STANDARD
NURSE PROTOCOL
FOR
PREVENTION OF
SEASONAL INFLUENZA
2014-2015 IMMUNIZATION CLINICAL REVIEW TEAM

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DEFINITION

Seasonal Influenza is a contagious respiratory illness caused by influenza viruses. It can cause mild to severe illness, and at times can lead to death. Every year in the United States, on average:

- 5% to 20% of the population gets seasonal influenza;
- more than 200,000 people are hospitalized from influenza-related complications; and
- about 36,000 people die from influenza-related causes.

Influenza viruses cause disease among persons in all age groups. Rates of infection are highest among children, but the risks for complications, hospitalizations, and deaths from influenza are higher among persons aged 65 years and older, young children, and persons of any age who have medical conditions that place them at increased risk for complications from influenza. Flu Complications include: pneumonia, bronchitis and sinus and ear infections. The flu can make chronic health problems worse. For example, people with asthma may experience asthma attacks while they have the flu, and people with chronic congestive heart failure may have worsening of this condition that is triggered by the flu.

ETIOLOGY

There are two main types of influenza (flu) virus: Types A and B. There is also a C type; however, it causes only mild upper respiratory illness, and is not associated with flu epidemics. Influenza A and B viruses are responsible for seasonal flu epidemics each year. Influenza A viruses can be broken down into sub-types. Over the course of a flu season, different types (A & B) and subtypes of influenza A viruses can circulate and cause illness. Influenza A viruses are divided into subtypes based on two proteins on the surface of the virus: the hemagglutinin (H) and the neuraminidase (N). There are 16 different hemagglutinin subtypes and 9 different neuraminidase subtypes, Influenza A viruses can be further broken down into different strains. The current subtypes of influenza A viruses found in people are A (H1N1) and A (H3N2).

Influenza viruses can change in two different ways.

One is called “antigenic drift.” These are small changes in the virus that happen continually over time. Antigenic drift produces new virus strains that may not be recognized by the body’s immune system. This process works as follows: a person infected with a particular flu virus strain develops antibody against that virus. As newer virus strains appear, the antibodies against the older strains no longer recognize the “newer” virus, and reinfection can occur. This is one of the main reasons why people can get the flu more than one time. In most years, one or two of the three virus strains in the influenza vaccine are updated to keep up with the changes in
the circulating flu viruses. So, people who want to be protected from flu need to get a flu shot every year.

The other type of change is called “antigenic shift.” Antigenic shift is an abrupt, major change in the influenza A viruses, resulting in new hemagglutinin and/or new hemagglutinin and neuraminidase proteins in influenza viruses that infect humans. Shift results in a new influenza A subtype or a virus with a hemagglutinin or a hemagglutinin and neuraminidase combination that has emerged from an animal population that is so different from the same subtype in humans that most people do not have immunity to the new (e.g., novel) virus. Such a “shift” occurred in the spring of 2009, when a new H1N1 virus with a new combination of genes emerged to infect people and quickly spread, causing a pandemic. When shift happens, most people have little or no protection against the new virus. While influenza viruses are changing by antigenic drift all the time, antigenic shift happens only occasionally. Type A viruses undergo both kinds of changes; influenza type B viruses change only by the more gradual process of antigenic drift.

All of the 2014-2015 influenza vaccine is made to protect against the following three viruses:

• an A/California/7/2009 (H1N1)pdm09-like virus

• an A/Texas/50/2012 (H3N2)-like virus

• a B/Massachusetts/2/2012-like virus.

Some of the 2014-2015 flu vaccine also protects against an additional B virus (B/Brisbane/60/2008-like virus).

Influenza viruses are spread from person to person primarily through large-particle respiratory droplet transmission (e.g., when an infected person coughs or sneezes near a susceptible person). Transmission via large-particle droplets requires close contact between source and recipient persons, because droplets do not remain suspended in the air and generally travel only a short distance (less than or equal to 1 meter) through the air. Contact with respiratory-droplet contaminated surfaces is another possible source of transmission. Airborne transmission (via small-particle residue [less than or equal to 5µm] of evaporated droplets that might remain suspended in the air for long periods of time) also is thought to be possible, although data supporting airborne transmission are limited.

