2014–2015 Recommendations from the Advisory Committee Immunization Practice (ACIP) June 2014 meeting.¹

- Strain selection for FluMist® 2014–2015²
  - A/California/7/2009 (H1N1)
  - A/Texas/50/2012 (H3N2)
  - B/Massachusetts/2/2012 (B Yamagata/16/88 lineage)
  - B/Brisbane/60/2008 (B/Victoria/2/87 lineage)

- The Oregon Immunization Program (OIP) and ACIP preferentially recommend the use of Live Attenuated Influenza Vaccine (LAIV) in healthy children 2–8 years of age.¹

- When both IIV and LAIV are available, LAIV should be used for healthy children ages ² through 8 years who have no contraindications or precautions.¹

- Influenza vaccination should not be delayed to procure a specific vaccine preparation if an appropriate one is already available.¹


I. Order:

1. It is strongly recommended, but not required, that the pharmacist check the ALERT Immunization Information System to determine whether the patient needs this vaccine and any other vaccines.

2. Screen clients ≥11 years for contraindications.

3. Provide an Adolescent Well Visit Flyer to those 11—18 years of age.

4. Provide a current Vaccine Information Sheet (VIS) answering any questions.

5. Obtain a signed Vaccination Administration Record (VAR)

6. While the recipient is in an upright position, head tilted back, place the tip just inside the nostril. With a single motion, depress plunger as rapidly as possible until the dose-divider clip prevents you from going further. Spray 0.1 ml from the LAIV sprayer intranasally into one nostril. (See section XI, p12)
   - Pinch and remove the dose-divider clip from the plunger.
   - Place the tip just inside the other nostril and depress the plunger as rapidly as possible to deliver the remaining 0.1ml dose (total dose of 0.2 ml).

7. For nasal use only. Do not administer parenterally. This live vaccine can be administered simultaneously with other inactivated and live vaccines. However, two live vaccines not administered on the same day should be given ≥28 days apart.

*IIV and RIV under separate order.

Immunizing Pharmacist Signature
Date

For multiple signatures see: 1.usa.gov/PharmacyImmunizationProtocols
II. LICENSED LIVE ATTENUATED INFLUENZA VACCINE (LAIV₄) 2014-2015

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Vaccine Components³</th>
<th>Acceptable Age Range</th>
<th>Thimerosal</th>
</tr>
</thead>
</table>
| LAIV₄ FluMist®¹²⁴ (MedImmune) | • A /California/7/2009 (H1N1)  
• A/Texas/50/2012 (H3N2)  
• B/Massachusetts/2/2012 (B Yamagata/16/88 lineage)  
• B/Brisbane/60/2008 (B/Victoria/2/87 lineage) | 2–49 years | NONE |

¹A live, quadrivalent, intranasally administered vaccine that replicates in the mucosa of the nasopharynx, inducing protective immunity against viruses included in the vaccine.

²Children who have received at least one dose of 2013-2014 seasonal vaccine need only one dose in 2014-2015.


⁴Persons who care for severely immunosuppressed persons who require a protective environment should not receive FluMist® given the theoretical risk of transmission of the live, attenuated vaccine virus.
III. RECOMMENDATIONS FOR USE

III.A. Vaccination with LAIV is indicated for healthy, non-pregnant persons 2–49 years of age in the following groups:

- Children ages 2—8 years receiving LAIV for the first time require 2 doses at least 28 days apart.
- School-age children
- Health-care workers (HCW)

If LAIV is not immediately available, IIV should be used. Vaccination should not be delayed in order to procure LAIV.
III.B. Persons who **SHOULD NOT RECEIVE FluMist® (LAIV)***

