

OREGON IMMUNIZATION PROTOCOL FOR PHARMACISTS

LIVE ATTENUATED INFLUENZA A (H1N1) 2009 MONOVALENT VACCINE

Update as of 11/03/09

- Although CDC recommends that the two doses of 2009 H1N1 vaccine be separated by ≥ 28 days (4 weeks) in the same series, 21 days is acceptable.
- Although CDC does not recommend that seasonal LAIV and H1N1 LAIV be administered at the same visit because of concerns about reduced immunogenicity for one vaccine, if both types of LAIV are inadvertently administered at the same visit, neither vaccine needs to be repeated.
- While vaccine is limited administration is to be targeted to:
 - Healthy persons 2–24 years of age
 - Healthy persons 25–49 years of age who live with or care for infants ≤ 6 months, or are health care or emergency medical personnel.

As more vaccine becomes available, other healthy 25–49 year olds should also 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. See Application instructions, page 9.
5. Administer the dosage of influenza vaccine recommended for the recipient's age intranasally.

For nasal use only. Do not administer parenterally. This live vaccine can be administered simultaneously with other inactivated vaccines. However, two live vaccines administered on the same day should be given ≥ 4 weeks apart. Administering both the live attenuated seasonal and the live attenuated H1N1 influenza vaccines at the same visit is NOT recommended because of concerns about competition between the 2 vaccine viruses. If you have only live vaccines for both seasonal and H1N1 influenza available, you should separate the doses of the live vaccines by at least 4 weeks. However, if both types of LAIV are inadvertently administered at the same visit, neither vaccine needs to be repeated.

Source: www.cdc.gov/H1N1flu/vaccination/top10_faq.htm.

Pharmacist Signature

Date

11/03/09

II. LICENSED Monovalent LIVE ATTENUATED H1N1 INFLUENZA VACCINE

Product Name	Vaccine Components	Acceptable Age Range	Thimerosal
MedImmune Live Intranasal Spray	10 FFU influenza A (H1N1) (A/California/7/2009) ¹	2–49 years	NONE
<p>¹A live, monovalent, intranasally administered vaccine that replicates in the mucosa of the nasopharynx, inducing protective immunity against viruses included in the vaccine. FFU: “focus-forming units.”</p>			

III. RECOMMENDATIONS FOR USE of Live Influenza A (H1N1):

A. Vaccination with H1N1/LAIV is indicated for healthy, non-pregnant persons 2–49 years of age who do not have one of the following disqualifiers:

Persons who **SHOULD NOT RECEIVE H1N1/LAIV**

- Persons <2 years or ≥50 years of age;¹
- 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;¹
- Persons with asthma, reactive airway disease, chronic disorders of the pulmonary or cardiovascular systems; metabolic diseases such as diabetes, renal dysfunction and hemoglobinopathies;¹
- Persons with known or suspected immunodeficiency diseases (e.g. HIV infection, malignancy, leukemia, lymphoma, aglobulinemia, and thymic abnormalities) or who are receiving immunosuppressive therapies;¹
- 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;²
- Pregnant women;¹
- 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
- Persons with a history of hypersensitivity, including anaphylaxis, to any of the components of LAIV or to eggs; or
- Household members of and HCWs who have close contact with severely immunosuppressed persons (e.g., patients with hematopoietic stem cell transplants) requiring care in a protected environment¹;

¹These persons should receive inactivated influenza vaccine.

²These persons could receive inactivated influenza vaccine if their health care provider recommended that the benefits outweighed the risks.

IV. H1N1 VACCINE SCHEDULE FOR Monovalent LAIV¹

Age Group	Doses	Dose
Healthy adolescents and adults 15-49	1 dose	0.2 ml per dose ²

¹ Contains live, attenuated influenza A/California/7/2009.

² Each 0.2 ml dose is administered as 0.1 ml per nostril.

Source: www.cdc.gov/H1N1flu/vaccination/top10_faq.htm

V. VACCINE STORAGE AND HANDLING

- The new formulation of H1N1 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 in a sharps or biohazard container.

Source: MedImmune package insert 09 September 2009 from

<http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM182406.pdf>

VI. CONTRAINDICATIONS

- A. History of Guillain-Barré syndrome.
- B. 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 H1N1 LAIV should be deferred for persons with a moderate or severe acute illness.
- B. If clinical judgment indicates that nasal congestion might impede vaccine delivery to nasopharyngeal mucosa, deferral of administration should be considered until condition resolved.
- C. Do not administer H1N1 LAIV to individuals with severe asthma or active wheezing as these individuals have not been studied in clinical trials.

