National Influenza Vaccination Disparities Partnership

Webinar
Talking to Patients about Flu: Sharing Facts and Addressing Misconceptions and Hesitancy

January 10, 2018
Questions & Answers

Type your question into the Q&A box

Please submit your evaluation at the end of the webinar
Presenter

Dr. Mark Sawyer

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University of California San Diego (UCSD) School of Medicine, Rady Children’s Hospital
Medical Director, UCSD Immunization Partnership
Member, American Academy of Pediatrics Committee on Infectious Disease

National Influenza Vaccination Disparities Partnership
WEBINAR
Objectives

• Identify available flu products for the 2017-18 flu season

• Review and address common misconceptions about flu viruses and vaccine effectiveness

• Review current flu recommendation from the Advisory Committee on Immunization Practices (ACIP)

• Suggest strategies to address flu vaccine hesitancy
INFLUENZA VACCINE 2017-2018

Mark H. Sawyer MD
UCSD School of Medicine/Rady Children’s Hospital
San Diego
San Diego Immunization Partnership
FluView: A weekly influenza surveillance report prepared by the Influenza Division under CDC.
WEEKLY INFLUENZA SURVEILLANCE – VISITS FOR ILI

FluView: A weekly influenza surveillance report prepared by the Influenza Division under CDC.
INFLUENZA VIRUS NOMENCLATURE

INFLUENZA ON EARTH

HOW WE PICK INFLUENZA VACCINE STRAINS

- Worldwide surveillance
- Sophisticated laboratory analysis
  - Serologic comparisons
  - Nucleic acid sequencing
- WHO expert panel
- FDA VRBPAC-Vaccines and Related Biological Products Advisory Committee
This slide, from the U.S. Food and Drug Administration, illustrates the production timeframe of seasonal influenza vaccine starting from surveillance to the administration of vaccine to the general public.

<table>
<thead>
<tr>
<th>Steps</th>
<th>JAN</th>
<th>FEB</th>
<th>MAR</th>
<th>APR</th>
<th>MAY</th>
<th>JUN</th>
<th>JUL</th>
<th>AUG</th>
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</table>
CDC Yearly Lab Work on Flu Viruses

- More than 1 million patient specimens are tested in clinical labs participating in CDC domestic disease surveillance.*
- About 90,000 specimens are tested in 93 state/local public health labs.
- CDC conducts full genetic sequencing on about 6,000 flu viruses each year.
- CDC tests about 2,000 flu viruses to determine their immune properties.
- CDC prepares as many as 50 viruses for possible use in vaccine production.

*2016-2017 influenza data as reported by CDC's Influenza Division, National Center for Immunization and Respiratory Diseases (NCIRD)
WHY DO WE GET IT WRONG?

- We choose the vaccine in February
- Influenza virus is an RNA virus and subject to antigenic drift
  - For influenza virus to multiply, the RNA has to be duplicated by RNA polymerase
  - RNA polymerases are not very accurate
    - RNA sequence: \( \ldots AG\text{C} U A A G A A \ldots \rightarrow \ldots AG\text{U} U A A G A A \ldots \)
    - Codons: \( \ldots AG\text{C} \rightarrow \text{UAA-GAA} \ldots \rightarrow \ldots AG\text{U} \rightarrow \text{UAA-GAA} \ldots \)
    - Amino acids: \( \ldots \text{XYZ} \ldots \rightarrow \text{QYZ} \ldots \)
  - Protein:
    - original structure
      - drifted structure
  - Immune response:
    - good \( \rightarrow \) not so good
- Over time, the virus changes

Influenza A (H3N2) and Influenza B strains are unchanged

New Influenza A (H1N1) strain A/Michigan replaces A/California based on minor changes in circulating strains

New product licensed for infants!