In the United States, annual epidemics of influenza typically occur during the fall or winter months, but the peak of influenza activity can occur as late as April or May.
SUBJECTIVE/OBJECTIVE

1. May or may not report history of exposure to an individual known to have seasonal influenza.
2. Denies any allergies to eggs or egg products. (Refer to Figure 1).
3. Denies severe reaction to an influenza vaccination or components in vaccine such as thimerosal or any antibiotic used in the formulation.
4. Denies anaphylactic reaction to latex. Latex in some pre-filled syringes flu presentations (e.g., Fluvirin®, Fluarix®, Fluarix Quadrivalent® and Flucelvax®)
5. Denies any contraindications to flu vaccine (Refer to Figure 2).

Note on abbreviations: This document includes abbreviations to refer to currently available influenza vaccines. Specifically:

- The former abbreviation TIV (Trivalent Inactivated Influenza Vaccine, previously used for inactivated influenza vaccines) has been replaced with the new abbreviation IIV (Inactivated Influenza Vaccine). For 2014-15, IIVs as a class will include:
  - egg-based and cell culture-based trivalent inactivated influenza vaccines (IIV3), and
  - egg-based quadrivalent inactivated influenza vaccine (IIV4).
- RIV refers to recombinant hemagglutinin influenza vaccine, available as a trivalent formulation (RIV3) for 2014-15;
- LAIV, IIV, and RIV denote vaccine categories; numeric suffix specifies the number of antigens in the vaccine.

Where necessary to refer specifically to cell culture-based vaccine, the prefix “cc” is used (e.g., “ccIIV3”).
FIGURE 1. Recommendations regarding influenza vaccination of persons who report allergy to eggs — Advisory Committee on Immunization Practices, United States, 2014–15 influenza season
CDC Advisory Committee on Immunization Practices, United States, 2014–15 influenza season egg allergy assessment

Refer to Figure 1 for egg allergy assessment or refer to a physician

- Can the person 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 person experience ONLY hives?
    - Yes: After eating eggs or egg-containing foods, does the person experience other symptoms such as:
      - Cardiovascular changes (e.g., hypotension)
      - Respiratory distress (e.g., wheezing)
      - Gastrointestinal (e.g., nausea or vomiting)
      - Reaction requiring epinephrine
      - Reaction requiring emergency medical attention
        - Yes: Administer RIV3, if patient is aged 18 through 49 yrs OR If RIV3 is not available, or patient is aged <18 years or >49 years, IIV should be administered by a physician with experience in the recognition and management of severe allergic conditions. Observe for reaction for at least 30 minutes after vaccination
        - No: Administer IIV, Observe for reaction for at least 30 minutes after vaccination
    - No: After eating eggs or egg-containing foods, does the person experience ONLY hives?
Refer to Figure 1 on previous page

**Abbreviations**: IIV = inactivated influenza vaccine; RIV3 = recombinant influenza vaccine, trivalent.

* Persons with egg allergy might tolerate egg in baked products (e.g., bread or cake). Tolerance to egg-containing foods does not exclude the possibility of egg allergy (Erlewyn-Lajeunesse M, Brathwaite N, Lucas JS, Warner JO. Recommendations for the administration of influenza vaccine in children allergic to egg. BMJ 2009;339:b3680).

† For persons 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 before vaccination. Alternatively, RIV3 may be administered if the recipient is aged 18 through 49 years.

Alternate Text: The figure above is a flow chart detailing recommendations regarding influenza vaccination of persons who report allergy to eggs in the United States for the 2014-15 influenza season. Persons with a history of egg allergy who have experienced only hives after exposure to egg should receive influenza vaccine. Because relatively few data are available for use of live attenuated influenza vaccine in this setting, inactivated influenza vaccines (IIV), or trivalent recombinant influenza vaccine (RIV3) should be used. RIV3 may be used for persons aged 18 through 49 years who have no other contraindications. However, IIV (egg- or cell-culture based) may also be used, with certain additional safety measures.
Influenza Vaccination of Persons with a History of Egg Allergy

