

**OREGON STATE PUBLIC HEALTH DIVISION, DHS
IMMUNIZATION PROGRAM**

**LIVE ATTENUATED INFLUENZA VACCINE (LAIV)
FLUMIST®**

2007-2008 Influenza Season updates:

- LAIV has been changed from a frozen to a refrigerated formulation this season.
- Age range newly licensed to cover all healthy 2–49 year olds.
- The total dose volume for each vaccine administered changed from .5 ml to .2 ml.
- All children ≥ 6 months but < 9 years of age who have not previously received any influenza vaccine should receive 2 doses of vaccine the first year they are vaccinated. The 2 doses should be separated by ≥ 4 weeks (whether LAIV or TIV).
- All children ≥ 6 months but < 9 years of age who receive only 1 dose in their 1st year of influenza vaccine should receive 2 doses the following year; then a single annual dose thereafter.
- All persons, including school-aged children, 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.
 - 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 administered ≥ 4 weeks apart.

Signature

Health Officer or Medical Provider

Date

October 5, 2007

II. LICENSED LIVE ATTENUATED INFLUENZA VACCINE 2007–2008

Product Name	Vaccine Components	Acceptable Age Range	Thimerosal
FluMist® ¹ (MedImmune)	A/Wisconsin 67/2005 (H3N2)-like A/Solomon Islands/3/2006 (H1N1), and B/Malaysia/2506/2004- like antigens	2–49 years	NONE
¹ A live, trivalent, intranasally administered vaccine that replicates in the mucosa of the nasopharynx, inducing protective immunity against viruses included in the vaccine.			

III. 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 or 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;*
- 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.

IV. VACCINE SCHEDULE FOR LAIV

Age Group	Vaccination Status	Dosage Schedule¹
Healthy children ages 2–8 years ²	Not previously vaccinated with any influenza vaccine	2 doses (0.2 ml each dose) ³ , separated by at least 4 weeks for initial season ^{4,5}
	Received only 1 dose in initial season	2 doses (0.2 ml each dose) ³ separated by at least 4 weeks in 2 nd season ^{4,5}
	Received only 1 dose in each of first two years of being vaccinated	1 annual dose during and after 3 rd year of being vaccinated
Healthy children and adults ages 9–49 years	Any	1 dose (0.2 ml) per season

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

² FluMist® use in children <24 months has been associated with increased risk of hospitalization and wheezing in clinical trials.

³ Administer as 0.1 ml per nostril

⁴ The minimum interval between the 1st and 2nd dose is 4 weeks.

⁵ These two doses do not have to match; live or inactivated influenza can be used for either dose. Regardless of whether inactivated (TIV) flu vaccine or live (LAIV) flu vaccine is used first, the second vaccine dose should be given ≥ 4 weeks later.

V. VACCINE STORAGE AND HANDLING

- The new formulation of LAIV (distributed after August 2007) 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.

Source: CDC. MMWR 2007; 56(RR-6):16.

VI. CONTRAINDICATIONS

- A. Individuals with a history of Guillain- Barré syndrome.
- B. Persons with a history of severe (anaphylactic) allergy to egg, egg proteins, gentamicin, gelatin or arginine.
- C. Concomitant aspirin therapy in children and adolescents
- D. Asthma
- 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 ≥24 months of age.

VII. PRECAUTIONS

- A. Administration of LAIV should be deferred for persons with a moderate or severe acute illness.
- B. Caution should be exercised if LAIV is administered to nursing mothers, 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 condition resolved.

VIII. SIDE EFFECTS AND ADVERSE REACTIONS

Summary of solicited events in <u>children 2–6 years of age</u> within 10 days of dose #1 (study MI-CP111)		
EVENT	FluMist® (refrigerated) N= 2170 %	Active Control (injectable TIV) N=2165 %
Runny Nose/ Nasal Congestion	51	42
Decreased Appetite	13	12
Irritability	12	11
Decreased Activity (Lethargy)	7	6
Sore Throat	5	6
Headache	3	3
Muscle Aches	2	2
Chills	2	2
Fever		
100–101°F Oral	6	4
101–102°F Oral	4	3
Sneezing	2	1

Source: FluMist® Intranasal Spray 2007–2008 Formula package insert (Table 2)

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 2007–2008 Formula package insert (Section 6.1)

IX. OTHER CONSIDERATIONS

A. Efficacy: One trial which studied children 60–71 months 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.

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.

C. Shedding Vaccine virus:

Nasopharyngeal secretions or swabs collected from vaccinees may test positive for influenza virus for up to three weeks after immunization.

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. Healthcare workers or hospital visitors who have received LAIV should refrain from contact with severely immunosuppressed patients (e.g., hematopoietic stem-cell transplant recipients) 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. The optimal time to vaccinate is in October and November, but providers can 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.

¹CDC. MMWR 2005; 54(RR-8):18. Available at: www.cdc.gov/mmwr/pdf/rr/rr5408.pdf.

X. ADVERSE EVENTS REPORTING:

Adverse events following immunization must be reported by public providers to the Oregon State Public Health Immunization Program, DHS, using a Vaccine Adverse Events Reporting System form (VAERS), according to state guidelines. Private providers report all adverse events directly to VAERS. VAERS phone number: (800)– 822-7967, and the website address is: www.vaers.org.

XI. REFERENCES:

1. *Epidemiology and Prevention of Vaccine-Preventable Diseases* (“Pink Book”). Atkinson W, Hamborsky J, Wolfe S, eds. 10th ed. Washington, DC: Public Health Foundation, 2007 235–55. Available at <http://www.cdc.gov/vaccines/pubs/pinkbook/default.htm>
2. CDC. Prevention and control of influenza. MMWR 2007; 56(RR-6). Available at: <http://www.cdc.gov/mmwr/PDF/rr/rr5606.pdf>
3. Using live, attenuated influenza vaccine for prevention and control of influenza. MMWR 2003; 52(RR-13). Available at <http://www.cdc.gov/mmwr/PDF/rr/rr5213.pdf>
4. MedImmune Vaccines, Inc. 2007–2008 FluMist® package insert. Available at http://www.medimmune.com/pdf/products/flumist_pi.pdf

For more information or to clarify any part of the above order, consult with your health officer, or contact the Oregon State Public Health Division Immunization Program at (971)–673-0300.

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