  GSK (Flulaval) licensed for children 6 months and older in November 2016
# US Flu VE Network: Vaccine effectiveness against influenza A/B, 2016–17

<table>
<thead>
<tr>
<th>Age group (yr)</th>
<th>Influenza positive</th>
<th>Influenza negative</th>
<th>Vaccine Effectiveness</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N vaccinated/Total (%)</td>
<td>N vaccinated/Total (%)</td>
<td>Unadjusted</td>
</tr>
<tr>
<td>All ages</td>
<td>883/2052 (43)</td>
<td>2761/5153 (54)</td>
<td>35 (27 to 41)</td>
</tr>
<tr>
<td>6 mo–8 yr</td>
<td>106/353 (30)</td>
<td>709/1318 (54)</td>
<td>63 (53 to 71)</td>
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<tr>
<td>9–17</td>
<td>123/402 (31)</td>
<td>245/606 (40)</td>
<td>35 (15 to 50)</td>
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<tr>
<td>18–49</td>
<td>203/529 (38)</td>
<td>716/1629 (44)</td>
<td>21 (3 to 35)</td>
</tr>
<tr>
<td>50–64</td>
<td>203/442 (46)</td>
<td>537/909 (59)</td>
<td>41 (26 to 53)</td>
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<tr>
<td>≥65</td>
<td>248/326 (76)</td>
<td>554/691 (80)</td>
<td>21 (-8 to 43)</td>
</tr>
</tbody>
</table>

* Multivariate logistic regression models adjusted for site, age, sex, race/ethnicity, self-rated general health status, days from illness onset to enrollment, and calendar time of illness onset.

<table>
<thead>
<tr>
<th>Influenza Season</th>
<th>Reference</th>
<th>Study Site(s)</th>
<th>No. of Patients</th>
<th>Adjusted Overall VE (%)</th>
<th>95% CI</th>
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<tbody>
<tr>
<td>2004-05</td>
<td>Belongia 2009</td>
<td>WI</td>
<td>762</td>
<td>10</td>
<td>-36, 40</td>
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<tr>
<td>2005-06</td>
<td>Belongia 2009</td>
<td>WI</td>
<td>346</td>
<td>21</td>
<td>-52, 59</td>
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<tr>
<td>2006-07</td>
<td>Belongia 2009</td>
<td>WI</td>
<td>871</td>
<td>52</td>
<td>22.70</td>
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<tr>
<td>2007-08</td>
<td>Belongia 2011</td>
<td>WI</td>
<td>1914</td>
<td>37</td>
<td>22.49</td>
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<tr>
<td>2008-09</td>
<td>Unpublished</td>
<td>WI, MI, NY, TN</td>
<td>6713</td>
<td>41</td>
<td>30, 50</td>
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<tr>
<td>2009-10</td>
<td>Griffin 2011</td>
<td>WI, MI, NY, TN</td>
<td>6757</td>
<td>56</td>
<td>23, 75</td>
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<tr>
<td>2010-11</td>
<td>Treanor 2011</td>
<td>WI, MI, NY, TN</td>
<td>4757</td>
<td>60</td>
<td>53, 66</td>
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<td>2011-12</td>
<td>Ohmit 2014</td>
<td>WI, MI, PA, TX, WA</td>
<td>4771</td>
<td>47</td>
<td>36, 56</td>
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<td>2012-13</td>
<td>McLean 2014</td>
<td>WI, MI, PA, TX, WA</td>
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<td>49</td>
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<td>2013-14</td>
<td>Gaglani 2016</td>
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<td>5999</td>
<td>52</td>
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<td>2014-15</td>
<td>Zimmerman 2016</td>
<td>WI, MI, PA, TX, WA</td>
<td>9311</td>
<td>19</td>
<td>10, 27</td>
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<td>2015-16*</td>
<td>Jackson 2017</td>
<td>WI, MI, PA, TX, WA</td>
<td>6879</td>
<td>48*</td>
<td>41, 55*</td>
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<tr>
<td>2016-17**</td>
<td>Unpublished final estimates</td>
<td>WI, MI, PA, TX, WA</td>
<td>7410</td>
<td>39**</td>
<td>32, 46</td>
</tr>
</tbody>
</table>

*Estimate from Nov 2, 2015—April 15, 2016.