With the exceptions of trivalent recombinant influenza vaccine (RIV3 [FluBlok], Protein Sciences) and cell culture-based inactivated influenza vaccine (ccIIV3 [Flucelvax], Novartis), currently available influenza vaccines are prepared by propagation of virus in embryonated chicken eggs. A review of published data (including data on 4,172 patients, 513 of whom were reported to have a history of severe allergic reaction to egg) noted that no occurrences of anaphylaxis were reported, although some milder reactions did occur, suggesting that severe allergic reactions to egg-based influenza vaccines are unlikely. On this basis, some guidance recommends that no additional measures are needed when administering influenza vaccine to egg-allergic persons. However, occasional cases of anaphylaxis in egg-allergic persons have been reported to the Vaccine Adverse Event Reporting System (VAERS) after administration of influenza vaccine (25,26). In published studies, vaccines containing as much as 0.7 µg/0.5 mL of ovalbumin have been tolerated (27,28); however, a threshold below which no reactions would be expected is not known (27). Among IIVs for which ovalbumin content was disclosed during the 2011–12 through 2013–14 seasons, the reported maximum amounts were ≤1 µg/0.5 mL dose. Ovalbumin is not directly measured for Flucelvax; it is estimated by calculation from the initial content in the reference virus strains to contain less than 5x10^-8 µg of total egg protein per 0.5mL dose, of which ovalbumin is a fraction (Novartis, personal communication, 2013). FluBlok is considered egg-free. However, neither Flucelvax nor FluBlok are licensed for use in children aged <18 years.
Primary Changes and Updates in the Recommendations

1. Persons with a history of egg allergy who have experienced only hives after exposure to egg should receive influenza vaccine. Because relatively few data are available for use of LAIV in this setting, IIV or trivalent recombinant influenza vaccine (RIV3) should be used. RIV3 may be used for persons aged 18 through 49 years who have no other contraindications. However, IIV (egg- or cell-culture based) may also be used, with the following additional safety measures (Figure 2):
   - Vaccine should be administered by a health care provider who is familiar with the potential manifestations of egg allergy; and
   - Vaccine recipients should be observed for equal to or greater than 30 minutes for signs of a reaction after administration of each vaccine. Although very rare, advise patient to seek immediate medical attention if a delayed reaction occurs.

2. Persons who report having had reactions to egg involving such symptoms as angioedema, respiratory distress, lightheadedness, or recurrent emesis; or who required epinephrine or another emergency medical intervention, may receive RIV3 if they are aged 18 through 49 years and there are no other contraindications. If RIV3 is not available or the recipient is not within the indicated age range, IIV should be administered by a physician with experience in the recognition and management of severe allergic conditions (Figure 2).

3. Regardless of allergy history, all vaccines should be administered in settings in which personnel and equipment for rapid recognition and treatment of anaphylaxis are available.

4. Persons who are able to eat lightly cooked egg (e.g., scrambled egg) without reaction are unlikely to be allergic. Egg-allergic persons might tolerate egg in baked products (e.g., bread or cake). Tolerance to egg-containing foods does not exclude the possibility of egg allergy.

5. For persons 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 before vaccination (Figure 2). Alternatively, RIV3 may be administered if the recipient is aged 18 through 49 years.

6. 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.
## Contraindications/Precautions to Seasonal Influenza Vaccine 2014-2015

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Contraindications</th>
<th>Precautions</th>
</tr>
</thead>
<tbody>
<tr>
<td>IIV</td>
<td>History of severe allergic reaction to any component of the vaccine, including egg protein, or after previous dose of any influenza vaccine.</td>
<td>Moderate to severe illness with or without fever. History of Guillain-Barré syndrome within 6 weeks of receipt of influenza vaccine.</td>
</tr>
<tr>
<td>RIV</td>
<td>History of severe allergic reaction to any component of the vaccine.</td>
<td>Moderate to severe illness with or without fever. History of Guillain-Barré syndrome within 6 weeks of receipt of influenza vaccine.</td>
</tr>
<tr>
<td>LAIV</td>
<td>Severe allergic reaction to any component of the vaccine, including egg protein, or after previous dose of any influenza vaccine. Moderate to severe illness with or without fever. History of Guillain-Barré syndrome within 6 weeks of receipt of influenza vaccine. Asthma in persons aged 5 years and older. Medical conditions which might predispose to higher risk for complications attributable to influenza.</td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Concomitant use of aspirin or aspirin-containing medications in children and adolescents.</strong> In addition, ACIP recommends LAIV4 not be used for pregnant women, immunosuppressed persons, persons with egg allergy, and children aged 2–4 years who have asthma or who have had a wheezing episode noted in the medical record within the past 12 months, or for whom parents report that a health care provider stated that they had wheezing or asthma within the last 12 months. LAIV should not be administered to persons who have taken influenza antiviral medications within the previous 48 hours. Persons who care for severely immunosuppressed persons who require a protective environment should not receive LAIV, or should avoid contact with such persons for 7 days after receipt.</td>
<td></td>
</tr>
</tbody>
</table>
**ASSESSMENT**
No contraindications
Candidate for seasonal influenza vaccine