VIII. MAIV SIDE EFFECTS AND ADVERSE REACTIONS BASED ON STUDIES CONDUCTED WITH FluMist®

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 <u>adults 18–49 years</u> 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 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.
- 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:**
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.
- H. Breastfeeding mothers** can get either live or inactivated H1N1 influenza vaccine. Preventing the flu in mothers can reduce the chance that the infant will get the flu. This is important for infants <6 months old since they are too young to be vaccinated.

¹ CDC. MMWR 2008; 57(RR-7):28. Available at: www.cdc.gov/mmwr/pdf/rr/rr5707.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: <http://vaers.hhs.gov>.

XI. REFERENCES:

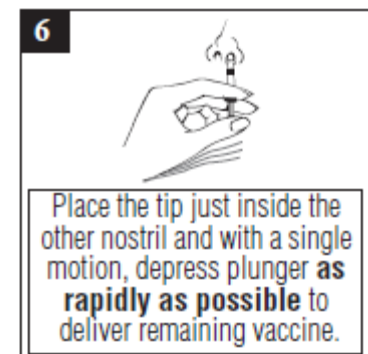
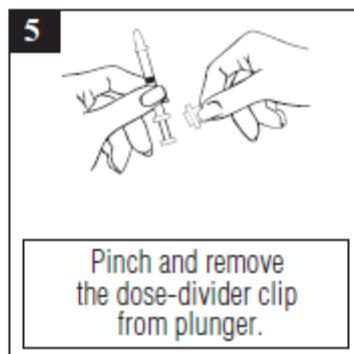
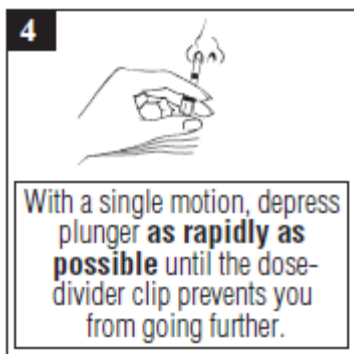
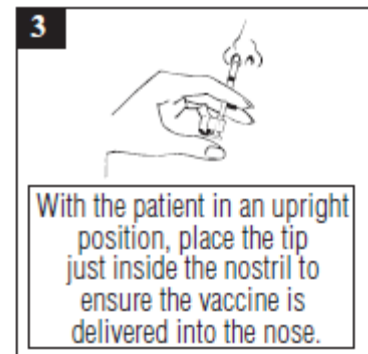
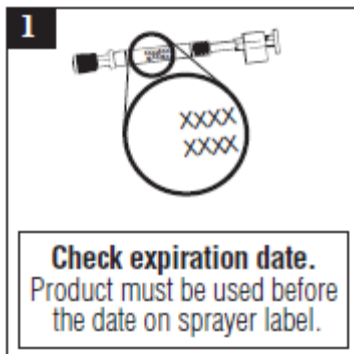
1. CDC. Frequently asked questions on use of influenza A (H1N1) 2009 monovalent vaccines (2009 H1N1 vaccines): Practical considerations for immunization programs and providers. From: www.cdc.gov/H1N1flu/vaccination/top10_faq.htm.
2. *Epidemiology and Prevention of Vaccine-Preventable Diseases* (“Pink Book”). Atkinson W, Hamborsky J, Wolfe S, eds. 10th ed. Washington, DC: Public Health Foundation, 2008 235–55. Available at <http://www.cdc.gov/vaccines/pubs/pinkbook/default.htm>.
3. 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.
4. Using live, attenuated influenza vaccine for prevention and control of influenza. MMWR 2003; 52(RR-13). Available at www.cdc.gov/mmwr/PDF/rr/rr5213.pdf.
5. MedImmune package insert 09 September 2009, from: http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/Approved_Products/UCM182406.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.

**To download a copy, visit our website at
<http://oregon.gov/dhs/ph/imm/provider/stdgordr.shtml>
To request this material in an alternate format (e.g., Braille),
Please call 971-673-0300**

Administration Instructions

Each sprayer contains a single dose; approximately one-half of the contents should be administered into each nostril. Refer to the administration diagram (Figure 1) for step-by-step administration instructions. Once the vaccine has been administered, the sprayer should be disposed of according to the standard procedures for medical waste (e.g., sharps container or biohazard container).



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