**Interim 2016-2017 VE estimates (4/20/2016-4/9/2017) were presented to ACIP in June 2017 [743KB, 19 pages].

INFLUENZA VACCINE EFFECTIVENESS DEPENDS ON:

- How you decide if someone has influenza
- What population do you study – most vaccines work less well in the very young and very old
- What do you mean by effective:
  - Prevents death
  - Prevents hospitalization
  - Prevents a visit to the doctor or emergency room
  - Prevents any symptoms
IS THE 2017-2018 VACCINE ONLY 10% EFFECTIVE?

- Based on experience in Australia with one strain (H3N2)
- No official estimates yet for the U.S. vaccine effectiveness this season
- United States’ effectiveness will depend on which strains circulate here
- So far, the majority of strains characterized in the United States are still similar to the vaccine strains
### Influenza Vaccine Products for the 2017–2018 Influenza Season

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Trade Name (vaccine abbreviation)</th>
<th>How Supplied</th>
<th>Mercury Content (mcg Hg/mL)</th>
<th>Age Group</th>
<th>Vaccine Product Billing Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>AstraZeneca</td>
<td>FluMist® (LAIIV4)</td>
<td>0.2 mL (single-use nasal spray)</td>
<td>0</td>
<td>2 through 49 years</td>
<td>90672 / 90672</td>
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<tr>
<td>GlaxoSmithKline</td>
<td>Fluarix (IV4)</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 subsidiary of GlaxoSmithKline</td>
<td>Flulaval (IV4)</td>
<td>0.5 mL (single-dose syringe)</td>
<td>&lt;25</td>
<td>6 months &amp; older</td>
<td>90686 / 90688</td>
</tr>
<tr>
<td></td>
<td>5.0 mL (multi-dose vial)</td>
<td></td>
<td></td>
<td>6 months &amp; older</td>
<td>90688 / 90688</td>
</tr>
<tr>
<td>Protein Sciences Corp.</td>
<td>Flublok (RIV3)</td>
<td>0.5 mL (single-dose syringe)</td>
<td>0</td>
<td>18 years &amp; older</td>
<td>90673 / 90673</td>
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<td></td>
<td>Flublok (RIV4)</td>
<td>0.5 mL (single-dose syringe)</td>
<td>0</td>
<td>18 years &amp; older</td>
<td>90682 / 90682</td>
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<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>
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<tr>
<td></td>
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<td>0.5 mL (single-dose syringe)</td>
<td>0</td>
<td>3 years &amp; older</td>
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<td>0.5 mL (single-dose syringe)</td>
<td>0</td>
<td>3 years &amp; older</td>
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<td>5.0 mL (multi-dose vial)</td>
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<td>6 through 35 months</td>
<td>90687 / 90687</td>
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<td>5.0 mL (multi-dose vial)</td>
<td>25</td>
<td>6 through 35 months</td>
<td>90688 / 90688</td>
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<td>5.0 mL (multi-dose vial)</td>
<td>25</td>
<td>6 through 35 months</td>
<td>90688 / 90688</td>
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<tr>
<td></td>
<td>Fluzone High-Dose (IIIV3-HD)</td>
<td>0.5 mL (single-dose syringe)</td>
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<td></td>
<td>Fluzone Intradermal (IV4-ID)</td>
<td>0.1 mL (single-dose microinjection system)</td>
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<td>18 through 64 years</td>
<td>90630 / 90630</td>
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<td>Seqirus</td>
<td>Afluria (IV3)</td>
<td>0.5 mL (single-dose syringe)</td>
<td>24.5</td>
<td>5 years &amp; older</td>
<td>90656 / 90656</td>
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<td>5.0 mL (multi-dose vial)</td>
<td>24.5</td>
<td>5 years &amp; older</td>
<td>90658 / 90658</td>
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<td>Afluria (IV4)</td>
<td>0.5 mL (single-dose syringe)</td>
<td>24.5</td>
<td>5 years &amp; older</td>
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<td>5.0 mL (multi-dose vial)</td>
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<td>90658 / 90658</td>
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<td>Fluad (altIV3)</td>
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<td>65 years &amp; older</td>
<td>90653 / 90653</td>
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<td>Fluvin (IV3)</td>
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<td>65 years &amp; older</td>
<td>90653 / 90653</td>
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<tr>
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<td>5.0 mL (single-dose syringe)</td>
<td>25</td>
<td>4 years &amp; older</td>
<td>90658 / 90658</td>
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<tr>
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<td></td>
<td>5.0 mL (multi-dose vial)</td>
<td>25</td>
<td>4 years &amp; older</td>
<td>90658 / 90658</td>
</tr>
</tbody>
</table>