**PLAN**
The plan is focused on prevention of seasonal influenza

**MATERIALS NEEDED**
- Needles
- Seasonal Influenza Vaccine
- Syringes
- Alcohol swabs
- Gloves
- Biohazard disposal container
- Hand hygiene supplies
- Emergency drugs, supplies and protocols
- Certified calibrated thermometer
- Cooler and cold packs
- VIS for influenza vaccine
- Patient Consent Forms
- Patient education materials

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IIV=Inactivated Influenza Vaccine; IIV3=Inactivated Influenza Vaccine, Trivalent; IIV4=Inactivated Influenza Vaccine, Quadrivalent; RIV=Recombinant Influenza Vaccine LAIV=Live-Attenuated Influenza Vaccine; IM=intramuscular; ID=intradermal; IN=intranasal.

* Immunization providers should check Food and Drug Administration-approved information for 2014-2015 influenza vaccines for the most complete and updated information, including (but not limited to) indications, contraindications, and precautions. Package inserts for US-licensed vaccines are available at http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm093833.htm.
DIAGNOSTIC STUDIES
Rapid Test is not recommended. The focus should be on prevention.

THERAPEUTIC

PHARMACOLOGIC

Vaccination (Prevention)
The primary option for reducing the effect of influenza is immunoprophylaxis. Vaccinating persons at high risk for complications and their contacts each year before seasonal increases in influenza virus circulation is the most effective means of reducing effects of influenza. It is associated with reduction in influenza-related respiratory illness, hospitalization and death.

Administer seasonal influenza vaccine in accordance with the tables:
- Recommended Influenza Vaccine Schedule;
- Recommended Dosages & Intervals; and
- Recommended Dosage and Route.
<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Age Group</th>
<th>Dosage &amp; Route</th>
<th>Number of Doses</th>
<th>Number of Doses</th>
<th>Pregnancy Category</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Fluzone®</td>
<td>6-35 months</td>
<td>0.25 mL IM</td>
<td>1 or 2</td>
<td>28 days</td>
<td>C</td>
</tr>
<tr>
<td></td>
<td>3 through 8 years</td>
<td>0.5 mL IM</td>
<td>1 or 2</td>
<td>28 days</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Greater than or equal to 9 years</td>
<td>0.5 mL IM</td>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Greater than or equal to 65 years</td>
<td>0.5 mL IM</td>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fluzone®</td>
<td>18 through 64 years</td>
<td>Intradermal</td>
<td>1</td>
<td></td>
<td>B</td>
</tr>
<tr>
<td>High Dose</td>
<td></td>
<td>0.1 mL</td>
<td></td>
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</tr>
<tr>
<td>Fluvirin®</td>
<td>4 through 8 years</td>
<td>0.5 mL IM</td>
<td>1 or 2</td>
<td>28 days</td>
<td>C</td>
</tr>
<tr>
<td></td>
<td>Greater than or equal to 9 years</td>
<td>0.5 mL IM</td>
<td>1</td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Fluarix®</td>
<td>3 through 8 years</td>
<td>0.5 mL IM</td>
<td>1 or 2</td>
<td>28 days</td>
<td>B</td>
</tr>
<tr>
<td></td>
<td>Greater than or equal to 9 years</td>
<td>0.5 mL IM</td>
<td>1</td>
<td></td>
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</tr>
<tr>
<td>FluLaval®</td>
<td>3 through 8 years</td>
<td>0.5 mL IM</td>
<td>1 or 2</td>
<td>28 days</td>
<td>B</td>
</tr>
<tr>
<td></td>
<td>Greater than or equal to 9 years</td>
<td>0.5 mL IM</td>
<td>1</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Afluria®</td>
<td>9 years of age and older</td>
<td>0.5 mL IM</td>
<td>1</td>
<td></td>
<td>B</td>
</tr>
</tbody>
</table>

Seasonal Influenza Protocol
### Inactivated Influenza Vaccine, Quadrivalent (IIV4)

