Influenza Vaccination for the 2013-2014 Season

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The 2012-2013 season

Percentage of Visits for Influenza-like Illness (ILI) Reported by the U.S. Outpatient Influenza-like Illness Surveillance Network (ILINet), Weekly National Summary, 2012-13 and Selected Previous Seasons
Impact of the 2012-2013 season

- 158 influenza-associated pediatric deaths reported in the 2012-13 season
  - 52% of children had influenza B infections
  - 64% of children were 5 years of age or older
  - 48% had a high risk condition
  - 90% of children who died were not vaccinated
Impact of the 2012-2013 season

• H7N9 influenza in China
  – First 3 cases were reported by China on March 31
  – Virus is different from other H7 viruses that have infected humans
  – Better adapted for infecting mammals than H5N1 but not fully adapted
  – Poultry believed to be the source of human infections
  – Low pathogenicity in poultry
  – All eyes on fall 2013...
ACIP recommendations

• RIV recommended for vaccination of persons 18 through 49 years of age with egg allergy of any severity
  – individuals with a severe egg allergy consult with a physician about their allergic conditions prior to vaccination if RIV3 is not available

• For individuals who have no known history of exposure to egg, but who are suspected of being egg-allergic on the basis of previously performed allergy testing, consultation with a physician with expertise in the management of allergic conditions should be obtained prior to vaccination
Algorithm for those with egg allergies

Can the individual eat lightly cooked egg (e.g., scrambled egg) without reaction? *†

No

After eating eggs or egg-containing foods, does the individual experience ONLY hives?

No

After eating eggs of egg-containing foods, does the individual experience other symptoms such as:

- Cardiovascular changes (e.g., hypotension)
- Respiratory distress (e.g., wheezing)
- Gastrointestinal (e.g., nausea/vomiting)
- Reaction requiring epinephrine
- Reaction requiring emergency medical attention

Yes

Administer RIV, if patient aged 18 through 49 yrs.; OR

Administer IIV

Observe for reaction for at least 30 minutes following vaccination

Yes

Administer RIV, if patient aged 18 through 49 yrs.; OR

Refer to a physician with expertise in management of allergic conditions for further evaluation
Has the child ever received influenza vaccine?

- **Yes**
  - Did the child receive a total of 2 or more doses of seasonal influenza vaccine since July 1, 2010?
    - **Yes**
      - 1 dose
    - **No/Don’t know**
      - 2 doses

- **No/Don’t know**
  - 2 doses

**Pediatric Algorithm**
ACIP recommendations

• Other New items:
  – New abbreviations (IIV [3 or 4]; RIV; cIIIV)
  – Four new vaccine products available for 2013-14
    • RIV3; cIIIV3; LAIV4; IIV4
  – No preferential recommendations otherwise

• Some questions to consider:
  – Preferential use for:
    • Elderly – Fluzone HD®??
    • Those with egg allergies – Flucelvax®??
    • Children – Better Efficacy – LAIV??
    • Those who fear needles – LAIV or Fluzone ID®??
  – When do we start vaccinating?
    • Is waning immunity through season truly a problem?
Latest Estimates of Vaccine Coverage

- 54.9% of children vaccinated
- 35.1% of adults vaccinated
- Health-Care Personnel
  - 70.5% vaccinated
  - Long-term care facilities had lower coverage than other facility types
  - Non-pharmacist/non-physician/non-nurse had lower coverage than other occupations
- Pregnant Women
  - 53% vaccinated
  - Majority vaccinated during pregnancy
- Results are preliminary
  - Final 2012-13 season results available in fall 2013
Things of focus for the next season

• Increase influenza vaccination coverage rates among all individuals ≥ 6 months.
  – Among adults in certain racial and ethnic groups.
  – Among health-care personnel, especially those working in long-term care facilities and non-pharmacist/physician/nurses.
  – Among pregnant women by recommending and offering vaccine

• Implement strategies to increase vaccination coverage in upcoming influenza seasons.
  – Enhancing Access to Vaccination Services
  – Increasing Community Demand for Vaccinations
  – Provider- or System-Based Interventions
  – Community-Based Interventions Implemented in Combination
Latest Vaccine Efficacy data (CDC)

- Adjusted VE against influenza A and B was 53% (47-58%)
  - Similar to early unadjusted VE of 62% (51-71%) and mid-season adjusted VE of was 56% (47-63%) against A and B
  - Similar to international interim VE estimates
- Vaccination reduced the risk of outpatient medical visits:
  - Due to influenza A(H3N2) by half (45%); exceptions for aged 9-17 and 65+ years
  - Due to influenza B by two-thirds (63%); consistent for all ages
- Similar VE against vaccine lineage B (Yamagata) and excluded B (Victoria)
  - Need further research to confirm and understand age differences
  - Need better understanding of cross-protection
Influenza Vaccine for 2013-2014 Season

