Inactivated Influenza Vaccine (IIV) Immunization Protocol

NAME AND STRENGTH OF VACCINE TO BE USED*

Age Group	Inactivated influenza vaccine (IIV) Trade Names	Dosage	Number of doses annually	Route
≥7 years	Afluria Quadrivalent, Fluarix Quadrivalent, Flucelvax Quadrivalent, FluLaval Quadrivalent, Fluzone Quadrivalent	0.5 mL	1 (some children may need 2 doses)	IM
≥ 65 years	Fluad Quadrivalent	0.5 mL	1	IM
	Fluzone High-Dose Quadrivalent	0.7 mL		

Products based on: Prevention and Control of Seasonal Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices--United States, 2021-22 Influenza Season (published 8.27.21)*

INTENDED AUDIENCE AND PATIENT POPULATION

(A) **Annual vaccination is recommended for all persons 7 years of age and older who do not have contraindications. Vaccine is especially important for these groups:**

(1) All persons ≥ 50 years of age

(2) Adults and children who have chronic pulmonary (including asthma), cardiovascular (excluding isolated hypertension), renal, hepatic, neurologic, hematologic or metabolic disorders (including diabetes mellitus)

(3) Persons who are immunocompromised due to any cause (including immunosuppression caused by medications or human immunodeficiency virus [HIV] infection)

(4) Women who are or will be pregnant during the influenza season

(5) Children and adolescents (7 through 18 years of age) who are receiving aspirin- or salicylate-containing medications and who might be at risk for experiencing Reye syndrome after influenza virus infection

(6) Residents of nursing homes and other long-term care facilities

(7) American Indians/Alaska Natives

(8) Persons who are extremely obese (body mass index [BMI] ≥40 for adults)

(9) Healthcare personnel, including all paid and unpaid persons working in healthcare settings who have the potential for exposure to patients or infectious materials.

(10) Household contacts (including children) and caregivers of children aged < 5 years and adults aged ≥50 years, particularly contacts of children aged ≤6 months

(11) Household contacts (including children) and caregivers of persons with medical conditions that put them at higher risk for severe complications from influenza

(12) Travelers, especially those at higher risk for complications of influenza, who want to reduce the risk for influenza infection should consider influenza vaccination, preferably at least 2 weeks before departure.

CONTRAINDICATIONS AND PRECAUTIONS

(A) History of severe allergic reaction (e.g., anaphylaxis) to any component of the vaccine (see product package insert for list of components) **or** to a previous dose of any influenza vaccine is a **contraindication** to receipt of vaccine.

(1) Per the Advisory Committee on Immunization Practices (ACIP): Persons with a history of egg allergy who have experienced only hives after exposure to egg should receive influenza vaccine. Any licensed, recommended influenza vaccine (i.e., any IIV4, LAIV4 or recombinant influenza vaccine) that is otherwise appropriate for the recipient's age and health status can used.

(2) Per ACIP: Persons who report having had reactions to egg involving symptoms other than hives (e.g., angioedema, respiratory distress, lightheadedness, or recurrent vomiting) or who required epinephrine or another emergency medical intervention can similarly receive any licensed, recommended influenza vaccine that is otherwise appropriate for the recipient's age and health status. The selected vaccine should be administered in an inpatient or outpatient medical setting (including, but not necessarily limited to, hospitals, clinics, health departments, and physician offices). Vaccine administration should be supervised by a healthcare provider who is able to recognize and manage severe allergic conditions.

(3) Per ACIP: History of a severe allergic reaction to a previous dose of any egg-based IIV, LAIV (live attenuated influenza vaccine) or RIV (recombinant influenza vaccine) is a precaution to use of ccIIV4 (cell culture-based inactivated influenza vaccine quadrivalent)

(B) Moderate or severe acute illness with or without fever is a general precaution for vaccination.

(C) History of Guillain-Barré syndrome (GBS) within 6 weeks of a previous dose of any type of influenza vaccine is considered to a precaution to influenza vaccination.

