IMMUNIZATION PROTOCOL FOR PHARMACISTS

LIVE ATTENUATED INFLUENZA VACCINE (LAIV)

FLUMIST®

2008-2009 Influenza Season updates based on ACIP recommendations issued in the August 8, 2008 issue of MMWR.

- Annual vaccination for all children aged 6 months through 18 years is recommended.*
- Highlighting previous recommendation that all persons, including school-aged children, who want to reduce the risk of influenza disease or transmitting it to others, should be vaccinated.

* If feasible, routine vaccination for children age 5 years through 18 years should begin in 2008 when the vaccine for the 2008-2009 influenza season becomes available.

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 given ≥4 weeks apart.

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Pharmacist signature Date

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

August 2008

II. LICENSED LIVE ATTENUATED INFLUENZA VACCINE 2008–2009

Product Name	II. Vaccine Components	Acceptable Age Range	Thimerosal
FluMist® [1] (MedImmune)	**A/Brisbane/ 59/2007 (H1N1)-like A/Brisbane/10/2007 (H3N2)-like, and B/Florida/4/2006-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. VACCINE SCHEDULE FOR LAIV:

Age Group	Dosage Schedule[1]
Healthy adolescents and adults15 – 49 years	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. RECOMMENDATIONS FOR USE

A. <u>Vaccination</u> with LAIV <u>is indicated</u> 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 <u>SHOULD NOT RECEIVE LAIV</u>

- 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 preceeding 12 months that their child had wheezing or asthma, or whose medical record indicates a wheezing episode has occurred during the preceeding 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.

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 administerd, the sprayer should be disposed of in a sharps or biohazard container.

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

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

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.

C. Concurrent aspirin therapy in children and adolescents

D. Asthma

E. Recurrent wheezing in children <5 years of age in the preceding 12 months

VII. PRECAUTIONS

A. Administration of LAIV should be postponed until after the acute phase of a severe or moderate 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 illness resolved.

VIII. SIDE EFFECTS AND ADVERSE REACTIONS:

Summary of solicited adverse events occurring in at least 1% of FluMist recipients 18–49 years

Side Effects	**Frequency**
Runny nose/nasal congestion	44%
Headache	40%
Sore throat	28%
Tiredness & weakness	26%
Muscle aches	17%
Cough	14%

Serious adverse events among healthy adults age 15–49 years occurred at a rate of < 1 %.

Adapted from 9/07 FluMist® package insert at:
http://www.medimmune.com/pdf/products/flumist_pi.pdf

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. (2007 FluMist® pkg insert)

C. Shedding Vaccine virus

Nasopharyngeal secretions or swabs collected from vaccinees may test positive for influenza virus for up to three weeks post 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. 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. The optimal time to vaccinate is in October and November, but providers can begin vaccinating with LAIV as soon as vaccine supplies are available

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[1]CDC. 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 to the Vaccine Adverse Events Reporting System (VAERS) at 1-800-822-7967. Forms and procedures can be fund 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.

XI. REFERENCES:

1. *Epidemiology and Prevention of Vaccine-Preventable Diseases,* ("Pink Book"). Atkinson W, Hamborsky J, Wolfe S, eds. eds. 10th ed. Washington, DC: Public Health Foundation, 2008 235–55. Available at http://www.cdc.gov/vaccines/pubs/pinkbook/default.htm
2. CDC. Prevention and control of influenza: receommendations 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. MedImmune Vaccines, Inc. 2008–2009 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 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.