#### Footnotes
1. IV/IIIV = egg-based trivalent/quadrivalent inactivated influenza vaccine (injectable); where necessary to refer to cell culture-based vaccine, the prefix “cc” is used (e.g., ccIV/3ccIV4; RIV3/RIV4 = trivalent/quadrivalent recombinant hemagglutinin influenza vaccine (injectable); ALIV = adjuvanted trivalent inactivated influenza vaccine.

2. An administration code should always be reported in addition to the vaccine product code. Note: Third party payers may have specific policies and guidelines that might require providing additional information on their claim forms.

3. Live attenuated influenza vaccine (LAIV; Flumist®) is not recommended by CDC’s Advisory Committee on Immunization Practices for use in the U.S. for the 2017–18 influenza season.

4. Afluria is approved by the Food and Drug Administration for intramuscular administration with the PharmJet Stratis Needle-Free Injection System for persons age 18 through 64 years.

5. CPT code 90754 was released on July 1, 2017 for implementation on January 1, 2018. Payers may implement the code based on beneficiaries’ needs any time after the code’s release. The CPT Editorial Panel adopted a 6-month period to allow payers adequate time to prepare their systems; however, processing periods for individual payers may accommodate a more abbreviated timeframe.

## What are the age restrictions?

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>&gt;6 mos</th>
<th>&gt;3 yrs</th>
<th>&gt;4 yrs</th>
<th>&gt;5 yrs</th>
<th>&gt;18 yrs</th>
<th>2-49 yrs</th>
<th>18-49 yrs</th>
<th>18-64 yrs</th>
<th>&gt;65 yrs</th>
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<td>Afluria IIV3 and IIV4/Seqiris</td>
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<td>FluBlok/RIV 3 and 4 Protein Sciences</td>
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</tbody>
</table>
**INFLUENZA CHART – AGES**

**PEDIATRIC/ADULT INFLUENZA VACCINE**

**2017-2018**

- **6-35 MONTHS OLD**
  - Fluzone Quadrivalent
  - Sandfør, Inc.
  - 0.35 ml single-dose syringe

- **6 MONTHS & OLDER**
  - Fluzone Quadrivalent
  - Sandfør, Inc.
  - 0.5 ml single-dose syringe

- **36 MONTHS & OLDER**
  - Fluzone Quadrivalent
  - Sandfør, Inc.
  - 0.5 ml single-dose syringe

- **4 YEARS & OLDER**
  - Fluzone Quadrivalent
  - Sandfør, Inc.
  - 0.5 ml single-dose syringe

- **5 YEARS & OLDER**
  - Fluzone Quadrivalent
  - Sandfør, Inc.
  - 0.5 ml single-dose syringe

- **2-49 YEARS OLD & HEALTHY**
  - Fluzone Quadrivalent
  - Medimmune, Inc.
  - Not recommended by ACIP for use in 2017-18.

