Interim Immunization Protocol

Inactivated and Recombinant Influenza Vaccines Inactivated Influenza Vaccine (Afluria®, Fluarix®, FluLaval®, Fluzone®), Recombinant Influenza Vaccine (Flublok®), cell cultured Influenza Vaccine (Flucelvax®), adjuvanted Inactivated Influenza Vaccine (Fluad®)	
Last Reviewed	28 July 2023
Last Revised	28 July 2023
Expiration Date	30 June 2024

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1. What's new

All egg-based inactivated influenza vaccines (See separate protocol for LAIV4 [FluMist®]) for use in the 2023–2024 influenza season[9] (Northern Hemisphere) contain the following:

- 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-like virus (B/Yamagata lineage)

All cell-culture-based inactivated or recombinant-based influenza vaccines for use in the 2023–2024 influenza season[9] (Northern Hemisphere) contain the following:

- A/Wisconsin/67/2022 (H1N1)pdm09-like virus (updated)
- A/Darwin/6/2021(H3N2)-like virus (updated)
- B/Austria/1359417/2021-like virus (B/Victoria lineage)-like (updated)
- B/Phuket/3073/2013-like virus (B/Yamagata lineage)

Based on recommendations from the Advisory Committee on Immunization Practices:[10]

A. Vaccination in July and August may be considered for pregnant persons during the third trimester, as vaccination of pregnant persons has been shown to reduce risk of influenza illness in their infants during the first months of life.
B. For most adults (particularly adults aged ≥65 years) and for pregnant persons in the first or second trimester, influenza vaccination during July and August should be avoided, unless there is concern that later vaccination might not be possible.
C. 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.
D. Children who require 1 dose may receive vaccine as soon as vaccine is available.

2. Oregon 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. Verify needle length for IM injection into the vastus lateralis or deltoid muscle.

F. To avoid shoulder injury related to vaccine administration, make sure staff who administer vaccines can recognize the anatomic landmarks for identifying the deltoid muscle and use proper intramuscular administration technique.[12]

G. Give the appropriate dose of influenza vaccine for the patient's age and the formulation being used intramuscularly (IM).

H. May be given with all ACIP-recommended child and adult vaccinations, including COVID-19 vaccines.

I. When co-administering COVID-19 vaccines and adjuvanted or high-dose influenza vaccines that might be more likely to cause a local reaction, different limbs should be used, if possible.[10]

I. Ask client to remain seated on the premises for 15 minutes after vaccination to decrease the risk of injury should they faint.

Health Officer Signature Date

Health Officer Signature Date

3. Vaccine schedule

Vaccine Schedule: Inactivated Influenza Vaccine (IIV) and Recombinant Influenza Vaccine (RIV) Schedule for the 2023–2024 Flu Season [1-8]			
Age Group	**Dose**	**No. of Doses**	**Route**
6–35 months	0.25 mL or 0.5 mL	1 or 2*	Intramuscular
3–8 years	0.5 mL	1 or 2*	Intramuscular
≥9 years	0.5 mL	1	Intramuscular