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Age Group</th>
<th>Dosage &amp; Route</th>
<th>Number of Doses</th>
<th>Number of Doses</th>
<th>Pregnancy Category</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Fluarix® Quadrivalent</strong></td>
<td>3 through 8 years</td>
<td>0.5 mL IM</td>
<td>1 or 2</td>
<td>28 days</td>
<td>B</td>
</tr>
<tr>
<td></td>
<td>Greater than or equal to 9 years</td>
<td>0.5 mL IM</td>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>FluLaval® Quadrivalent</strong></td>
<td>3 through 8 years</td>
<td>0.5 mL</td>
<td>1 or 2</td>
<td>28 days</td>
<td>B</td>
</tr>
<tr>
<td></td>
<td>Greater than or equal to 9 years</td>
<td>0.5 mL</td>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Fluzone® Quadrivalent</strong></td>
<td>6 months Through 35 months</td>
<td>0.25 mL IM</td>
<td>1 or 2</td>
<td>28 days</td>
<td>C</td>
</tr>
<tr>
<td></td>
<td>36 months through 8 years</td>
<td>0.5 mL IM</td>
<td>1 or 2</td>
<td>28 days</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Greater than or equal to 9 years</td>
<td>0.5 mL IM</td>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vaccine</td>
<td>Age Group</td>
<td>Dosage &amp; Route</td>
<td>Number of Doses</td>
<td>Minimum interval from dose 1 to 2</td>
<td>Pregnancy Category</td>
</tr>
<tr>
<td>---------------------------------</td>
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</tr>
<tr>
<td><strong>Recombinant Influenza Vaccine Trivalent (RIV3)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Flublok®</td>
<td>18 through 49 years</td>
<td>0.5 mL IM</td>
<td>1</td>
<td>------</td>
<td>B</td>
</tr>
<tr>
<td><strong>Inactivated Influenza Vaccine, Trivalent, Cell Culture-based (ccIIV3)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Flucelvax®</td>
<td>18 years of age and older</td>
<td>0.5 mL IM</td>
<td>1</td>
<td>------</td>
<td>B</td>
</tr>
<tr>
<td><strong>Live Attenuated Influenza Vaccine (LAIV4)</strong></td>
<td></td>
<td></td>
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<td></td>
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</tr>
<tr>
<td>FluMist®</td>
<td>Greater than or equal to 24 months through 8 years</td>
<td>0.2 mL Intranasal</td>
<td>1 or 2</td>
<td>28 days</td>
<td>Do not use in pregnancy</td>
</tr>
<tr>
<td>FluMist®</td>
<td>Greater than or equal to 9 years through 49 years of age</td>
<td>0.2 mL intranasal</td>
<td>1</td>
<td>------</td>
<td></td>
</tr>
</tbody>
</table>
Abbreviations: IM = intramuscular; ID = intradermal; IN = intranasal; ACIP = Advisory Committee on Immunization Practices.

* Immunization providers should check Food and Drug Administration–approved prescribing information for 2014–15 influenza vaccines for the most complete and updated information, including (but not limited to) indications, contraindications, warnings, and precautions. Package inserts for U.S.-licensed vaccines are available at http://www.fda.gov/biologicsbloodvaccines/vaccines/approvedproducts/ucm093833.htm.

† For adults and older children, the recommended site of vaccination is the deltoid muscle. The preferred site for infants and young children is the anterolateral aspect of the thigh. Specific guidance regarding site and needle length for intramuscular administration can be found in ACIP’s General Recommendations on Immunization (available at http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6002a1.htm).

1 Trivalent inactivated vaccine, high-dose: A 0.5-mL dose contains 60 µg of each vaccine antigen (180 µg total).

2 Trivalent inactivated vaccine, intradermal: A 0.1-mL dose contains 9 µg of each vaccine antigen (27 µg total). ** The preferred site is over the deltoid muscle. Fluzone Intradermal is administered using the delivery system included with the vaccine.

3 Age indication per package insert is greater than or equal to 5 years; however, ACIP recommends Afluria not be used in children aged 6 months through 8 years because of increased risk for febrile reactions noted in this age group with bioCSL’s 2010 Southern Hemisphere IIV3. If no other age-appropriate, licensed inactivated seasonal influenza vaccine is available for a child aged 5 through 8 years who has a medical condition that increases the child’s risk for influenza complications, Afluria can be used; however, providers should discuss with the parents or caregivers the benefits and risks of influenza vaccination with Afluria before administering this vaccine. Afluria may be used in persons aged greater than or equal to 9 years.

