm (Eastern Time)

Free Continuing Education. Registration Not Required.

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