Protocol for Live Attenuated Influenza Vaccine (FluMist® Quadrivalent)

1. What's New

A. The 2023-2024 season U.S. flu vaccines will contain an updated influenza A(H1N1) pdm09 component:[1]
   a. A/Victoria/4897/2022 (H1N1) pdm09-like virus for egg-based vaccines and
   b. A/Wisconsin/67/2022 (H1N1) pdm09-like virus for cell-based or recombinant vaccines.

B. All persons ages ≥6 months with egg allergy should receive influenza vaccine. Any influenza vaccine (egg based or non-egg based) that is otherwise appropriate for the recipient's age and health status can be used.[2]

2. Immunization Protocol[1,2]

A. Administer a 0.2-mL dose, Intranasally, to persons 7-49 years of age without contraindications. The number of doses indicated varies by age and vaccine history. See appendix for administration instructions.

B. May be given concomitantly with all ACIP-recommended child and adult vaccinations. Live vaccines not given on the same day must be separated by at least 28 days.

3. Vaccine Schedule

Live Attenuated Influenza Vaccine (LAIV) Schedule for the 2023-2024 Flu Season[1] Dose and Route – 0.2-mL, Intranasal		
Dose	**Acceptable Age Range**	**Minimum Acceptable Spacing**
1	7-49 years	
2	7-8 years	28 days, see flowchart in recommendations for use for determining 1 or 2 doses

4. Licensed Vaccines

Product Name	Presentation	FDA Approved Age Range	Thimerosal
FluMist® Quadrivalent[1]	0.2 mL pre-filled intranasal sprayer	2-49 years	None

5. Recommendations for Use[1, 2]

A. All persons 7–49 years of age without contraindications.

B. Children <9 years of age receiving flu vaccine for the first time need 2 doses. Doses should be separated by 28 days. Children who receive the first dose at age 8 years and turn 9 during flu season should still receive the 2nd dose in the same season.

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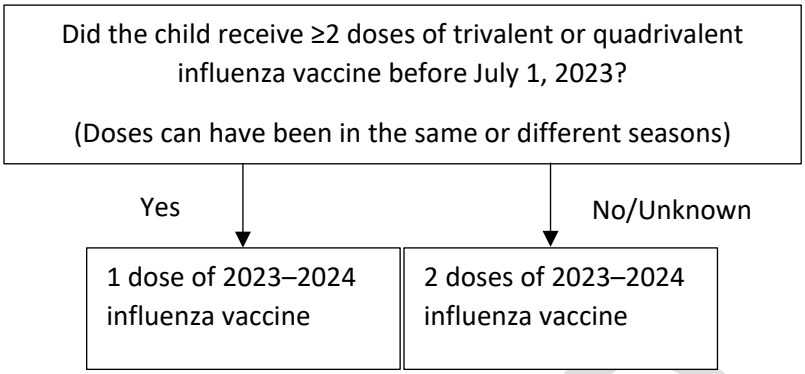

C. Do not use LAIV in pregnant women.
D. Persons with history of egg allergy may receive any vaccine (egg-based or non-egg-based) that is otherwise appropriate for their age and health status. Beginning with the 2023-2024 season, additional safety measures are no longer recommended for flu vaccination of people who are allergic to eggs beyond those recommended for receipt of any vaccine, regardless of the severity of previous reaction to egg. All vaccines should be administered in settings in which personnel and equipment needed for rapid recognition and treatment of allergic reactions are available, such as a pharmacy.
E. Providers should offer flu vaccination to unvaccinated persons by the end of October, if possible. Vaccination should continue to be offered if unexpired vaccine is available.

6. Contraindications[1,2]

A. Severe allergic reaction (e.g., anaphylaxis) to a previous dose or to any vaccine component. However, ACIP makes an exception for an allergy to egg (see Persons with a History of Egg Allergy above).
   a. Most flu shots and the nasal spray flu vaccine are manufactured using egg-based technology. Because of this, they contain a small amount of egg proteins, such as ovalbumin. However, studies that have examined the use of both the nasal spray vaccine and flu shots in egg-allergic and non-egg-allergic patients indicate that severe allergic reactions in people with egg allergies are unlikely.

Vaccine	Contains
FluMist® Quadrivalent[1]	Monosodium glutamate, hydrolyzed porcine gelatin, arginine, sucrose, dibasic potassium phosphate, monobasic potassium phosphate, ovalbumin, gentamicin sulfate, ethylenediaminetetraacetic acid (EDTA).

