

IMMUNIZATION PROTOCOL FOR PHARMACISTS

LIVE ATTENUATED INFLUENZA VACCINE (LAIV)

FLUMIST®

2009–2010 Influenza Season updates based on ACIP recommendations issued in the July 24, 2009, MMWR:

- **AS SOON AS VACCINE IS AVAILABLE:** Beginning with the 2009–10 influenza season, vaccinate all people 6 months–18 years of age, adults, persons ≥ 50 years, all persons who live with or care for persons at high risk for influenza-related complications, and all contacts with children aged < 6 mo. (MMWR July 2009 pg. 27)
- Vaccinate all healthy persons 2–49 years of age with TIV or LAIV (FluMist®)*
- All persons who want to reduce the risk of influenza disease or transmitting it to others, should be vaccinated,

I. **ORDER:**

1. Screen for contraindications.
2. Provide the current Vaccine Information Statement (VIS), answering any questions.
3. Obtain a signed Vaccine Administration Record (VAR).
4. 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 X)
 - 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).

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 ≥ 4 weeks apart.

*TIV under separate order. Standing orders for H1N1 will be provided in a separate document.

Pharmacist signature

Date

(July 30, 2009)

Original provided courtesy of the Oregon State Public Health Division Immunization Program

II. LICENSED LIVE ATTENUATED INFLUENZA VACCINE 2009-2010

Product Name	II. Vaccine Components	Acceptable Age Range	Thimerosal
FluMist® ¹ (MedImmune)	A/SouthDakota/6/2007 (H1N1) (an A/Brisbane/59/2007-like), A/Uruguay/716/2007 (H3N2) (an A/Brisbane/10/2007-like), and B/Brisbane/60/2008.	2–49 years	NONE

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

III. VACCINE SCHEDULE FOR LAIV:

Age Group	Dosage Schedule
Healthy adolescents and Adults 15-49 years ¹	1 dose (0.2ml) per season ²
¹ If the vaccine recipient sneezes after administration, the dose should not be repeated	² Administer as 0.1 ml per nostril

IV. 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
- Vaccine is delivered intranasally.
- Supplied in a package of 10 pre-filled, single-use sprayers
- The 0.2 ml sprayer dose is thimerosal-free.
- Once LAIV has been administered, the sprayer should be disposed of in a sharps or biohazard container.

NOTE: For information regarding product storage and stability under conditions other than those stated above, contact MedImmune Vaccines Inc. or online at <http://www.FluMist.com>

V. RECOMMENDATIONS FOR USE

- A. Vaccination with LAIV is indicated** for healthy, non-pregnant persons 2–49 years of age in the following groups:
- **Household contacts and caregivers** of persons in any of the following high risk groups:
 - children <5 years of age
 - pregnant women
 - persons ≥ 50 years of age
 - children and adolescents who are receiving long-term aspirin therapy and, therefore, might be at risk for Reye syndrome;
 - persons with chronic disorders of the pulmonary or cardiovascular systems, including asthma;
 - persons with chronic metabolic diseases such as diabetes, renal dysfunction, or hemoglobinopathies;
 - persons with any condition that can compromise respiratory function or the handling of respiratory secretions or that can increase the risk for aspiration;
 - residents of nursing homes and other chronic-care facilities; or
 - immunosuppressed persons other than those requiring a protected environment (e.g., hematopoietic stem-cell transplant recipients)
 - **Health-care workers**
 - **School-age children**
 - **All persons who want to reduce the risk of becoming ill with influenza or of transmitting it to others**

B. Persons who SHOULD NOT RECEIVE LAIV

- Persons <2 years or ≥50 years of age;*
- 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;*
- Children aged 2-4 years whose parents or caregivers report that a health-care provider has told them during the preceding 12 months that their child had wheezing or asthma, or whose medical record indicates a wheezing episode has occurred during the preceding 12 months;*
- Persons with known or suspected immunodeficiency diseases or receiving immunosuppressive therapies (e.g. HIV, malignancy, leukemia, lymphoma, aglobulinemia, and thymic abnormalities);*
- Children or adolescents receiving aspirin or salicylates (because of the association of Reye syndrome with wild-type influenza virus infection);
- Persons with a history of Guillain–Barré Syndrome;**
- Pregnant women*;
- 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;*
- Persons with a history of hypersensitivity, including anaphylaxis, to any of the components of LAIV or to eggs; or
- 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.* and
- Residents of nursing homes and other chronic-care facilities.*

* These persons should receive inactivated influenza vaccine.

** These persons could receive inactivated influenza vaccine if their health care provider recommended that the benefits outweigh the risks.