4 Information not included in package insert. Estimated to contain less than 50 femtograms (5x10^-8 µg) of total egg protein (of which ovalbumin is a fraction) per 0.5 mL dose of Flucelvax.

5 FluMist is shipped refrigerated and stored in the refrigerator at 35°F–46°F (2°C–8°C) after arrival in the vaccination clinic. The dose is 0.2 mL divided equally between each nostril. Health care providers should consult the medical record, when available, to identify children aged 2 through 4 years with asthma or recurrent wheezing that might indicate asthma. In addition, to identify children who might be at greater risk for asthma and possibly at increased risk for wheezing after receiving LAIV, parents or caregivers of children aged 2 through 4 years should be asked, "In the past 12 months, has a health care provider ever told you that your child had wheezing or asthma?" Children whose parents or caregivers answer "yes" to this question and children who have asthma or who had a wheezing episode noted in the medical record within the past 12 months should not receive FluMist.

6 Starting in 2014-2015, CDC recommends use of the nasal spray vaccine for healthy* children 2 through 8 years of age when it is immediately available and if the child has no contraindications or precautions to that vaccine. If the nasal spray vaccine is not immediately available and the flu shot is, vaccination should not be delayed and a flu shot should be given.
### Pregnancy Risk Categories

<table>
<thead>
<tr>
<th>Category</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>A</strong></td>
<td>Controlled studies in pregnant women fail to demonstrate a risk to the fetus in the first trimester with no evidence of risk in later trimesters. The possibility of fetal harm appears remote.</td>
</tr>
<tr>
<td><strong>B</strong></td>
<td>Either animal-reproduction studies have not demonstrated a fetal risk but there are not controlled studies in pregnant women, or animal-reproduction studies have shown an adverse effect (other than a decrease in fertility) that was not confirmed in controlled studies in women in the first trimester and there is no evidence in later trimesters.</td>
</tr>
<tr>
<td><strong>C</strong></td>
<td>Either studies in animals have revealed adverse effects on the fetus and there are no controlled studies in women, or studies in women and animals are not available. Drugs should be given only if the potential benefits justify the potential risk to the fetus.</td>
</tr>
<tr>
<td><strong>D</strong></td>
<td>There is positive evidence of human fetal risk, but the benefits from use in pregnant may be acceptable despite the risk (e.g., if the drug is needed in a life-threatening situation or for a serious disease for which safer drugs cannot be used or are ineffective).</td>
</tr>
<tr>
<td><strong>X</strong></td>
<td>Studies in animals or humans beings have demonstrated fetal abnormalities or there is evidence of fetal risk based on human experience, or both, and the risk of the use of the drug in pregnant women clearly outweighs any possible benefit. The drug is contraindicated in women who are or may become pregnant.</td>
</tr>
</tbody>
</table>
FIGURE 3. Influenza vaccine dosing algorithm for children aged 6 months through 8 years — Advisory Committee on Immunization Practices, United States, 2014–15 influenza season*

* For simplicity, this algorithm takes into consideration only doses of seasonal influenza vaccine received since July 1, 2010, to determine the number of doses needed for the 2014–15 season. As an alternative approach in settings where vaccination history from before July 1, 2010, is available, if a child aged 6 months through 8 years is known to have received either 1) at least 1 dose of 2013–14 seasonal influenza vaccine, or 2) at least two seasonal influenza vaccines during any previous season, and at least 1 dose of a 2009(H1N1)–containing vaccine (i.e., seasonal vaccine since 2010–11 or the monovalent 2009[H1N1] vaccine), then the child needs only 1 dose for 2014–15. Using this approach, children aged 6 months through 8 years need only 1 dose of vaccine for 2014–15 if they have received any of the following: 1) at least 1 dose of 2013–14 seasonal influenza vaccine; or 2) 2 or more doses of seasonal influenza vaccine since July 1, 2010; or 3) 2 or more doses of seasonal influenza vaccine before July 1, 2010, and 1 or more doses of monovalent 2009(H1N1) vaccine; or 4) 1 or more doses of seasonal influenza vaccine before July 1, 2010, and 1 or more doses of seasonal influenza vaccine since July 1, 2010.

