Interim Immunization Protocol

Live Attenuated Influenza Vaccine (LAIV)	
Last Reviewed	28 July 2023
Last Revised	28 July 2023
This order expires	30 June 2024

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1. What's new

Live attenuated influenza vaccine for use in the 2023–2024 influenza season[2] (Northern Hemisphere) contains the following:

Quadrivalent:

- A/Victoria/4897/2022 (H1N1)pdm09-like virus (updated);
- A/Darwin/9/2021 (H3N2)-like virus;
- B/Austria/1359417/2021-like virus (B/Victoria lineage);
- B/Phuket/3073/2013 (Yamagata lineage)-like virus

Based on recommendations from the Advisory Committee on Immunization

Practices:[3]

A. For most adults, influenza vaccination during July and August should be avoided unless there is concern that later vaccination might not be possible.
B. Children who require 2 doses should receive the first dose as soon as vaccine is available to allow the second dose to be received by the end of October.
C. Children who require 1 dose may receive vaccine as soon as vaccine is available.

See separate order for inactivated (IIV) and recombinant (RIV) influenza vaccines.

2. Oregon model immunization protocol:

A. Check the ALERT Immunization Information System (IIS) to determine whether the patient needs this vaccine and any other vaccines. This is recommended, but not required, for influenza administration only.

B. Screen clients for contraindications and precautions.

C. Provide a current Vaccine Information Statement (VIS), answering any questions.

D. Record all required data elements in the client's permanent health record.

E. Give FluMist® Intranasally.

F. May be given with all ACIP-recommended child and adult vaccinations.

Health Officer Signature Date

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3. Vaccine schedule

Vaccine Schedule: Live Attenuated Influenza Vaccine (LAIV) Schedule for the 2023–2024 Flu Season [3]			
Age Group	**Dose**	**No. of Doses**	**Route**
2–8 years	0.2 mL: 0.1 mL per nostril	1 or 2*	Intranasal
9–49 years	0.2 mL: 0.1 mL per nostril	1	Intranasal