• New Formulation
  – Introduction of IIV4 (Inactivated Influenza Vaccine – quadrivalent)
  – Vs. IIV3 (Inactivated Influenza Vaccine – trivalent)

• New technology
  – First cell culture based vaccine in the US (ccIIV)
    • Flucelvax®
  – First recombinant vaccine in the US (RIV)
    • Flublok®
2013-2014 Influenza Vaccine Strains

- A/California/7/2009 (H1N1)-like virus
- H3N2 virus antigenically like the cell-propagated prototype virus A/Victoria/361/2011
- B/Massachusetts/2/2012-like virus

Quadrivalent influenza vaccines should contain the above three strains and the following additional B strain:
- B/Brisbane/60/2008-like virus
New Influenza Vaccine Formulation - Quadrivalent

- Contains 2 influenza A and 2 influenza B strains
  - Currently approved from MedImmune, GSK, and Sanofipasteur.
- Addresses the 50% possibility of a mismatch for the B strain each season
- IIV4 and LAIV quadrivalent likely to have some premium pricing
- No visibility as to how many doses are available
  - GSK and sanofi will have both IIV3 and IIV4 on the market simultaneously
  - All LAIV will be quadrivalent
  - No preferential use recommendation
New Influenza Vaccine Technology – Cell Culture Vaccine

- **Flucelvax®** from Novartis Vaccines
  - trivalent
  - Uses cultured animal mammalian cells instead of chicken eggs to grow vaccine virus
  - The production process may *not* be totally egg free but rather "functionally" egg free
    - No guidance on use in those with egg allergies
  - Side effects similar to IIV3
  - FDA approved for adults 18 years and older

- **CPT Code**: 90661
New Influenza Vaccine Technology – Cell Culture Vaccine

- Flucelvax® from Novartis Vaccines (CMS payment)
  - Prior to FDA approval, CPT code 90661 was not payable by CMS
  - With FDA approval of Flucelvax®, CMS is revising the ASC payment indicator for CPT code 90661 from “Y5” to “L1” (Influenza vaccine; pneumococcal vaccine. Packaged item/service; no separate payment made.) effective November 20, 2012.
  - CMS can now pay for Flucelvax®.
New Influenza Vaccine Technology – Recombinant DNA

• Flublok® from Protein Sciences
  – trivalent
  – HA DNA sequence produced by recombinant technology and expressed in baculovirus that infects an insect cell line.
  – Totally egg-free process
    • ACIP recommends use in those with severe egg allergies
  – Side effects similar to IIV3; no latex in vial stoppers
  – FDA approved for adults 18 – 49
  – 16 week shelf life
  – CPT code: 90673
Other Influenza Vaccines

• **Fluzone ID®**
  – Novel microinjection system for intradermal delivery
  – Ultra-fine needle that is 90% shorter than the typical needle
  – Licensed for use in adults 18-64 years of age
  – Contains 9 mcg of influenza virus hemagglutinin for each strain
  – Similar safety profile as TIV, erythema most common complaint
  – CPT code: 90654
Other Influenza Vaccines

• Fluzone HD®
  – Contains 4 times the amount of antigen - 60 mcg of influenza virus hemagglutinin for each strain
  – Indicated for 65 and older; most common complaint is injection site pain and erythema
  – Medicare covers this higher dose formulation
    • CPT code: 90662
    • Payment Rate: $30.923 (2012)
  – FDA approval based on serological data; effectiveness studies ongoing. Data collection hindered by past few “mild” flu seasons
Q codes (Medicare only)