SIDE EFFECTS AND ADVERSE REACTIONS

(A) Local reactions at the site of injection are the most common adverse reaction. The symptoms include: soreness, erythema, and induration at the site of injection. Erythema, induration, swelling and pruritus occur more frequently with the intradermal route of administration. These symptoms are usually transient, lasting 1-2 days.

(B) Fever, chills, malaise, and myalgias are rare (<1% of vaccine recipients) and most often occur in those with no prior exposure to the viral influenza antigens. Watch for these symptoms within 6-12 hours of injection; they generally persist for 1-2 days.

(C) Immediate, hypersensitivity (presumably allergic) reactions occur rarely after influenza vaccination. Watch for hives, angioedema, allergic asthma, or systemic anaphylaxis. Persons who have a history of hives, swelling of the lips and tongue, or experienced acute respiratory distress should consult a physician for evaluation to determine if vaccination should proceed or be deferred.

ADMINISTRATION

(A) Administer **one dose** of 2021-22 inactivated influenza vaccine (IIV) to:

(1) All persons aged 9 years or older

(2) Children aged 7 years through 8 years who **have previously received ≥2 total doses** of trivalent or quadrivalent influenza vaccine ≥4 weeks apart before July 1, 2021. The 2 previous doses do not need to have been administered in the same or consecutive seasons.

(B) Administer **two doses** of 2021-22 inactivated influenza vaccine (IIV) separated by ≥ 4 weeks to:

(1) Children aged 7 years through 8 years **who have not previously received ≥2 total doses** of trivalent or quadrivalent influenza vaccine ≥4 weeks apart before July 1, 2021. Two doses are recommended even if the child turns age 9 years between receipt of dose 1 and dose 2.

(2) Children aged 7 years through 8 years whose influenza vaccination history is not known

(C) Timing of vaccine administration

(1) Vaccinations should be administered once every year.

(2) Vaccination should be offered by the end of October. Vaccination soon after vaccine becomes available can be considered for *pregnant women* in the third trimester. *Children who need 2 doses* should receive their first dose as soon as possible after vaccine becomes available to allow the second dose to be received by the end of October.

(3) For non-pregnant adults, vaccination in July and August should be avoided unless there is concern that later vaccination might not be possible.

(4) Vaccination should continue to be offered as long as influenza viruses are circulating and unexpired vaccine is available.

(5) Current guidance for the administration of COVID-19 vaccines (available at https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html) indicates that these vaccines can be administered with other vaccines, including influenza vaccines; providers should consult this page for updated information.

(D) Procedures

(1) Patient or legal guardian, or parent/legal guardian of person younger than 18 years of age, must first sign a consent form before the vaccination is administered.

(2) Provide patient/parent/legal guardian with a copy of the most current federal Vaccine Information Statement (VIS) for inactivated influenza vaccine.

(3) **For intramuscular vaccine product:** Inject 0.5 mL of vaccine **intramuscularly** into the thickest point of a relaxed **deltoid** muscle. Most patients will receive 25 gauge, 1-inch needle. For frail patients with little muscle mass, a 5/8-inch needle will be used. For patients weighing less than 130 lbs [60 kg], a 5/8-inch needle may be used for injection in the deltoid muscle only if the subcutaneous tissue is not bunched and the injection is made at a 90-degree angle. For obese patients, a 1½ - inch needle will be used. Persons aged 18-64 years may receive Afluria Quadrivalent intramuscularly via the PharmaJet Stratis Needle-Free Injection System into the deltoid muscle.

(4) Give with caution to persons on anticoagulant therapy or with bleeding tendencies. After giving the injection, apply steady pressure to the injection area.

(5) Dispose of all supplies properly.

(6) Record the date of administration, name/manufacturer/strength/dose of the immunization, lot number and expiration date of the immunization, route of administration, location of the injection site, positive identification of the person administering the vaccine, and the supervising pharmacist if a pharmacy intern administers the immunization.

(7) Monitor patients in the general vicinity of the administering pharmacist or pharmacy intern for at least **10 minutes** after giving the injection and treat accordingly.

(8) Advise patient to report any adverse reaction to their pharmacist or primary care physician.