*Minimum spacing 28 days

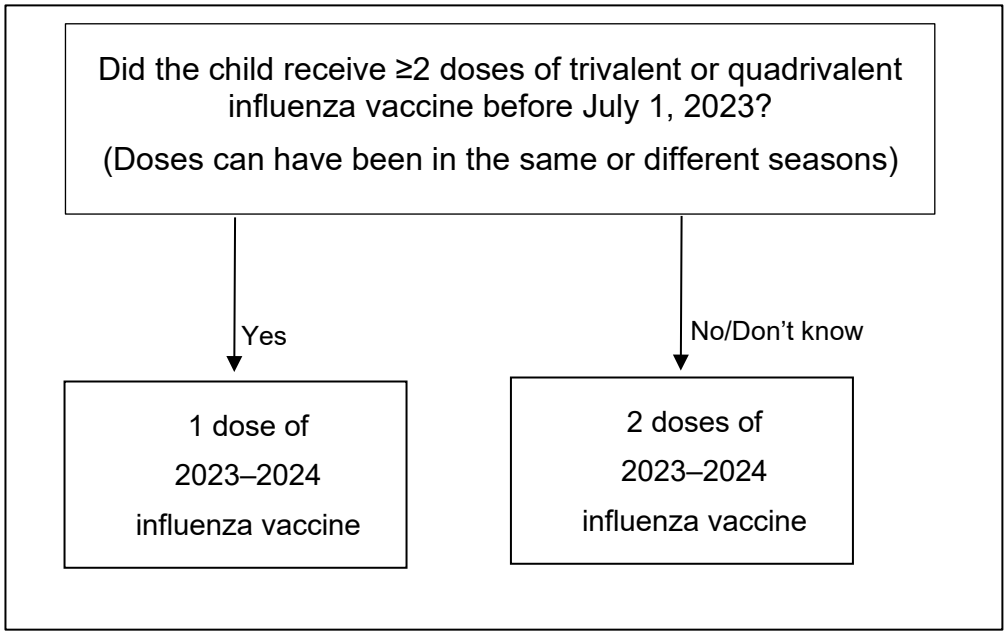
4. Licensed influenza vaccine

Trade Name	Presentation	Acceptable Age Range	Thimerosal (µg Hg/0.5 mL)
Afluria Quadrivalent[1]	0.5-mL pre-filled syringes	≥3 years	
	5-mL multi-dose vial	≥6 months	24.5
Fluad Quadrivalent[2]	0.5-mL pre-filled syringes	≥65 years	None
Fluarix Quadrivalent[3]	0.5-mL pre-filled syringes	≥6 months	None
Flublok Quadrivalent[4]	0.5-mL pre-filled syringes	≥18 years	None
Flucelvax Quadrivalent[5]	0.5-mL pre-filled syringes	≥6 months	None
	5-mL multi-dose vial		25
FluLaval Quadrivalent[6]	0.5-mL pre-filled syringes	≥6 months	None
Fluzone High Dose Quadrivalent[7]	0.7-mL pre-filled syringes	≥65 years	None
Fluzone Quadrivalent[8]	0.5-mL pre-filled syringes	≥6 months	None
	0.5-mL single dose vial		None
	5-mL multi-dose vial		25

5. Recommendations for use

A. All persons ≥6 months of age who do not have contraindications. Children <9 years of age receiving flu vaccine for the first time need 2 doses, separated by at

least 28 days. Children who receive the first dose at age 8 years and turn 9 during flu season should receive the 2nd dose in the same season.[10]



B. Pregnant women may be vaccinated with inactivated influenza vaccine during any trimester.[10]

C. 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.[10]

D. Vaccination in July or August should generally be avoided, even if vaccine is available, unless there is serious concern that later vaccination might not be possible. Exceptions should be made for pregnant people in their third trimester and children needing 2 doses in this influenza season.[10]

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.[10]

6. Contraindications:

A. A history of severe allergic reaction to a previous dose of any influenza vaccine or any component of the vaccine, excluding egg protein. For persons with severe egg allergy, refer to Recommendations for use, section C. [10]

Vaccine	Potential allergens[14]
Afluria	Sodium chloride, monobasic sodium phosphate, dibasic sodium phosphate, monobasic potassium phosphate, potassium chloride, calcium chloride, sodium taurodeoxycholate, ovalbumin, sucrose, neomycin sulfate, polymyxin B, beta-propiolactone, thimerosal (multidose vials)
Fluad Quadrivalent	Squalene, polysorbate 80, sorbitan trioleate, sodium citrate dihydrate, citric acid monohydrate, neomycin, kanamycin, barium, hydrocortisone, egg proteins (≤1.0 mcg), cetyltrimethylammonium bromide (CTAB), formaldehyde
Fluarix	Octoxynol-10 (TRITON X-100), α-tocopheryl hydrogen succinate, polysorbate 80 (Tween 80), hydrocortisone, gentamicin sulfate, ovalbumin, formaldehyde, sodium deoxycholate, sodium phosphate-buffered isotonic sodium chloride
Flublok	Sodium chloride, monobasic sodium phosphate, dibasic sodium phosphate, polysorbate 20 (Tween 20), baculovirus and *Spodoptera frugiperda* cell proteins, baculovirus and cellular DNA, Triton X-100
Flucelvax Quadrivalent	Madin-Darby Canine Kidney (MDCK) cell protein, phosphate buffered saline, protein other than HA, MDCK cell DNA, polysorbate 80, cetyltrimethlyammonium bromide, and βpropiolactone, Thimerosal (multi-dose vials)
FluLaval	Ovalbumin, formaldehyde, sodium deoxycholate, α-tocopheryl hydrogen succinate, polysorbate 80, thimerosal (multi-dose vials), phosphate-buffered saline solution.
Fluzone High Dose and Fluzone	formaldehyde, egg protein, octylphenol ethoxylate (Triton X-100), sodium phosphate-buffered isotonic sodium chloride solution, thimerosal (multi-dose vials)

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.[10]

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.[10]

C. Individuals with bleeding disorders are at risk of hematoma following IM injection.[12]

D. History of severe allergic reaction to a previous dose of an egg-based influenza vaccine is a precaution to both Flublok and Flucelvax.[10]

8. Other considerations:

A. **Adverse events**: Appropriate medical treatment and supervision must be available to manage possible anaphylactic reactions following administration. Epinephrine hydrochloride solution (1 mg/mL) and other appropriate agents and equipment must be available for immediate use in case of anaphylactic or acute hypersensitivity reaction.[12]

B. **Immunity**: Adults have antibody protection against influenza virus about 2 weeks after vaccination.[10]

C. **Foreign travelers:** Travelers who want to reduce the risk for influenza infection should consider influenza vaccination, preferably at least 2 weeks before departure. In particular, persons who live in the United States and are at higher risk for complications of influenza and who were not vaccinated with influenza vaccine during the previous Northern Hemisphere fall or winter should consider receiving influenza vaccine before departure if they plan to travel to the tropics, with organized tourist groups or on cruise ships, or to the Southern Hemisphere during the Southern Hemisphere influenza season (April–September).[10]

