

Immunizing Pharmacist Protocol

Inactivated and Recombinant Influenza Vaccines	
Inactivated Influenza Vaccine (IIV), Recombinant Influenza Vaccine (RIV), cell cultured Influenza Vaccine (ccIV), adjuvanted Inactivated Influenza Vaccine (aIIV)	
Last Reviewed	25 August 2020
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1. What’s new

- Changes from interim protocol
 - Removal of FluLaval multi-dose vial presentation
 - Updated reference for 20-21 ACIP influenza recommendations.

All egg-based inactivated influenza vaccines for use in the 2020–2021 influenza season¹⁰ (Northern Hemisphere) contain the following:

Trivalent vaccines:

- A/Guangdong-Maonan/SWL1536/2019 (H1N1)pdm09-like virus (updated)
- A/Hong Kong/2671/2019 (H3N2)-like virus (updated)
- B/Washington/02/2019 (B/Victoria lineage)-like virus (updated)

Quadrivalent:

Above strains, plus:

- B/Phuket/3073/2013-like (Yamagata lineage) virus

All cell-culture-based inactivated or recombinant-based influenza vaccines for use in the 2020–2021 influenza season¹⁰(Northern Hemisphere) contain the following:

- A/Hawaii/70/2019 (H1N1)pdm09-like virus (updated)
- A/Hong Kong/2671/2019 (H3N2)-like virus (updated)
- B/Washington/02/2019 (B/Victoria lineage)-like virus (updated)
- B/Phuket/3073/2013-like (Yamagata lineage) virus

Based on recommendations from the Advisory Committee on Immunization Practices:¹¹

- A. Routine annual influenza vaccination is recommended for all persons aged ≥ 7 years who do not have contraindications.
- B. Children aged 7 years through 8 years who require 2 doses should receive their first dose as soon as possible after vaccine becomes available, and the second dose ≥ 4 weeks later. 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. Persons with a history of egg allergy of any severity may receive any licensed, recommended, and age-appropriate influenza vaccine (See §5C below).
- D. Injectable flu must be given IM. Any dose given SQ must be repeated.
- E. For those requiring only one dose for the season, vaccination in July or August is too early, especially for older people, because of the likelihood of reduced protection against flu infection later in the flu season. September and October are good times to get vaccinated.²

See separate order for LAIV4 (FluMist®).

2. Oregon immunization model standing order:

- 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.
- 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.⁹ See appendices for additional information.
- 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.
- I. Ask client to remain seated on the premises for 15 minutes after vaccination to decrease the risk of injury should they faint.

Pharmacist Signature

Date

3. Vaccine schedule

Vaccine Schedule: Inactivated Influenza Vaccine (IIV) and Recombinant Influenza Vaccine (RIV) Schedule for the 2019–2020 Flu Season¹⁻⁹			
Age Group	Dose	No. of Doses	Route
7–8 years	0.5 mL	1 or 2*	Intramuscular
≥9 years	0.5 mL	1	Intramuscular

*Minimum spacing 28 days

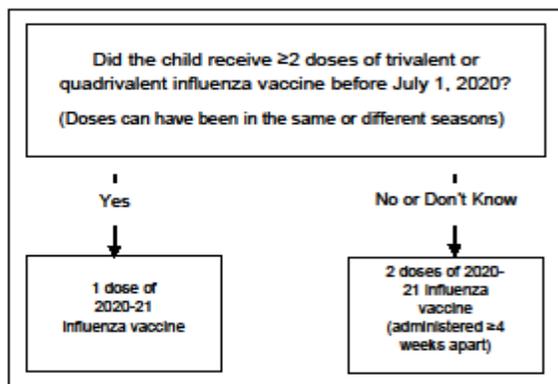
4. Licensed influenza vaccine

Trade Name	Presentation	Acceptable Age Range	Thimerosal (µg Hg/0.5 mL)
Afluria Quadrivalent ¹	0.5-mL pre-filled syringes	≥7 years	None
	5-mL multi-dose vial	≥7 years	24.5
Fluad ²	0.5-mL pre-filled syringes	≥65 years	None
Fluad Quadrivalent ³			
Fluarix Quadrivalent ⁴	0.5-mL pre-filled syringes	≥7 years	None
Flublok Quadrivalent ⁵	0.5-mL pre-filled syringes	≥18 years	None
Flucelvax Quadrivalent ⁶	0.5-mL pre-filled syringes	≥7 years	None
	5-mL multi-dose vial		25
FluLaval Quadrivalent ⁷	0.5-mL pre-filled syringes	≥7 years	None
Fluzone High Dose ⁸	0.7-mL pre-filled syringes	≥65 years	None
Fluzone Quadrivalent ⁹	0.5-mL pre-filled syringes	≥7 years	None
	0.5-mL single dose vial		None
	5-mL multi-dose vial		25

5. Recommendations for use¹¹

- A. All persons ≥7 years of age without contraindications. 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.



For children aged 8 years who need 2 doses of vaccine, both doses should be administered even if the child turns 9 years between receipt of dose 1 and dose 2.

- B. Pregnant women may be vaccinated with inactivated influenza vaccine during any trimester.
- C. Persons with a history of egg allergy of any severity **may receive** any licensed, recommended, and age-appropriate influenza vaccine. Persons with such history who receive an egg-based vaccine should be supervised by a health care provider who is able to identify and manage severe allergic reactions.
Flublok Quadrivalent⁵ and Flucelvax Quadrivalent⁶ have no egg-based ingredients.
- D. For those requiring only one dose for the season, vaccination in July or August is too early, especially for older people, because of the likelihood of reduced protection against flu infection later in the flu season. September and October are good times to get vaccinated.¹¹
- 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.