(E) Monitoring parameters

(1) Patients who faint should be placed supine. Check their pulse and blood pressure immediately.

(2) Watch for rapidly falling blood pressure, difficulty breathing, sustained unconsciousness. Observe for adequate airway and pulse; administer CPR if needed. Have another member of the pharmacy staff call 911. Follow procedures in next section for treatment of severe allergic/anaphylactic reactions.

(3) Treat externally for shock. Keep patient warm, head low and feet elevated.

(4) Contact protocol physician as soon as possible to report the condition of the patient.

PROTOCOL FOR MANAGEMENT OF SEVERE ALLERGIC/ANAPHYLACTIC REACTIONS

(A) Pre-Vaccination Procedures
(1) Be prepared to call 911.
(2) Take a thorough history for allergies and prior adverse events before any immunization.
(3) Allow adequate physical space for fainting or collapse without injury and to lay patient flat on a hard surface in the event CPR is needed.
(4) Maintain current competency in vaccine administration and in cardiopulmonary resuscitation; observe all vaccinees for at least 10 minutes after immunization; remind vaccinees to report any adverse events to you.

(B) Supplies to Stock
(1) Epinephrine USP, 1 mg/ml (1:1000). May be in vials of solution, *Ana-Guard* syringes, or in an *Epi-Pen* (0.15 mg & 0.3 mg). At least three adult and children's doses of epinephrine will be available wherever immunizations are given.
(2) Diphenhydramine liquid and injection
(3) Blood-pressure cuff, adult size, with stethoscope

(C) Recognition of Anaphylactic Reaction
(1) Sudden onset of itching, redness, with or without hives, within several minutes of administering a medication. The symptoms may be localized or generalized.
(2) Angioedema (swelling of the lips, face, throat)
(3) Bronchospasm

(D) Emergency treatment
(1) If itching and swelling are confined to the extremity where the immunization was given, observe patient closely for a suitable period of time, watching for generalized symptoms. If none occur, go to paragraph D(8).

(2) If symptoms are generalized, activate the emergency medical system (EMS). Call 911 **and** the protocol physician for instruction. This should be done by a second person, while the immunizer treats and observes the patient.

(3) Administer epinephrine IM (refer to dosing chart). Standard dose is 0.01mg/kg up to 0.5 mg maximum in adolescents and adults. Site of administration can be the anterolateral thigh if using auto-injector, or deltoid muscle above the vaccine injection site.

(4) Administer diphenhydramine by IM injection (refer to dosing chart). DO NOT administer diphenhydramine or any other drug by mouth if the patient is not fully alert or if the patient has respiratory distress.

(5) Monitor the patient closely until EMS arrives. Perform CPR and maintain airway, if necessary. Keep patient in supine position unless they are having breathing difficulty. If breathing is difficult, patient's head may be elevated, provided blood pressure is adequate to prevent loss of consciousness. Monitor vital signs frequently.

(6) If EMS has not arrived and symptoms still persist, repeat dose of epinephrine every 10-20 minutes for up to 3 doses, depending on patient response.

(7) Record all vital signs, medications administered to the patient, including the time, dosage, response, and other relevant clinical information.

(8) Patient must be referred for medical evaluation, even if symptoms resolve completely. Symptoms may recur after epinephrine and diphenhydramine wear off, as much as 24 hours later. After the event is concluded, complete a VAERS form. Report forms may be obtained online at www.vaers.hhs.gov or by calling 1-800-822-7967.