D. **Lactation**: Inactivated and recombinant influenza vaccines are safe for breastfeeding mothers and their infants.[12]

E. **Immunocompromised:** Persons with immunocompromising conditions should receive an age-appropriate IIV or RIV4. Immune response to influenza vaccines might be blunted in persons with some conditions, such as persons with congenital immune deficiencies, persons receiving cancer chemotherapy, and persons receiving immunosuppressive medications.[13]

F. **Novel adjuvants:** Because of the limited data on the safety of simultaneous administration of two or more vaccines containing novel adjuvants and the availability of nonadjuvanted influenza vaccine options, selection of a nonadjuvanted influenza vaccine may be considered in situations in which influenza vaccine and another vaccine containing a novel adjuvant are to be administered concomitantly. However, vaccination should not be delayed if a specific product is not available.

G. **Antiviral agents** for influenza: consult CDC's most recent recommendations for guidance on clinical management of influenza using antiviral agents. Available at: www.cdc.gov/flu/professionals/antivirals/summary-clinicians.htm

H. **Hematopoietic Stem Cell Transplant (HSCT) recipients:** Influenza vaccine should be administered beginning at least 6 months after HSCT and annually thereafter for the life of the patient. A dose of vaccine can be given as soon as 4 months after the transplant, but a second dose should be considered in this situation. Do not use live influenza vaccine in this population.[13]

I. **Ocular and Respiratory Symptoms after Vaccination: Oculo-respiratory syndrome** (ORS) The cause of ORS has not been established; however, studies suggest that the reaction is not IgE-mediated. When assessing whether a patient who experienced ocular and respiratory symptoms should be revaccinated, providers should determine whether signs and symptoms concerning for IgE-mediated immediate hypersensitivity are present. Health care providers who are unsure whether symptoms reported represent an IgE-mediated hypersensitivity immune response should seek advice from an allergist/immunologist. See www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/flu.html.

9. Side effects and adverse reactions[1-8]

Inactivated and recombinant influenza vaccines	
Local reactions: soreness, erythema, induration at injection site	up to 60%
Fever, malaise, chills	10%-15%
Severe Allergic reactions	1.3 per million doses

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	Discard	Latex	Temp	Storage Issues
Afluria[1]	Discard opened multi-dose vials 28 days after opening.	No	2◦– 8◦C	Store in original package to protect from light. Store multi-dose vials in recommended conditions.
Fluad Quadrivalent[2]				
Fluarix[3]				
Flublok[4]				
Flucelvax[5]	Use opened multi-dose vials through the expiration date			
FluLaval[6]	Discard opened multi-dose vials 28 days after opening			
Fluzone High Dose and Fluzone[7,8]	Use opened multi-dose vials through the expiration date			

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. Shoulder injury related to vaccine administration within 7 days; C. Vasovagal syncope within 7 days; D. Guillain-Barré Syndrome within 42 days; E. Any acute complication or sequelae (including death) of above events; F. Any event described in the manufacturer's package insert as a contraindication to additional doses of vaccine.

12. References

1. Afluria® 2023–2024 package insert. Available at: www.fda.gov/media/117022/download. Accessed 28 Jul 2023.
2. Fluad® Quadrivalent 2023 –-2024 package insert. Available at: www.fda.gov/media/135432/download. Accessed 28 Jul 2023.
3. Fluarix Quadrivalent® 2023–2024 package insert. Available at: www.fda.gov/media/79278/download. Accessed 28 Jul 2023.
4. Flublok® RIV4 2023–2024 package insert. Available at: www.fda.gov/media/123144/download. Accessed 28 Jul 2023.
5. Flucelvax® IIV4 2023–2024 package insert. Available at: www.fda.gov/media/115862/download. Accessed 28 Jul 2023.
6. FluLaval® Quadrivalent 2023–2024 package insert. Available at: www.fda.gov/media/115785/download. Accessed 28 Jul 2023.
7. Fluzone® High-dose Quadrivalent 2023–2024 package insert. Available at: www.fda.gov/media/139731/download. Accessed 28 Jul 2023.
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9. Food and Drug Administration. Influenza Vaccine for the 2023-2024 Season. Available at: https://www.fda.gov/vaccines-blood-biologics/lot-release/influenza-vaccine-2023-2024-season. Accessed 28 Jul 2023.
10. 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 28 Jul 2023.
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12. 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 28 Jul 2023.

13. Rubin LG, Levin MJ, Ljungman P, et al. 2013 IDSA Clinical practice guideline for vaccination of the immunocompromised host. Clin Infect Dis 2014; 58:e44–100. Available at: https://academic.oup.com/cid/article/58/3/e44/336537. Accessed 28 Jul 2023.

14. Centers for Disease Control and Prevention. Vaccine Excipient Summary, November 1, 2021. Available at: www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/b/excipient-table-2.pdf. Accessed 28 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 protocol is available at: model immunization protocols.