**Reminders:**

- **DOSAGE**
  - Fluzone syringes (dose differs by age)
  - 0.25 ml, 0.5 ml
  - Fluzone syringes (same dose for all ages)
  - 0.5 ml, 0.3 ml

- **Children under 9 years of age with a history of ≤2 doses of influenza vaccine are recommended to receive 2 doses this flu season. See bet.de/fluvax.2017**

- **Fluzone Quadrivalent**
  - Gilead Sciences
  - 0.5 ml single-dose vial

- **Fluzone High-Dose Trivalent**
  - Sanofi Pasteur
  - 0.5 ml single-dose syringe

- **Fluvax Quadrivalent**
  - Gilead Sciences
  - 0.5 ml single-dose vial

- **Fluzone Intradermal Quadrivalent**
  - Sanofi Pasteur
  - 0.1 ml single-dose syringe

- **Fluzone Intradermal Trivalent**
  - Sanofi Pasteur
  - 0.1 ml single-dose syringe

- **Fluzone Intradermal Quadrivalent**
  - Sanofi Pasteur
  - 0.1 ml single-dose syringe

- **Fluzone Intradermal Quadrivalent**
  - Sanofi Pasteur
  - 0.1 ml single-dose syringe

- **Fluzone Intradermal Quadrivalent**
  - Sanofi Pasteur
  - 0.1 ml single-dose syringe

- **Fluzone Intradermal Quadrivalent**
  - Sanofi Pasteur
  - 0.1 ml single-dose syringe

**Available from California Department of Public Health EZIZ.org**

http://eziz.org/assets/docs/IMM-859.pdf
INFLUENZA VACCINES – HOW TO KEEP THEM STRAIGHT?

- Is it trivalent or quadrivalent?
- Is it injectable or nasal?
- Is it made in eggs or in cell cultures?
- Is it a special product?
- What are its age restrictions?
- Who makes it/what is the brand name?
Currently, there are 7 quadrivalent IIV vaccines expected for 2017-2018.

Approximately 75% of this year’s vaccine will be quadrivalent.

Some companies making IIV4 vaccines will also have their old IIV3 vaccines on the market.

Some products are only available as trivalent.

CDC expresses no preference between trivalent and quadrivalent.
IS IT MADE IN EGGS?

- All are made in eggs except FluBlok/Protein Sciences Corp and Flucelvax/Novartis
- Flublok is a recombinant vaccine (like Hep B vaccine) and may be referred to as RIV
- Flucelvax is a whole virus vaccine, but it is made in cells and may be referred to as cclIV
IS IT A SPECIAL PRODUCT?

- IIV High dose-Fluzone High Dose/Sanofi
  - Recommended for those 65 years of age and over
  - More antigen, more local side effects
  - Slightly better effectiveness in seniors

- IIV adjuvanted-Fluad/Seqirus – NEW this year
  - Recommended for those 65 years of age and over

- IIV Intradermal-Fluzone Intradermal/Sanofi
  - Recommended for those 18-64 years of age
WHAT HAPPENED TO LAIV?

LAIV is not recommended for use this influenza season
LAIV – POOR EFFECTIVENESS

- CDC Influenza VE Network study
- Outpatients with cough illness <8 days
- Test-negative design
- PCR confirmed cases

Preliminary: LAIV and IIV vaccine effectiveness among 2-17 yrs, by influenza type/subtype, 2015-16

https://www.cdc.gov/vaccines/acip/meetings/minutes-archive.html
Low effectiveness for 3 years in a row

https://www.cdc.gov/vaccines/acip/meetings/minutes-archive.html
The recommendation to avoid use of LAIV was originally made for the 2016–17 season.

ACIP/CDC has repeated this recommendation for 2017-2018.

This recommendation will be reevaluated as new data becomes available.

WHO SHOULD GET A FLU VACCINE?