- Persons <2 years or ≥50 years of age;¹
  - Children aged 2-17 years who are receiving aspirin or other salicylate therapy
  - Persons who have had severe allergic reactions to the vaccine or its components;
- Pregnant women;¹
- Immunosuppressed persons;¹
- Persons with egg allergy;²
  - Recommendations for persons with symptoms other than hives are:
    - Receive recombinant influenza vaccine (RIV3) if age 18 through 49 and there are no other contraindications
    - IIV should be administered by a physician with experience in the recognition and management of severe allergic conditions, who have resuscitative resources and who will maintain a 30 minute wait period after vaccination
- Persons with asthma or recurrent wheezing, reactive airway disease, chronic disorders of the pulmonary or cardiovascular systems; metabolic diseases such as diabetes, renal dysfunction and hemoglobinopathies;¹
- Persons who have taken influenza antiviral medications within the previous 48 hours;
- Persons with a history of Guillain–Barré syndrome;
- Persons who have any condition (e.g., cognitive dysfunction, spinal cord injuries, seizure disorders, or other neuromuscular disorders) that can compromise respiratory function or the handling of respiratory secretions or that can increase the risk for aspiration;¹
- Children ages 2-4 years who have had a wheezing episode noted in the medical record within the past 12 months, or for whom parents report that a healthcare-provider stated that they had wheezing or asthma within the last 12 months;¹
- Household members and HCWs who have close contact with severely immunosuppressed persons (e.g., patients with hematopoietic stem cell transplants) requiring care in a protected environment;¹
- Residents of nursing homes and other chronic-care facilities.¹
- FluMist® Quadrivalent has not been studied in immunocompromised persons.¹
- The safety of FluMist Quadrivalent in individuals with underlying medical conditions that may predispose them to complications following wild-type influenza infection has not been established.²

¹ These persons, with no contraindications or precautions, should receive inactivated influenza vaccine.
² These persons could receive inactivated influenza vaccine if their health care provider recommended that the benefits outweigh the risks.
### IV. VACCINE SCHEDULE FOR LAIV FOR 2014–2015 SEASON¹

<table>
<thead>
<tr>
<th>AGE GROUP</th>
<th>VACCINATION STATUS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Healthy children ages 2–8 years</td>
<td>Never had flu vaccine</td>
</tr>
<tr>
<td></td>
<td>Received &lt;2 doses</td>
</tr>
<tr>
<td></td>
<td>History unknown</td>
</tr>
<tr>
<td></td>
<td>Have received ≥2 doses</td>
</tr>
<tr>
<td>Number of doses this season²,⁴ (0.2 mL per dose)</td>
<td>²,³</td>
</tr>
<tr>
<td></td>
<td>²,³,⁴</td>
</tr>
<tr>
<td></td>
<td>²,³</td>
</tr>
<tr>
<td></td>
<td>1</td>
</tr>
</tbody>
</table>

¹If the vaccine recipient sneezes after administration, the dose should not be repeated.

²These two doses do not have to match; live or inactivated influenza can be used for either dose.

³The 2nd dose needs to be separated from the 1st dose by ≥28 days.

⁴Children who have received at least one dose of 2013-2014 seasonal vaccine need only one dose in 2014-2015.

<table>
<thead>
<tr>
<th>AGE GROUP</th>
<th>VACCINATION STATUS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Healthy children and adults ages 9–49 years</td>
<td>Any</td>
</tr>
<tr>
<td>Number of doses this season</td>
<td>1 dose (0.2 mL)</td>
</tr>
</tbody>
</table>

¹If the vaccine recipient sneezes after administration, the dose should not be repeated.
Healthy Children >6 months of age—8 years of age:¹


* Doses should be administered at least 4 weeks apart.

† For the sake of simplicity, this algorithm takes into consideration only doses of seasonal influenza vaccine received since July 1, 2010. As an alternative approach in settings where vaccination history from before July 1, 2010 is available, if a child ages 6 months through 8 years is known to have received at least 2 seasonal influenza vaccines during any previous season, and at least 1 dose of a 2009 (H1N1)-containing vaccine (i.e., 2010–11, 2011–12, 2012–13, or 2013–14, seasonal vaccine or the monovalent 2009 [H1N1] vaccine), then the child needs only 1 dose for the 2014–15 season. Using this approach, children aged 6 months through 8 years need only 1 dose of vaccine in the 2014–15 season, if they have received any of the following:

