Live, Intranasal Influenza Immunization Protocol

NAME AND STRENGTH OF VACCINE TO BE USED

Age Group	Product	Dosage	Number of doses annually	Route
7-49 years	**Live, attenuated influenza vaccine quadrivalent (LAIV4)** (FluMist® Quadrivalent)	0.2 mL	1 (2 doses for some children aged 7 through 8 years)	Intranasal

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) Healthy, nonpregnant persons 7 to 49 years of age

(1) **Note:** The injectable inactivated influenza vaccine is preferred over live, attenuated influenza vaccine for physicians, nurses, family members, or anyone else coming in close contact with anyone with a **severely** weakened immune system (requiring care in a protected environment, such as a bone marrow transplant unit).

CONTRAINDICATIONS AND PRECAUTIONS

(A) Contraindications

(1) History of severe allergic reaction (e.g., anaphylaxis) to any component of the vaccine (see package insert for list of components)

(a) 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 and age-appropriate influenza vaccine (i.e., any IIV, LAIV or recombinant influenza vaccine) that is otherwise appropriate for the recipient's health status may be used.

(b) Per ACIP: Persons who report having had reactions to egg involving symptoms other than hives (i.e., angioedema, respiratory distress, lightheadedness, or recurrent vomiting) or who required epinephrine or another emergency medical intervention, may similarly receive any licensed, recommended and age-appropriate influenza vaccine that is otherwise appropriate for the recipient's 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 health care provider who is able to recognize and manage severe allergic conditions.

(2) History of severe allergic reaction after a previous dose of any influenza vaccine

(3) Concomitant aspirin- or salicylate-containing therapy in children and adolescents because of the potential risk for Reye syndrome

(4) Children and adults who are immunocompromised due to any cause (including immunosuppression caused by medications, congenital or acquired immunodeficiency states, HIV infection, anatomic asplenia, or functional asplenia (e.g., due to sickle-cell anemia)

(5) Close contacts and caregivers of severely immunosuppressed persons who require a protected environment

(6) Pregnancy

(7) Persons with active communication between the cerebrospinal fluid (CSF) and the oropharynx, nasopharynx, nose, or ear or any other cranial CSF leak

(8) Persons with cochlear implants

(9) Receipt of influenza antiviral medication within the previous 48 hours for oseltamivir and zanamivir, previous 5 days for peramivir, and previous 17 days for baloxavir

(10) Under no circumstance should the live, attenuated influenza vaccine be administered parenterally

(B) Precautions

(1) Moderate or severe acute illness, with or without fever; defer if nasal congestion is present.

(2) History of Guillain-Barré syndrome (GBS) within 6 weeks after receipt of any influenza vaccine

(3) Asthma in persons aged $\geq$ 5 years

(4) Persons who have 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])

(4) Healthcare personnel and others who receive LAIV should avoid providing care for severely immunosuppressed patients requiring a protected environment for 7 days after vaccination. Hospital visitors who have received LAIV should avoid contact with severely immunocompromised patients for at 7 days after vaccination.

(5) Live, attenuated influenza vaccine may be given at the same time as other vaccines (per CDC recommendations). However, if two live vaccines (e.g., MMR or varicella) are not given on the same day, they should be given at least four weeks apart.

SIDE EFFECTS AND ADVERSE REACTIONS

(A) Cough, runny nose or nasal congestion, sore throat, headache, chills, and tiredness/weakness have been reported in some adults within seven days after the vaccine.

(B) 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. The potential exists for hypersensitivity reactions to any vaccine component.

ADMINISTRATION

(A) Administer **one dose** of 2020-21 live, attenuated influenza quadrivalent vaccine (LAIV4) to:

(1) Persons aged 9 years through 49 years

(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 two previous doses need not have been administered in the same or consecutive seasons)

(B) Administer **two doses** of 2020-21 live, attenuated influenza quadrivalent vaccine (LAIV4) separated by at least 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. 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. For non-pregnant adults, vaccination in July and August should be avoided unless there is concern that later vaccination might not be possible.

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

(4) 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 live, intranasal influenza vaccine.

(3) Administer one 0.2 mL dose; administer half of the dose (approximately 0.1 mL) from a single FluMist Quadrivalent sprayer into each nostril while the recipient is in an upright position.

(4) The used sprayer should be disposed of properly according to the standard procedures for biohazard waste products.

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

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

(7) 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 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.

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

(3) 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.

(4) 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.

(5) 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.

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

(7) 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.

SEE PAGE 7 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.