VI. CONTRAINDICATIONS:

- A. Individuals with a history of Guillain-Barré syndrome.
- B. Persons with a history of severe (anaphylactic) allergy to egg gentamicin, gelatin or arginine, or with life-threatening reactions to previous influenza vaccinations.¹
- C. Concomitant aspirin therapy in children and adolescents (2-17 years of age).²
- D. Asthma (TIV is approved for persons with asthma or wheezing)
- E. Recurrent wheezing in children <5 years of age.

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.

FluMist® is not licensed for children ≤24 months of age. MMWR July 2009, Pg 20

¹FluMist® package insert, July 2009, sect. 4.1

²FluMist® package insert, July 2009, sect. 4.2

VII. PRECAUTIONS

- A. Administration of LAIV should be deferred for persons with a moderate or severe acute illness, with or without fever.
- B. 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.
- C. If clinical judgment indicates that nasal congestion might impede vaccine delivery to nasopharyngeal mucosa, deferral of administration should be considered until illness resolved.

VIII. SIDE EFFECTS AND ADVERSE REACTIONS:

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

EVENT	FluMist® Group %	Placebo Group %
Runny Nose	44	27
Headache	40	38
Sore Throat	28	17
Tiredness/weakness	26	22
Muscle Aches	17	15
Cough	14	11
Chills	9	6
Nasal Congestion	9	2
Sinusitis	4	2

Source: FluMist® Intranasal Spray July 2009 Formula package insert (Section 14.2, Table 5)

IX. OTHER CONSIDERATIONS

A. Efficacy: 85% efficacious among 15 – 49 year olds.

B. Use with Influenza Antiviral Medications

Since the concurrent use of LAIV with antiviral compounds that are active against influenza A and B has not been evaluated, it is not advisable to administer LAIV until 48 hours after the cessation of antiviral therapy.

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. 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 aged ≥50 years.

E. Health-care workers or hospital visitors who have received LAIV should refrain from contact with severely immunosuppressed patients for 7 days after receipt of vaccine.¹

F. Timing of LAIV Administration

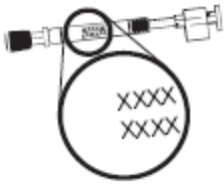
Administration of LAIV is not subject to tiered timing recommendations because it is not approved for use among populations at high risk. Providers should begin vaccinating with LAIV as soon as vaccine supplies are available.

G. Common Adverse reactions occurring in 10% or more of individuals receiving LAIV and at a rate at least 5% higher than in those receiving placebo: runny nose or nasal congestion in recipients of all ages, fever more than 100°F in children 2 to 6 years, and sore throat in adults.

¹ CDC. MMWR July 2009. Available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr58e0724a1.htm>


X: APPLICATION PROCEDURE:

1




Check expiration date.
Product must be used before the date on sprayer label.

2




Remove rubber tip protector. Do not remove dose-divider clip at the other end of the sprayer.

3




With the patient in an upright position, place the tip just inside the nostril to ensure FluMist is delivered into the nose.

4




With a single motion, depress plunger **as rapidly as possible** until the dose-divider clip prevents you from going further.

5



Pinch and remove the dose-divider clip from plunger.

6



Place the tip just inside the other nostril and with a single motion, depress plunger **as rapidly as possible** to deliver remaining vaccine.



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

XI. 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: <http://vaers.hhs.gov>. In addition, a copy of the completed VAERS form should be sent to the patient's primary provider, per ORS 855-041-0510.

XII. REFERENCES:

1. *Epidemiology and Prevention of Vaccine-Preventable Diseases* ("Pink Book"). Atkinson W, Hamborsky J, Wolfe S, eds. 11th ed. Washington, DC: Public Health Foundation, 2009 135–156. Available at <http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/flu-508.pdf>

2. CDC. Prevention and control of influenza: recommendations of the Advisory Committee on Immunization Practices (ACIP), 2008. MMWR 2008; 57(RR-7). Available at www.cdc.gov/mmwr/pdf/rr/rr5707.pdf.
3. CDC. Prevention and control of seasonal influenza with vaccines: recommendations of the Advisory Committee on Immunization Practices (ACIP), 2009. MMWR 2009; 58. Available at <http://www.cdc.gov/mmwr/pdf/rr/rr58e0724.pdf>
4. MedImmune Vaccines, Inc. 2009 FluMist® package insert. Available at <http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM123743.pdf>

For more information or to clarify any part of the above order, consult with the vaccine recipient's primary health care provider, a consulting physician, or contact Oregon State Public Health Division Immunization Program at (971) 673-0300.

Electronic copy of this protocol available at:
<http://www.oregon.gov/dhs/ph/imm/provider/pharmpro.shtml>.
To request this material in an alternate format (e.g., Braille),
Please call (971) 673-0300.