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

¹ Children who have received at least one dose of 2013-2014 seasonal vaccine need only one dose in 2014-2015.
V. VACCINE STORAGE AND HANDLING

- LAIV is shipped at 2°–8°C (35°–46°F).
- LAIV must be stored upon receipt in the refrigerator at 2°–8°C (35°–46°F).
- DO NOT FREEZE\(^1\)
- Vaccine is administered intranasally.
- Supplied in a package of 10 pre-filled, single-use sprayers
- The 0.2 ml sprayer dose is thimerosal-free.
- The single-use intranasal sprayer contains no natural rubber latex
- Once LAIV has been administered, the sprayer should be disposed of in a sharps or biohazard container.

\(^1\)LAIV inadvertently exposed to freezing temperatures should be placed at refrigerator temperature and used as soon as possible.

**NOTE:** For information regarding product storage and stability under conditions other than those stated above, contact MedImmune Vaccines Inc. online at [www.FluMist.com](http://www.FluMist.com).
### VI. CONTRAINDICATIONS

| A. | Persons with a history of severe (anaphylactic) allergy to egg, gentamicin, gelatin or arginine, or with life-threatening reactions to previous influenza vaccinations.¹ |
| B. | Some licensed inactivated influenza vaccines are available without any hen’s egg products: Flucelvax® and Recombinant Influenza Vaccine FluBlok®. |
| C. | Concomitant aspirin therapy in children and adolescents (2-17 years of age).² |
| D. | Asthma: Inactivated influenza vaccine is approved for persons with asthma or wheezing. |
| E. | FluMist® Quadrivalent has not been studied in immunocompromised persons¹. |

### VII. PRECAUTIONS

| A. | Individuals with a history of Guillain- Barré syndrome. |
| B. | Recurrent wheezing in children <5 years of age.¹ |
| C. | Administration of LAIV should be deferred for persons with a moderate or severe acute illness, with or without fever. |
| D. | Caution should be exercised if LAIV is administered to nursing mothers, because of the possibility of virus shedding, and since it is not known whether this vaccine is excreted in human milk. |
| E. | If clinical judgment indicates that nasal congestion might impede vaccine delivery to nasopharyngeal mucosa, deferral of administration should be considered until illness is resolved. |

In a clinical trial, among children 6–23 months of age, wheezing requiring bronchodilator therapy or with significant respiratory symptoms occurred in 5.8% of FluMist® recipients compared to 3.8% of active control recipients. Wheezing was not increased in children ≥23 months of age.

¹FluMist® package insert, July 2014, sect. 5.1, 5.2
### VIII. SIDE EFFECTS AND ADVERSE REACTIONS

#### Summary of solicited events in children 2–6 years of age within 10 days of dose #1 (study MI-CP111)

<table>
<thead>
<tr>
<th>EVENT</th>
<th>FluMist® (refrigerated) N=2170 %</th>
<th>Active Control (injectable TIV) N=2165 %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Runny Nose/ Nasal Congestion</td>
<td>51</td>
<td>42</td>
</tr>
<tr>
<td>Decreased Appetite</td>
<td>13</td>
<td>12</td>
</tr>
<tr>
<td>Irritability</td>
<td>12</td>
<td>11</td>
</tr>
<tr>
<td>Decreased Activity (Lethargy)</td>
<td>7</td>
<td>6</td>
</tr>
<tr>
<td>Sore Throat</td>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td>Headache</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>Muscle Aches</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Chills</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Fever</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&gt;100° F Oral</td>
<td>13</td>
<td>11</td>
</tr>
<tr>
<td>&gt;100–101°F Oral</td>
<td>6</td>
<td>4</td>
</tr>
<tr>
<td>&gt;101–102°F Oral</td>
<td>4</td>
<td>3</td>
</tr>
</tbody>
</table>

#### Summary of solicited events in adults 18–49 years occurring in at least 1% of FluMist® recipients (study AV009; LAIV-3)