Everyone 6 months of age and older!
**WHO IS NOT GETTING A FLU VACCINE?**

<table>
<thead>
<tr>
<th>Group</th>
<th>2015-2016 Unvaccinated</th>
</tr>
</thead>
<tbody>
<tr>
<td>Seniors</td>
<td>37%</td>
</tr>
<tr>
<td>Adults ≥18 years</td>
<td>58%</td>
</tr>
<tr>
<td>Adults, 18-64 years, high risk</td>
<td>54%</td>
</tr>
<tr>
<td>Pregnant women</td>
<td>50% overall 33%</td>
</tr>
<tr>
<td></td>
<td>if offered 80%</td>
</tr>
<tr>
<td></td>
<td>if not offered</td>
</tr>
<tr>
<td>Children</td>
<td>41%</td>
</tr>
</tbody>
</table>

[www.cdc.gov/flu](http://www.cdc.gov/flu)

Influenza vaccine for children aged 6 months through 8 years, 2017–18 influenza season

VACCINES DURING PREGNANCY
RATIONALE

- Routine protection of adult women
- Special protection because of increased risk of disease during pregnancy (e.g., influenza)
- Protection of infants immediately after birth through passive transfer of antibody (e.g., pertussis)
- Protection of infants by prevention of transmission of disease from mother to baby
### CHANGES IN PREGNANCY THAT INCREASE RISK OF INFECTION

**Gestation** | **Risk of Hospitalization**
---|---
1st trimester | 7.6/10,000
2nd trimester | 15.8/10,000
3rd trimester | 26.2/10,000

- Modulated immune response
- Expanded vascular volume
- Decreased lung capacity
- Increased oxygen consumption

IMMUNIZATION OF PREGNANT WOMEN PROTECTS THEIR BABIES

- 316 mother-infant pairs in Bangladesh in 2004-2005
- Mothers immunized randomly with influenza vaccine or pneumococcal vaccine
- 63% vaccine effectiveness in preventing lab-confirmed influenza in babies
- 36% reduction in febrile respiratory in mothers

Association of spontaneous abortion with receipt of inactivated influenza vaccine containing H1N1pdm09 in 2010–11 and 2011–12

James G. Donahue, Burney A. Kieke, Jennifer P. King, Frank DeStefano, Maria A. Mascola, Stephanie A. Irving, T. Craig Cheetham, Jason M. Glanz, Lisa A. Jackson, Nicola P. Klein, Allison L. Naleway, Eric Weintraub, Edward A. Belongia

Commentary

Commentary on: “Association of spontaneous abortion with receipt of inactivated influenza vaccine containing H1N1pdm09 in 2010–11 and 2011–12”

Christina D. Chambers, Ronghui Xu, Allen A. Mitchell

“The current findings cannot be considered causal, and could be due to chance. Nevertheless, it is important to consider these in the context of previous work, which taken as a whole does not support any change in the ACIP recommendations to vaccinate against influenza during pregnancy. In the meantime, it is important to search for opportunities to ask the same research question in other datasets.”

Current manufacturing techniques have lowered the amount of ovalbumin contained in influenza vaccines to an amount that does not trigger allergic reactions.

Review of published data on 4,172 egg-allergic patients: No cases of anaphylaxis after IIV.

Anaphylaxis to influenza vaccine in egg-allergic patients is no more common than anaphylaxis to any other vaccine.

Any influenza vaccine product can be given to egg-allergic individuals, including those who have had anaphylaxis to egg; you should be just as prepared to treat an anaphylactic reaction to influenza vaccine as you are for any other vaccine.

30-minute waiting period dropped to 15 minutes.

SUMMARY

▪ Influenza season has started early this year

▪ Circulating strains of influenza are always changing

▪ We do not yet know how effective this year’s vaccine is, but vaccination in the most important thing people can do to avoid influenza

▪ There is a new FDA-approved influenza vaccine product this year for 6-month-old children

▪ Large portions of our population do not get influenza vaccine every year; we need to keep working to improve coverage rates

▪ Influenza vaccine continues to be recommended routinely during pregnancy to protect the mother and the baby

▪ It is safe to give influenza vaccine to egg-allergic people
WHERE TO GO FOR MORE INFORMATION

- Your local health department
  (San Diego HHSA Immunization Branch [SDIZ.org])

- Your state health department
  (California Department of Public Health [www.cdph.ca.gov])

- CDC
  (cdc.gov/vaccines)
Questions & Answers

Type your question into the Q&A box
THANK YOU!

This flu season protect yourself, your family, your friends, and your community from the flu.