B. Concomitant aspirin or salicylate-containing therapy in children and adolescents through age 17 years of age.
C. Children and adults who are immunocompromised due to any cause, including but not limited to immunosuppression caused by medications, congenital or acquired immunodeficiency states, HIV infection, anatomic asplenia, or functional asplenia (such as that due to sickle cell anemia).

D. Close contacts and caregivers of severely immunosuppressed persons who require a protected environment.
E. Pregnancy.
F. Persons with active communication between the cerebrospinal fluid (CSF) and the oropharynx, nasopharynx, nose, or ear or any other cranial CSF leak.
G. Persons with cochlear implants, because of the potential for CSF leak that might exist for a period after implantation (providers might consider consultation with a specialist concerning the risk for persistent CSF leak if an age-appropriate inactivated or recombinant vaccine cannot be used).
H. Receipt of influenza antiviral medication within the previous 48 hours for oseltamivir and zanamivir, previous 5 days for peramivir, and previous 17 days for baloxavir. The interval between influenza antiviral receipt and LAIV4 during which interference might potentially occur might be further prolonged in the presence of medical conditions that delay medication clearance (e.g., renal insufficiency).

Antiviral Drug	Potential Interference Interval
Baloxavir	17 days before- 2 weeks after
Peramivir	5 days before- 2 weeks after
Oseltamivir or Zanamivir	48 hours before- 2 weeks after

7. Warnings and Precautions[1,2]

A. Guillain-Barré Syndrome (GBS). If GBS has occurred within 6 weeks of any prior influenza vaccination, the decision to give FluMist® Quadrivalent should be based on careful consideration of the potential benefits and potential risks.
B. Asthma in persons aged ≥5 years.
C. Other underlying medical condition (other than those listed under contraindications) that might predispose to complications after wild-type influenza virus infection (e.g., chronic pulmonary, cardiovascular [except isolated hypertension], renal, hepatic, neurologic, hematologic, or metabolic disorders [including diabetes mellitus]).

8. Other Considerations[1,2,4]

A. Lactation: FluMist® Quadrivalent is not absorbed systemically by the mother following intranasal administration and breastfeeding is not expected to result in exposure of the child to the vaccine components.

9. Side Effects and Adverse Reactions[1]

Adverse Event	Frequency
Nasal Congestion	Up to 58%
Low grade fever, headache, sore throat	5-20%
Allergic reactions	Less than 1%

10. Storage and Handling[1]

A. Store medications according to OAR 855-041-1036.

B. All clinics and pharmacies enrolled with the Vaccines for Children (VFC) Program must immediately report any storage and handling deviations to the Oregon Immunization Program at 971-673-4VFC (4823).

Vaccine	Temp	Storage Issues	Notes
FluMist® Quadrivalent[1]	2°to 8°C (36° to 46° F)	Do not freeze. Keep enclosed in outer carton to protect from light.	A single temperature excursion up to 25°C (77°F) for 12 hours has been shown to have no adverse impact on the vaccine. No further excursions are allowed. Once administered or expired, the sprayer should be disposed of according to the standard procedures for medical waste (e.g., sharps container or biohazard container)

11. References

1. FluMist® Quadrivalent 2023–2024. [Package insert]. Available at https://www.fda.gov/media/160349/download. Accessed 21 July 2023.
2. Centers for Disease Control and Prevention. (2023, June 29). 2023-2024 CDC Flu Vaccination Recommendations Adopted. Centers for Disease Control and Prevention. Accessed 23 July 2023. https://www.cdc.gov/flu/spotlights/2022-2023/flu-vaccination-recommendations-adopted.htm
3. Centers for Disease Control and Prevention. (2022, August 25). *Prevention and control of seasonal influenza with vaccines: Recommendations of the Advisory Committee on Immunization Practices - United States, 2022–23 influenza season*. Centers for Disease Control and Prevention. https://www.cdc.gov/mmwr/volumes/71/rr/rr7101a1.htm?s_cid=rr7101a1_w
4. Centers for Disease Control and Prevention. (2022, September 20). Influenza vaccination: A summary for clinicians. Centers for Disease Control and Prevention. Accessed 23 July 2023. https://www.cdc.gov/flu/professionals/vaccination/vax-summary.htm

12. Appendix

A. N/A