

Immunization Protocol (Interim)

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[®])	
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1. What’s new

At the June 2025 meeting, the ACIP reaffirmed the recommendation for a routine annual influenza vaccination for persons 6 months and older who do not have contraindications.⁹ ACIP withdrew the recommendation for multidose vials of influenza vaccine that contain thimerosal. All doses for the 2025-2026 season will be trivalent influenza vaccine in single dose vials or pre-filled syringes.

All egg-based inactivated influenza vaccines (See separate protocol for LAIV3 [FluMist[®]]) for use in the 2025-2026 influenza season⁹ (Northern Hemisphere) contain the following:

- A/Victoria/4897/2022 (H1N1)pdm09-like virus
- A/Croatia/Y10136RV/2023 (H3N2)-like virus (updated)
- B/Austria/1359417/2021 (B/Victoria lineage)-like virus

All cell-culture-based inactivated or recombinant-based influenza vaccines for use in the 2025-2026 influenza season⁹ (Northern Hemisphere) contain the following:

- A/Wisconsin/67/2022 (H1N1)pdm09-like virus
- A/District of Columbia/27/2023 (H3N2)-like virus (updated)
- B/Austria/1359417/2021 (B/Victoria lineage)-like virus

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.
- 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.
- I. Ask client to remain seated on the premises for 15 minutes after vaccination to decrease the risk of injury should they faint.
- J. Appropriate medical treatment used to manage immediate allergic reactions must be immediately available in the event an anaphylactic reaction occurs following administration.

Health Officer Signature

Date

Health Officer Signature

Date

3. Vaccine schedule¹⁻⁸

Vaccine Schedule: Inactivated Influenza Vaccine (IIV) and Recombinant Influenza Vaccine (RIV) Schedule for the 2025–2026 Flu Season

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

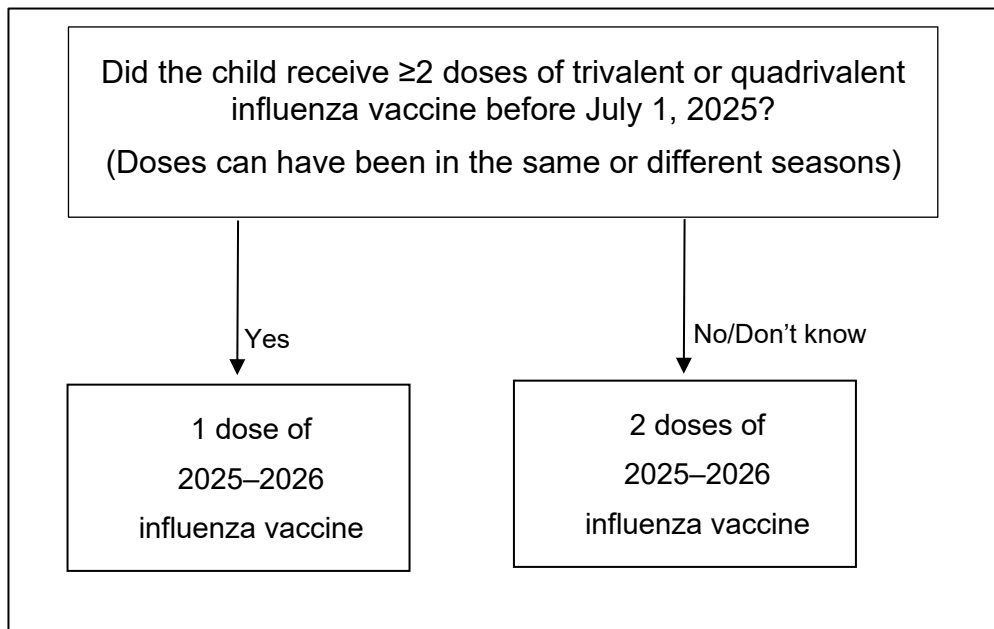
*Minimum spacing 28 days

4. Licensed influenza vaccine¹⁻⁸

Trade Name	Presentation	Acceptable Age Range
Afluria Trivalent	0.5-mL pre-filled syringes	≥3 years
	0.25 mL pre-filled syringes for children 6–35 months of age	≥6 months
Fluad Trivalent	0.5-mL pre-filled syringes	≥65 years
Fluarix Trivalent	0.5-mL pre-filled syringes	≥6 months
Flublok Trivalent	0.5-mL pre-filled syringes	≥9 years
Flucelvax Trivalent	0.5-mL pre-filled syringes	≥6 months
FluLaval Trivalent	0.5-mL pre-filled syringes	≥6 months
Fluzone High Dose Trivalent	0.5-mL pre-filled syringes	≥65 years
Fluzone Trivalent	0.5-mL pre-filled syringes	≥6 months

