ACIP Influenza Vaccine Recommendations
2013-14 Season

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Objective

- Provide a summary of influenza vaccine guidance for 2013-14, reflecting ACIP discussion and vote in February and June, 2013.
The 2013-14 ACIP influenza vaccination recommendations are not official until adopted by the Director, CDC.
No major changes in the recommendations

- Annual vaccination recommended for all persons aged 6 months and older
- Some minor changes related to vaccination in setting of egg allergy

Overall vaccine supply anticipated to be similar to last year based on manufacturers report to Flu Vaccine Summit in May 2013

But, a number of new things to discuss…

- Virus composition of the 2013-14 vaccine
  - Trivalent and quadrivalent vaccines
- New vaccine products and abbreviations
Influenza Vaccine Virus Strains for 2013-14

- Both trivalent and quadrivalent vaccines will be available

- Trivalent vaccines will contain:
  - An A/California/7/2009 (H1N1)-like virus,
  - An H3N2 virus antigenically like the cell-propagated prototype virus A/Victoria/361/2011, and
  - A B/Massachusetts/2/2012-like virus (Yamagata lineage).

- Quadrivalent vaccines, will contain, in addition:
  - A B/Brisbane/60/2008-like virus (Victoria lineage)
Quadrivalent Influenza Vaccines—Rationale

- Two lineages of influenza B viruses: Victoria and Yamagata
  - Immunization against virus from one lineage provides only limited cross-protection against viruses in the other

- Trivalent vaccines contain only one B vaccine virus
  - Only one B lineage is represented

- Predominant lineage is difficult to predict in advance of the season

- Quadrivalent vaccines contain one virus from each B lineage
Influenza Vaccine Abbreviations

- **TIV** (Trivalent Inactivated Influenza Vaccine) replaced with **IIV** (Inactivated Influenza Vaccine):
  - IIV refers to inactivated vaccines (egg and cell-culture based)
  - Includes trivalent (IIV3) and quadrivalent (IIV4) vaccines;
  - Where necessary, cell-culture-based IIV is referred to as ccIIV/ ccIIV3;

- **RIV** refers to recombinant HA influenza vaccine
  - Trivalent (RIV3) for 2013-14;

- **LAIV** refers to Live Attenuated Influenza Vaccine
  - Quadrivalent (LAIV4), for 2013-14.)
Recently-approved Influenza Vaccines

Quadrivalent influenza vaccine, live attenuated (LAIV4):
- Flumist® Quadrivalent (MedImmune)

Quadrivalent influenza vaccines, inactivated (IIV4):
- Fluarix® Quadrivalent (GSK)
- Fluzone® Quadrivalent (Sanofi Pasteur)

Cell culture-based influenza vaccine (ccIIV3):
- Flucelvax® (Novartis)

Recombinant hemagglutinin (HA) vaccine (RIV3):
- FluBlok® (Protein Sciences)
Flumist® Quadrivalent (LAIV4)

- MedImmune

- Will replace trivalent LAIV starting 2013-14
  - Same presentation (intranasal sprayer) and administration

- Recommendations same as those for trivalent LAIV
  - Healthy, non-pregnant persons aged 2-49 years

- Similarly immunogenic to LAIV3

- No preferential recommendation for LAIV vs. IIV where either is otherwise appropriate

- Acceptable alternative to other licensed products used within indications and recommendations
Fluarix® Quadrivalent (IIV4)

- GlaxoSmithKline
- Approved for persons aged 3 years and older
- Available in 0.5mL prefilled syringes for IM injection
- Both Fluarix® (IIV3) and Fluarix® Quadrivalent (IIV4) available
  - Likely more IIV3 available than IIV4 during 2013-14
- Similarly immunogenic to trivalent
- Acceptable alternative to other licensed products used within indications and recommendations
Fluzone® Quadrivalent (IIV4)

- Sanofi Pasteur

- Approved for persons aged 6 months and older

- Three different presentations, all for IM injection
  - 0.25 mL prefilled syringes for 6 through 35 months
  - Also in 0.5mL syringes and 0.5 mL vials

- Both Fluzone® (IIV3) and Fluzone® Quadrivalent (IIV4) will be available
  - Likely more IIV3 available than IIV4 in 2013-14

- Similarly immunogenic to trivalent

- Acceptable alternative to other licensed products used within indications and recommendations
Vaccines Produced via Non-Egg-Based Technologies

- May permit more rapid scale up of vaccine production (e.g., as might be needed during a pandemic)