6. Contraindications:

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

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 [®] Fluad Quadrivalent [®]	Squalene, polysorbate 80, sorbitan trioleate, sodium citrate dihydrate, citric acid monohydrate, neomycin, kanamycin, barium, hydrocortisone, egg proteins, 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, cetyltrimethylammonium bromide, and β propiolactone, 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 phosphatebuffered 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.¹¹
- 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.¹¹
- C. Individuals with bleeding disorders are at risk of hematoma following IM injection.¹¹

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.¹¹
- B. **Unvaccinated children <9 years of age:** Children <9 years old receiving flu vaccine for the first time need 2 doses. Doses must 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. Children with a history of any 2 previous doses in any previous season(s) only need a single seasonal booster dose.¹¹
- C. **Immunity:** Adults have antibody protection against influenza virus about 2 weeks after vaccination.¹¹
- D. **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).¹¹

- E. **Lactation:** Inactivated and recombinant influenza vaccines are safe for breastfeeding mothers and their infants. Breastfeeding does not adversely affect the immune response.¹²
- F. **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.¹¹
- G. **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.
- H. **Antiviral agents** for influenza: consult CDC’s most recent recommendations for guidance on clinical management of influenza using antiviral agents. Available at: <https://www.cdc.gov/flu/professionals/antivirals/summary-clinicians.htm>
- I. **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
- J. **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 reactions¹⁻⁹

Inactivated and recombinant influenza vaccines	
Local reactions: soreness, erythema, induration at injection site	15%–20% of recipients

Fever, malaise, chills	uncommon
Allergic reactions	rare

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 ² and Fluad ³ Quadrivalent	Use opened multi-dose vials through the expiration date			
Fluarix ⁴				
Flublok ⁵				
Flucelvax ⁶				
FluLaval ⁷	Discard opened multi-dose vials 28 days after opening			
Fluzone High Dose and Fluzone ^{8,9}	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
<ul style="list-style-type: none"> 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[®] 2020–2021 package insert. Available at: www.fda.gov/media/117022/download. Accessed 21 Jul 2020.
2. Fludax[®]IIV3 2020–2021 package insert. Available at: www.fda.gov/media/94583/download. Accessed 21 Jul 2020.
3. Fludax[®] Quadrivalent 2020–2021 package insert. Available at: www.fda.gov/media/135432/download. Accessed 21 Jul 2020.
4. Fluarix Quadrivalent[®] 2020–2021 package insert. Available at: <https://www.fda.gov/media/79278/download>. Accessed 21 July 2020.
5. Flublok[®] RIV4 2020–2021 package insert. Available at: <https://www.fda.gov/media/123144/download>. Accessed 21 Jul 2020.
6. Flucelvax[®]IIV4 2020–2021 package insert. Available at: <https://www.fda.gov/media/115862/download>. Accessed 21 July 2020.
7. FluLaval[®] Quadrivalent 2020–2021 package insert. Available at: <https://www.fda.gov/media/115785/download> Accessed 21 July 2020.
8. Fluzone[®] High-dose Quadrivalent 2020–2021 package insert. Available at: <https://www.fda.gov/media/139731/download>. Accessed 21 July 2020.
9. Fluzone[®] Quadrivalent 2020–2021 package insert. Available at: <https://www.fda.gov/media/119856/download>. Accessed 21 July 2020.
10. Recommended composition of influenza virus vaccines for use in the 2020 - 2021 northern hemisphere influenza season, World Health Organization, available at www.who.int/influenza/vaccines/virus/recommendations/2020-21_north/en/
11. Grohskopf LA, Alyanak E, Broder KR, Blanton LH, Fry AM, Jernigan DB, Atmar RL. Prevention and control of seasonal influenza with vaccines: recommendations of the Advisory Committee on Immunization Practices—United States, 2020–21 influenza season. MMWR 2020;69(No. RR-8):1–24.

Available at: <https://www.cdc.gov/mmwr/volumes/69/rr/pdfs/rr6908a1-H.pdf>.
Accessed 25 Aug 2020.

12. AAP COMMITTEE ON INFECTIOUS DISEASES. Recommendation for prevention and control of influenza in children, 2019–2020. *Pediatrics* 2019;144(4):e20192478 Available at: <https://pediatrics.aappublications.org/content/pediatrics/early/2019/08/29/peds.2019-2478.full.pdf> Accessed 23 Sep 2019.
13. Kroger AT, Duchin J, Vázquez M. General Best Practice Guidelines for Immunization. Best Practices Guidance of the Advisory Committee on Immunization Practices (ACIP). 2017. Available at: www.cdc.gov/vaccines/hcp/acip-recs/general-recs/downloads/general-recs.pdf. Accessed 31 Aug 2018.
14. 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 31 Aug 2018.
15. Centers for Disease Control and Prevention. *Epidemiology and Prevention of Vaccine-Preventable Diseases*. Hamborsky J, Kroger A, Wolfe C, eds. 13th ed. Washington D.C. Public Health Foundation, 2015. Available at: www.cdc.gov/vaccines/pubs/pinkbook/index.html

13. Appendix- NA

None.

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 standing order is available at: [standing orders](#)