- Q2033: Influenza Vaccine, Recombinant Hemagglutinin Antigens, For Intramuscular Use (Flublok).
- Q2034: Influenza virus vaccine, split virus, for intramuscular use (Agriflu)
- Q2035: Influenza virus vaccine, split virus, when administered to individuals 3 years of age and older, for intramuscular use (Afluria)
- Q2036: Influenza virus vaccine, split virus, when administered to individuals 3 years of age and older, for intramuscular use (Flulaval)
- Q2037: Influenza virus vaccine, split virus, when administered to individuals 3 years of age and older, for intramuscular use (Fluvirin)
- Q2038: Influenza virus vaccine, split virus, when administered to individuals 3 years of age and older, for intramuscular use (Fluzone)
- Q2039: Influenza virus vaccine, split virus, when administered to individuals 3 years of age and older, for intramuscular use (Not Otherwise Specified)
<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Trade Name</th>
<th>How Supplied</th>
<th>Mercury Content (µg Hg/0.5mL)</th>
<th>Age Group</th>
<th>Product Code</th>
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<tr>
<td>CSL Limited</td>
<td>Afluria (IIV3)</td>
<td>0.5 mL (single-dose syringe)</td>
<td>0</td>
<td>9 years &amp; older</td>
<td>90656</td>
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<td></td>
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<td>GlaxoSmithKline</td>
<td>Fluarix (IIV3)</td>
<td>0.5 mL (single-dose syringe)</td>
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<td>Fluarix (IIV4)</td>
<td>0.5 mL (single-dose syringe)</td>
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<td>3 years &amp; older</td>
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<td>ID Biomedical Corp. of Quebec, a subsidiary of GlaxoSmithKline</td>
<td>FluLaval (IIV3)</td>
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<td>18 years &amp; older</td>
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<td>MedImmune</td>
<td>FluMist (LAIV4)</td>
<td>0.2 mL (single-use nasal spray)</td>
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<td>Novartis</td>
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<td>Flucelvax (ccIIV3)</td>
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<td>Fluzone High-Dose (IIV3)</td>
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<td>Fluzone Intradermal (IIV3)</td>
<td>0.1 mL (single-dose microinjection system)</td>
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<td>18 through 64 years</td>
<td>90654</td>
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Manufacturer Production Estimates

- Sanofi Pasteur
  - Anticipates delivering same number of doses of IIV3 (in multiple formulations) as previous season (60M doses)
- Protein Sciences
  - Anticipate delivering 250,000 doses of RIV3
- Novartis Vaccines
  - Anticipate delivering 30M doses of IIV3 and ccIIV3
- Merck Vaccines
  - Anticipates delivering 10M doses of IIV3
  - CSL Biotherapies will resume distribution of Afluria® in the United States for the 2014–2015 season by initiating the prebooking of the vaccine late 2013
- MedImmune
  - Anticipates delivering 12 - 15M doses of LAIV4 (no LAIV3 in market)
- GSK Vaccines
  - Anticipates delivering 22 - 24M doses, with up to 10M doses of IIV4
Web-based Vaccine Locator

- Second year for the web-based Influenza Vaccine Locator!
  - Powered by HealthMap from Harvard University
  - Search by address, zip, city/state, or pharmacy name
  - Results display in order of proximity from search criteria
  - Advanced search- 5-50 mile radius
- Also includes all adult vaccines!
Web-based Vaccine Locator

• 700+ provider accounts registered with 65,000+ locations
  – More than 20,000 have already included information on all adult vaccines
• Simple provider registration process – batch upload or manual entry (for small sized providers)
• Physician practices are welcome to sign up
• Go to: flushot.healthmap.org
Continuing issue of attention for providers

• Complementary providers and partners have increasing interest and role in influenza immunization
  – Includes pharmacy, community immunizers, occupational health immunizers, and obstetrical providers
  – Pharmacy business model does not want to intrude on the pediatric medical home
  – Anytime, anywhere concept may be reducing some of market share for traditional appointment-based vaccination clinics
  – Anecdotally, large marketing campaigns by retail pharmacies appeared to have driven increased vaccination in physician offices
  – Involve more partners to further help communications among diverse provider types
    • Opportunity to bring together disparate providers to iron out differences of opinion
Continuing influenza messaging...

- Key communication messages will continue
  - Continue to focus on tailoring message to specific target populations
    - Pregnant women
    - Healthcare professionals
    - Adults over 65 years of age
    - Adults with chronic conditions

- NIVW announced: December 8 -14, 2013
Continuing influenza messaging...

- We have routine universal recommendation – that part is simple
- But now, we have multiple vaccine types that are indicated for different populations! Will need to have clear and **unified** guidance and messaging. Eg.
  - Should IIV4 be preferred over IIV3?
  - What about Fluzone HD®?
  - Should ccllIV (less than 50 femtograms of ovalbumin) be used for those with confirmed severe egg allergies?
- And questions about efficacy and duration abound
- And where will we will with regard to H7N9?
• IAC Influenza Resources:
  www.immunize.org/influenza/

• Summit Web site:
  www.preventinfluenza.org

• Thank You for your kind attention!

• Any questions?
Why do we immunize against influenza?

Amanda, died at age 4 1/2 yrs from influenza
Lucio, died at age 8 yrs from influenza complications
Alana, died at age 5 1/2 yrs from influenza
Breanne, died at age 15 mos from influenza complications
Barry, a veteran fire-fighter, died at age 44 yrs from influenza

Slide Courtesy of Families Fighting Flu