Suggested Dosing of Epinephrine and Diphenhydramine

Age Group Dose	**Weight * in kg**	**Weight * in lbs**	**Epinephrine Dose** ** 1 mg/mL injectable (1:1000 dilution) intramuscular	**Diphenhydramine (Benadryl)** 12.5 mg/5 mL liquid 25 and 50 mg capsules or tablets 50 mg/mL injectable
1-6 mos	4-7 kg	9-15 lbs	0.05 mg (0.05 ml)	5 mg
7- 18 mos	7-11 kg	15-24 lbs	0.1 mg (0.1 ml)	10 mg
19-36 mos	11-14 kg	24-31 lbs	0.15 mg (0.15 ml)	15 mg
37-48 mos	14-17 kg	31-37 lbs	0.15 mg (0.15 ml)	20 mg
49-59 mos	17-19 kg	37-42 lbs	0.2 mg (0.2 ml)	
5-7 yrs	19-23 kg	42-51 lbs	0.2 mg (0.2 ml)	30 mg
8-10 yrs	23-35 kg	51-77 lbs	0.3 mg (0.3 ml)	
11-12 yrs	35-45 kg	77-99 lbs	0.4 mg (0.4 ml)	40 mg
13 yrs & older	45+ kg	99+ lbs	0.5 mg (0.5 ml)	50-100 mg

*Dosing by body weight is preferred

**Epinephrine can also be administered using an autoinjector available in 0.15 mg and 0.3 mg doses. Children weighing 15 to 30 kg should receive 0.15 mg if given by autoinjector.

ACCIDENTAL NEEDLE STICK

(A) Procedures

(1) Wash needle stick site with soap and water.

(2) Report the exposure to the physician on the protocol. Prompt reporting is essential because, in some cases, post-exposure treatment may be recommended and it should be started as soon as possible. **The National Clinicians' Post Exposure Prophylaxis Hotline (PEPline) has current recommendations (888.448.4911).**

(3) Discuss risks of acquiring HBV, HCV, HIV and the need for post-exposure treatment with the provider managing your exposure.

(4) Person giving the vaccination should already have received the Hepatitis B vaccine (extremely safe and effective).

(5) Follow-up testing should be available to all workers concerned about possible infection through occupational exposure.

(B) Treatment of Exposure

HCV - no treatment available

HBV - Post-exposure treatment of HBV is highly effective in preventing infection. Treat exposure as soon as possible after exposure, preferably within 24 hours and no later than 7 days after exposure. Hepatitis B vaccine and hepatitis B immune globulin (HBIG) are both approved for treatment use. If any symptoms suggesting HBV infection develop, patient should contact a physician.

HIV - Start as soon as possible, ideally within 72 hours of exposure. Benefit of treatment delayed beyond 72 hours is not defined. No medications are FDA-approved for prevention. Pharmacist will follow current HIV prevention guidelines recommended by CDC. Truvada® (emtricitabine and tenofovir disoproxil fumarate) plus Isentress® (raltegravir) OR Truvada® plus Tivicay® (dolutegravir) are recommended for 28 days with repeated testing to confirm HIV negative status.

(C) Precautions During Follow-Up

HBV – no precaution recommended

HCV – low risk, so no precautions are recommended

HIV - 6-12 weeks is when most of the signs and symptoms of infection show. Do not donate blood, semen, or organs during this time. Do not have sexual intercourse during this time, or else use a condom consistently and correctly. Women should not breast feed. HIV is transmitted through breast milk.

See page 8 for Physician Authorization

Administration of the influenza vaccine, under the direction of the physician who signed below, may be performed by the following individuals:

_____ _____ _____

_____ _____ _____

Administration of the influenza vaccine, under the direction of the physician who signed below, may be performed at the following location(s) including street address(es):

_____

_____

As the authorizing physician, I will review, on a biennial basis, the activities of the health care providers administering the vaccine under this protocol.

Date: _____
*MUST BE RENEWED WITH PHYSICIAN ON A BIENNIAL BASIS

Physician Signature: _____

Physician Name: _____

Address: _____

City: _____ State: _____ Zip:_____

Medical License #: _____

Pharmacist in Charge Name:_____

Pharmacist in Charge Signature_____

Date_____ Pharmacist in Charge License #_____

Pharmacy Name_____

Pharmacy Address_____

City_____ State_____ Zip_____

PHYSICIAN/BOARD OF HEALTH NOTIFICATION
For patients younger than 18 years of age, notify the individual's primary care physician, or if the individual has no family physician, the County Board of Health of the district in which the individual lives, within 30 days after administering the immunization; document accordingly.