* Minimum spacing 28 days

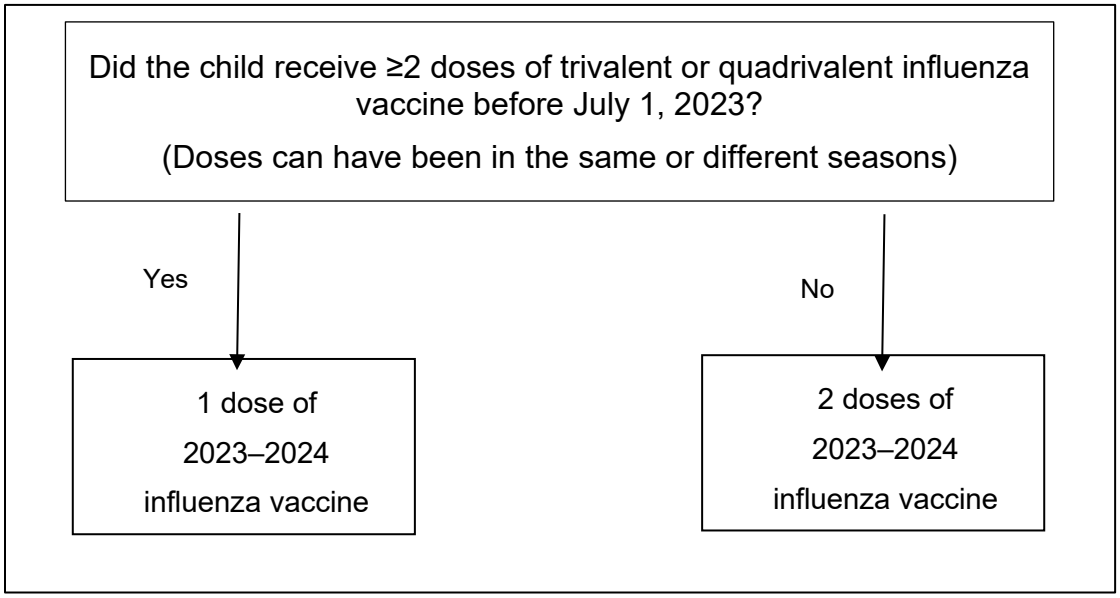
4. Licensed influenza vaccine

Trade Name	Presentation	Acceptable Age Range	Thimerosal
FluMist®[1] Quadrivalent	0.2-mL pre-filled intranasal sprayer	2–49 years	None

5. Recommendations for use[3]

A. All persons 2–49 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.



C. Do not use LAIV in pregnant women.

D. Egg allergy, regardless of severity, in no longer considered a contraindication to receipt of influenza vaccine. Persons with egg allergy should receive influenza vaccine unless another contraindication exists. Any age-appropriate influenza vaccine (egg-based or non-egg-based) may be used. No additional safety measures beyond those necessary for any vaccination are needed.[3]

E. Providers should offer flu vaccination to unvaccinated persons by the end of October, if possible. Vaccination should continue to be offered as long as unexpired vaccine is available.[3]

6. Contraindications:

A. A severe allergic reaction (requiring epinephrine or emergency medical attention) to a previous dose of influenza vaccine.

Vaccine	Potential allergen(s)
FluMist®[1] Quadrivalent	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 aged 2 through 4 years who have received a diagnosis of asthma or 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.[3]

D. Children and adults who are immunocompromised due to any cause (including immunosuppression caused by medications, congenital or acquired immunodeficiency states, anatomic or functional asplenia or by HIV infection).

E. Close contacts and caregivers of severely immunosuppressed persons who require a protected environment.

F. Pregnancy.

G. Persons with cerebrospinal fluid leak or cochlear implants.

H. Receipt of influenza antiviral medication (see §8F below).[3]

7. Warnings and precautions:

A. Persons with moderate or severe illnesses with or without fever should delay immunization until illness has resolved. However, mild acute illness (with or without fever) does not contraindicate use of influenza vaccine.[5]

B. Persons with a history of Guillain-Barré Syndrome (GBS) within 6 weeks following influenza vaccination have a substantially greater likelihood of subsequently developing GBS than persons without such a history. Whether influenza vaccination might be causally associated with this risk for recurrence is not known. Consult with an individual's health care provider and consider avoiding a subsequent influenza vaccination in persons known to have developed GBS within **6 weeks** of a previous influenza vaccination. Experts believe that the benefits of influenza vaccination justify yearly vaccination for most persons who have a history of GBS and who are at risk for severe complications from influenza.[3]

C. Asthma in persons ≥5 years of age.[3]

D. Other underlying medical conditions that might predispose to complications after wild-type influenza infection (e.g., chronic pulmonary, cardiovascular [except isolated hypertension], renal, hepatic, neurologic, hematologic, or metabolic disorders including diabetes mellitus).[3]

8. Other considerations:

A. **Immunocompromising conditions:** The Infectious Diseases Society of America (IDSA) has published detailed guidance for the selection and timing of vaccines for persons with specific immunocompromising conditions, including congenital immune disorders, stem cell and solid organ transplants, anatomic and functional asplenia, and therapeutic drug-induced immunosuppression, as well as for persons with cochlear implants or other conditions leading to persistent cerebrospinal fluid–oropharyngeal communication. Because of the dearth of safety data for LAIV4 in most of these populations and the availability of alternative vaccines, IIV or RIV4 should be used instead of LAIV4 for persons affected by these conditions.[3]

B. **Adverse events**: Appropriate medical treatment and supervision must be available to manage possible anaphylactic reactions following administration. Epinephrine hydrochloride solution (1:1,000) and other appropriate agents and equipment must be available for immediate use in case of anaphylactic or acute hypersensitivity reaction.[5]