Children in this age group for whom one of these conditions is not met require 2 doses for 2014–15.
Refer to Figure 3 on previous page

† Doses should be administered at least 4 weeks apart.
Alternate Text: The figure above is a flow chart detailing the influenza vaccine dosing algorithm for children aged 6 months through 8 years in the United States for the 2014-15 influenza season. Two approaches are recommended for determination of the necessary doses for the 2014-15 season; both are acceptable. The first approach considers only doses of seasonal influenza vaccine received since July 1, 2010. Where adequate vaccination history from before the 2010-11 season is available, the second approach may be used.

<table>
<thead>
<tr>
<th>Recommended Dosage and Route</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.25 mL or 0.5 mL administered intramuscularly for IIV. For adults and older children, the recommended site of vaccinations is the deltoid muscle. The preferred site for infants and young children is the anterolateral aspect of the thigh. *</td>
</tr>
<tr>
<td>0.1mL administered intradermally for IIV**</td>
</tr>
<tr>
<td>0.2mL administered intranasally for LAIV***</td>
</tr>
</tbody>
</table>

*Please refer to the Georgia Immunization Program Manual Chapter 13 (Quality Assurance-Attachment D) on vaccine administration recommendations for appropriate site and needle size.


*** NOTE: Before using the nasal spray, gently blow your nose to clear the nostrils. If the vaccine recipient sneezes after administration, the dose should not be repeated. However, if nasal congestion is present that might impede delivery of the vaccine to the nasopharyngeal mucosa, deferral of administration should be considered until resolution of the illness, or TIV should be administered instead.
<table>
<thead>
<tr>
<th>Simultaneous Vaccine Administration</th>
</tr>
</thead>
<tbody>
<tr>
<td>May be administered simultaneously with any of the following routinely recommended vaccines: DTaP, Tdap, Td, RV, MMR, Varicella, Hib, Hepatitis A, Hepatitis B, IPV, PPSV23, PCV13, HPV, Zoster, MCV4, and MPSV4</td>
</tr>
</tbody>
</table>

**NOTE:** See current ACIP statement regarding FluMist® and simultaneous administration with other vaccines. See package insert for the safety and immunogenicity of this practice.
PATIENT EDUCATION/COUNSELING

1. Provide the current Vaccine Information Sheet to the patient, guardian, or caretaker prior to immunization and answer any questions related to the vaccine prior to giving the immunization.

2. Emphasize that inactivated influenza vaccine contains noninfectious killed viruses and cannot cause influenza.

3. Coincidental respiratory disease unrelated to influenza vaccination can occur after vaccination.

4. If two doses are required to achieve immunity, arrange for information about need for second dose and stress importance of second dose of vaccine.

5. Stress the importance of hand hygiene.

6. Support staying at home if ill.

7. Pregnant and postpartum women do not need to avoid contact with persons recently vaccinated with LAIV.

8. Persons receiving antiviral drugs within the period 2 days before to 14 days after vaccination with LAIV should be revaccinated at a later date with any approved vaccine formulation.

9. Individuals who care for the severely immunocompromised (those living in a protective environment) should receive either IIV or RIV3.

FOLLOW UP

Patients who do not have regularly scheduled visits during the fall should be reminded by mail, telephone or other means of the need for vaccination. Use the reminder recall system on GRITS immunization registry.

CONSULTATION/REFERRAL

1. Refer individuals who have ever had a severe allergic reaction to eggs to medical doctor with experience in management of severe allergic conditions.

2. Refer to physician for complications of influenza, and/or history of Guillain-Barré Syndrome.
REFERENCES


4. CDC, Key Facts About Seasonal Influenza (Flu), [http://www.cdc.gov/flu/keyfacts.htm] (September 26, 2013).


10. Licensure of a High-Dose Inactivated Influenza Vaccine for Persons Aged ≥65 Years (Fluzone High-Dose) and Guidance for Use, Weekly MMWR, April 30, 2010/ 59 (16): 485-486.


12. Prevention and Control of Seasonal Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices (ACIP), MMWR, August 18, 2011, Vol.60


15. CDC. ACIP adult immunization schedule, United States, 2013 (available at [http://www.cdc.gov/vaccines/schedules/hcp/adult.html])