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.⁹



- B. All persons should receive an age-appropriate influenza vaccine, with the following exception: solid organ transplant recipients aged 18–64 years on immunosuppressive medication regimens may receive either high-dose inactivated or adjuvanted inactivated vaccine as acceptable options (without a preference over other age-appropriate IIVs or RIV3).¹⁰
- C. Pregnant women may be vaccinated with inactivated influenza vaccine during any trimester.¹⁰
- D. Egg allergy, regardless of severity, is 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
- E. 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
- F. 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 D.¹⁰

Vaccine	Potential allergens
Afluria ¹	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
Fluad, Adjuvanted ²	Squalene, polysorbate 80, sorbitan trioleate, sodium citrate dihydrate, citric acid monohydrate, neomycin, kanamycin, hydrocortisone, egg proteins (≤ 0.4 mcg), cetyltrimethylammonium bromide (CTAB), formaldehyde
Fluarix ³	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 ⁴	Sodium chloride, monobasic sodium phosphate, dibasic sodium phosphate, polysorbate 20 (Tween 20), baculovirus and <i>Spodoptera frugiperda</i> cell proteins, baculovirus and cellular DNA, Triton X-100
Flucelvax ⁵	Madin-Darby Canine Kidney (MDCK) cell protein, phosphate buffered saline, protein other than HA, MDCK cell DNA, polysorbate 80, cetyltrimethylammonium bromide, and β propiolactone
FluLaval ⁶	Ovalbumin, formaldehyde, sodium deoxycholate, α -tocopheryl hydrogen succinate, polysorbate 80, thimerosal (multi-dose vials), phosphate-buffered saline solution.
Fluzone High Dose ⁷ and Fluzone ⁸	formaldehyde, egg protein, octylphenol ethoxylate (Triton X-100), sodium phosphate-buffered isotonic sodium chloride solution

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.

8. Other considerations:

- A. **Immunity:** Adults have antibody protection against influenza virus about 2 weeks after vaccination.¹⁰
- B. **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
- C. **Lactation:** Inactivated and recombinant influenza vaccines are safe for breastfeeding mothers and their infants.¹⁰
- D. **Immunocompromised:** Persons with immunocompromising conditions should receive an age-appropriate IIV or RIV, with the exception of solid organ transplant recipients (See Recommendations for Use).¹¹

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.¹¹
- E. **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.¹⁰

- F. **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, and a second dose should be considered in this situation. Do not use live influenza vaccine in this population.¹¹

9. Side effects and adverse reactions¹⁻⁸

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	Latex	Temp	Storage Issues
Afluria ¹	No	2°– 8°C	Store in original package to protect from light. Do not freeze.
Fluad ²			
Fluarix ³			
Flublok ⁴			
Flucelvax ⁵			
FluLaval ⁶			
Fluzone High Dose and Fluzone ^{7,8}			

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[®] IIV3 2025–2026 package insert. Available at: www.fda.gov/media/81559/download. Accessed 24 Jul 2025.
2. Flud[®] aIIV3 (Adjuvanted) 2025 -2026 package insert. Available at: www.fda.gov/media/179766/download. Accessed 24 Jul 2025.
3. Fluarix[®] IIV3 2025–2026 package insert. Available at: www.fda.gov/media/84804/download. Accessed 24 Jul 2025.
4. Flublok[®] RIV3 2025–2026 package insert. Available at: www.fda.gov/media/179778/download. Accessed 24 Jul 2025.
5. Flucelvax[®] 2025–2026 package insert. Available at: www.fda.gov/media/85322/download. Accessed 24 Jul 2025.
6. FluLaval[®] ccIIV3 2025–2026 package insert. Available at: www.fda.gov/media/74537/download?attachment. Accessed 24 Jul 2025.
7. Fluzone[®] High-dose IIV3 2025–2026 package insert. Available at: www.fda.gov/media/139731/download. Accessed 24 Jul 2025.
8. Fluzone[®] IIV3 2025–2026 package insert. Available at: www.fda.gov/media/170019/download. Accessed 24 Jul 2025.

9. Dugan V. 2024-25 Influenza Season Update and Seasonal Influenza Vaccine Recommendations for the 2025-26 U.S. Influenza Season. Presentation to the Advisory Committee on Immunization Practices, June 26, 2025. Available at: <https://www.cdc.gov/acip/downloads/slides-2025-06-25-26/04-dugan-influenza-508.pdf>. Accessed 24 Jul 2025.
10. Grohskopf L, Blanton L, Ferdinands J, et al. Prevention and Control of Seasonal Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices—United States 2024–25 Influenza Season. MMWR 2024;73(No. RR-5):1–25. Available at: <https://www.cdc.gov/mmwr/volumes/73/rr/rr7305a1.htm>. Accessed 24 Jul 2025.
11. 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 24 Jul 2025.

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:

www.oregon.gov/oha/ph/preventionwellness/vaccinesimmunization/immunizationproviderresources/pages/stdgordr.aspx