C. **Lactation:** FluMist is not absorbed systemically by the mother following intranasal administration and breastfeeding is not expected to result in

exposure of the child to FluMist.[1]

D. **Immunity**: Adults have antibody protection against influenza virus about 2 weeks after vaccination.[3]

E. **Influenza Antiviral Medications**: May reduce the effectiveness of FluMist® Quadrivalent. If antiviral agents and FluMist® are given concomitantly, revaccination should be considered.[1]

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

F. **Coadministration with other live virus vaccines**: LAIV may be given concomitantly with other live virus vaccines. Live vaccines not given on the same day must be separated by at least 28 days.

G. **Shedding Vaccine Virus**: Nasopharyngeal secretions or swabs collected from vaccines 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. Persons who care for severely immunosuppressed persons who require a protective environment should not receive FluMist® given the theoretical risk of transmission of the live, attenuated vaccine virus.[1]

H. **Administering LAIV**: Severely immunosuppressed persons should not administer LAIV. However, other persons at high risk from 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 ≥50 years of age.[3]

9. Side effects and adverse reactions[1]

Live attenuated influenza vaccine

Nasal congestion	Up to 58% of recipients
Low grade fever, headache, sore throat	5%–20%
Allergic reactions	Less than 1%

10. Storage and handling

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®[1] Quadrivalent	2°–8°C	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. Adverse events reporting

Report suspected adverse events to the Vaccine Adverse Events Reporting System (VAERS) online at https://vaers.hhs.gov/reportevent.html.

VAERS Reporting Table: https://vaers.hhs.gov/resources/infoproviders.html

Event and interval from vaccination
A. Anaphylaxis or anaphylactic shock within 7 days; B. Vasovagal syncope within 7 days; C. Guillain-Barré Syndrome within 42 days; D. Any acute complication or sequelae (including death) of above events; E. Any event described in the manufacturer's package insert as a contraindication to additional doses of vaccine.

12. References

1. FluMist® Quadrivalent 2023–2024 package insert. Available at:www.fda.gov/media/160349/download. Accessed 27 Jul 2023.
2. Food and Drug Administration. Influenza Vaccine for the 2023–2024 Season. Available at: www.fda.gov/vaccines-blood-biologics/lot-release/influenza-vaccine-2023-2024-season. Accessed 27 Jul 2023.
3. Grohskopf LA. Influenza Vaccine Safety Update and Proposed Recommendations for the 2023–24 Influenza Season. June 21, 2023. Available at: www.cdc.gov/vaccines/acip/meetings/downloads/slides-2023-06-21-23/03-influenza-grohskopf-508.pdf. Accessed 27 Jul 2023.
4. American Academy of Pediatrics Committee on Infectious Diseases. Recommendations for prevention and control of influenza in children, 2022–2023. Pediatrics 2022;150(4): e2022059274. Available at:https://publications.aap.org/pediatrics/article/150/4/e2022059274/189385/Recommendations-for-Prevention-and-Control-of. Accessed 28 Jul 2023.
5. Kroger AT, Bahta L, Long S, Sanchez P. General Best Practice Guidelines for Immunization. Best Practices Guidance of the Advisory Committee on Immunization Practices (ACIP). Available at: www.cdc.gov/vaccines/hcp/acip-recs/general-recs/downloads/general-recs.pdf. Accessed 27 Jul 2023.
6. Centers for Disease Control and Prevention. Vaccine Excipient Summary. November 2021. Available at: www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/b/excipient-table-2.pdf. Accessed 27 Jul 2023.

To request this material in an alternative format (e.g., Braille) or to clarify any part of the above order, contact the Oregon Health Authority Immunization Program at 971-673-0300 and 711 for TTY. For other questions, consult with the vaccine recipient's primary health care provider or a consulting physician.

Electronic copy of this immunization protocol is available at: immunization protocols