<table>
<thead>
<tr>
<th>EVENT</th>
<th>FluMist-3® Group %</th>
<th>Placebo Group AV009 %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Runny Nose</td>
<td>44</td>
<td>27</td>
</tr>
<tr>
<td>Headache</td>
<td>40</td>
<td>38</td>
</tr>
<tr>
<td>Sore Throat</td>
<td>28</td>
<td>17</td>
</tr>
<tr>
<td>Tiredness/Weakness</td>
<td>26</td>
<td>22</td>
</tr>
<tr>
<td>Muscle Aches</td>
<td>17</td>
<td>15</td>
</tr>
<tr>
<td>Cough</td>
<td>14</td>
<td>11</td>
</tr>
<tr>
<td>Chills</td>
<td>9</td>
<td>6</td>
</tr>
<tr>
<td>Nasal Congestion</td>
<td>9</td>
<td>2</td>
</tr>
<tr>
<td>Sinusitis</td>
<td>4</td>
<td>2</td>
</tr>
</tbody>
</table>

Source: FluMist® Intranasal Spray July 2014 formula package insert (Table 2, pg. 7, pg. 9)  
IX. OTHER CONSIDERATIONS

A. Efficacy: One trial which studied children 60–71 months of age who received 2 doses in their first season showed a 94% efficacy compared to 89% for those who received only 1 dose in their first season. Vaccine efficacy is 85% among 15 – 49 year olds.

B. Use with Influenza Antiviral Medications
Persons who have taken influenza antiviral medications within the previous 48 hours should not receive LAIV. Furthermore, antiviral agents should not be administered until two weeks after receipt of LAIV. If antiviral agents and FluMist® are administered concomitantly, revaccination should be considered when appropriate.

C. Shedding Vaccine virus
Nasopharyngeal secretions or swabs collected from vaccinees may test positive for influenza virus for up to three weeks post immunization. In rare instances, shed vaccine viruses can be transmitted from vaccine recipients to unvaccinated persons.1

D. Administering LAIV
Severely immunosuppressed persons should not administer LAIV.1 However, other persons at high risk for influenza complications may administer LAIV. These include persons with underlying medical conditions placing them at high risk, including pregnant women, persons with asthma, and persons ages ≥50 years.

E. Health-care workers or hospital visitors who have received LAIV should refrain from contact with severely immunosuppressed patients (e.g., patients with hematopoietic stem cell transplants) for 7 days after receipt of vaccine.2 People who have contact with others with lesser degrees of immunosuppression (for example, people with diabetes, people with asthma taking corticosteroids, or people infected with HIV) can get LAIV (FluMist®).3

F. Timing of LAIV Administration
Providers should begin vaccinating with LAIV as soon as vaccine supplies are available.

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2 CDC. MMWR July 2013. Available at www.cdc.gov/mmwr/preview/mmwrhtml/rr6207a1.htm?s_cid=rr6207a1_w, accessed 30 Jul 2014

3 CDC The nasal-spray flu vaccine (live attenuated influenza vaccine [LAIV]). Available at www.cdc.gov/flu/about/qa/nasalspray.htm, accessed 30 Jul 2014
X. ADVERSE EVENTS REPORTING

Adverse events following immunization must be reported to the Vaccine Adverse Events Reporting System (VAERS) at 1-800-822-7967. Forms and procedures can be found at the VAERS website: www.vaers.hhs.gov. In addition, a copy of the reporting form should be reported to the patient’s primary provider, per Oregon Revised Statute (ORS) 855-019-0280(4).

XI: APPLICATION PROCEDURE:

[Images of application procedure steps]

Note: Active inhalation (i.e., sniffing) is not required by the patient during FluMist administration.
REFERENCES


To request this material in an alternative format (e.g., Braille) or to clarify any part of the
above order, contact the Oregon Health Authority Immunization Program at 971.673.0300 or
711 for TTY. For other questions, consult with the vaccine recipient’s primary health care
provider or a consulting physician.

   Electronic copy of this protocol available at:
   1.usa.gov/PharmacyImmunizationProtocols

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