- Two vaccines this season, both trivalent:
  - Cell culture-based
  - Recombinant hemagglutinin (HA)
Flucelvax® (ccIIV3)

- Novartis

- Approved for persons aged 18 and older

- Vaccine virus propagated in Madin Darby Canine Kidney cells

- Available in 0.5mL prefilled syringes for IM injection

- Vaccine viruses for ccIIV are not propagated in eggs; however, initial reference strains have been passaged in eggs
  - Cannot be considered egg-free, though expected to contain less egg protein than other IIVs

- Acceptable alternative to other licensed products used within indications and recommendations
FluBlok® (RIV3)

- Protein Sciences

- Approved for persons aged 18 through 49 years

- 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

- Acceptable alternative to other licensed products used within indications and recommendations
Other Vaccines Available for 2013-14

- **Standard dose IIVs (multiple brands)**
  - For ≥6 mos., *BUT* age indications differ by brand

- **High dose IIV (Fluzone® High Dose)—65 yrs. and over**

- **Intradermal IIV (Fluzone® Intradermal)—18 through 64 yrs.**

- **ACIP currently expresses no preferences**
Influenza Vaccination for Persons with Egg Allergies—2011-12 and 2012-13

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

- **Yes**
  - Administer vaccine per usual protocol

- **No**
  - After eating eggs or egg-containing foods, does the individual experience ONLY hives?
    - **Yes**
      - Administer IIV
      - Observe for reaction for at least 30 minutes following vaccination
    - **No**
      - After eating eggs or 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**
            - Refer to a physician with expertise in management of allergic conditions for further evaluation
          - **No**

Influenza Vaccination for Persons with Egg Allergies—2013-14: First Modification

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 or 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 RIV3, if patient aged 18 through 49 yrs.;
              - OR
              - Refer to a physician with expertise in management of allergic conditions for further evaluation
          - **No**
            - Administer RIV3, if patient aged 18 through 49 yrs.;
              - OR
              - Administer IIV
              - Observe for reaction for at least 30 minutes following vaccination

- **Yes**
  - Administer vaccine per usual protocol
Addition of the following:

- For individuals with 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
  - Alternatively, RIV3 may be administered if the recipient is aged 18 through 49 years
One Dose or Two?
Vaccine for Children 6 Months Through 8 Years

- Children aged 6 months through 8 years require 2 doses in first season they are vaccinated

- If previously vaccinated, need to have received 2009 (H1N1)-containing vaccine (2009 monovalent, or 2010-11, 2011-12, or 2012-13 seasonal vaccines)

- This season (as the last), there are two acceptable approaches for determining the number of doses

- These differ in whether or not vaccination history prior to the 2010-2011 season is considered

Dose algorithm for 6mo through 8yr olds, 2013-14 season—First approach

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*

* Doses should be administered a minimum of 4 weeks apart.

**MMWR 2012; 61(32):613-618.**
Dose algorithm for 6mo through 8yr olds, 2013-2014 season—Alternative approach

If vaccination history before 2010–11 is available

If child received

- ≥2 seasonal influenza vaccines during any previous season,
- And ≥1 dose of a 2009(H1N1)-containing vaccine (monovalent 2009(H1N1) or 2010-11, 2011-12 or 2012-13 seasonal vaccine),
- Then the child needs only 1 dose in 2013–14.
- Children 6mos—8yrs for whom this is not the case need 2 doses

Need only 1 dose of vaccine in 2013–14 if:

- ≥2 doses of seasonal influenza vaccine since July 1, 2010; or
- ≥2 of seasonal influenza vaccine before July 1, 2010, and ≥1 dose of monovalent 2009(H1N1) vaccine; or
- ≥1 dose of seasonal influenza vaccine before July 1, 2010, and ≥1 dose of seasonal influenza vaccine since July 1, 2010

Vaccination of Adults

- Influenza vaccination clinics that include adults (e.g. healthcare personnel) are also a great time to review their need for other vaccines, e.g. Tdap, zoster, pneumococcal PPSV23 and PCV13, etc.

- While influenza vaccination levels of healthcare personnel are increasing, immunity and/or vaccination status for other vaccines should also be checked: e.g., Tdap, Hepatitis B, varicella, MMR

- Resources for adult patients in addition to their primary care providers can be found at [www.cdc.gov/vaccines/adults](http://www.cdc.gov/vaccines/adults).
  - Adult immunization schedule
  - Adult vaccine quiz
  - Vaccine provider locator
  - Education/communications resources
Thank You!

And special thanks to Dr. Lisa Grohskopf, CDC, for sharing her slides

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