Live, Intranasal Influenza A (H1N1) Immunization Protocol

NAME AND STRENGTH OF VACCINE TO BE USED

Age Group	Product	Dosage	Number of doses	Route
14-49 years	**Influenza A (H1N1) 2009 Monovalent Vaccine Live, Intranasal** by MedImmune	0.2 mL	1	Intranasal

INTENDED AUDIENCE AND PATIENT POPULATION

(A) Healthy persons 14-49 years of age

(1) Healthy persons 14 through 24 years of age

(2) Household contacts and caregivers for children younger than 6 months of age

(3) Healthcare and emergency medical services personnel

(4) Once vaccination programs and providers are meeting the demand for vaccine among the persons in the above initial target groups, vaccination should be expanded to all persons aged 25--49 years or as recommended by the Centers for Disease Control and Prevention (CDC).

Note: The injectable influenza vaccine is preferred over live, intranasal influenza A (H1N1) monovalent vaccine for physicians, nurses, family members, or anyone else coming **in close contact with anyone with a weakened immune system.**

CONTRAINDICATIONS AND PRECAUTIONS

(A) Contraindications

(1) Under no circumstance should the live, intranasal influenza A (H1N1) vaccine be administered parenterally

(2) Severe allergic reaction to a previous influenza vaccination

(3) Hypersensitivity to eggs or to any other component of the vaccine (see package insert for list of components)

(4) Persons with previous history of Guillain-Barré syndrome (GBS)

(5) Pregnant women

(6) Adolescents 14-18 years of age receiving aspirin or other salicylates because of the association of Reye syndrome with aspirin and wild-type influenza virus infection

(7) History of asthma, reactive airways disease or other chronic disorders of the pulmonary or cardiovascular systems; other underlying medical conditions, including such metabolic diseases as diabetes, renal dysfunction and hemoglobinopathies

(8) Individuals with known or suspected immune deficiency diseases such as combined immunodeficiency, agammaglobulinemia, and thymic abnormalities and conditions such as human immunodeficiency virus infection, malignancy, leukemia, or lymphoma

(9) Patients who may be immunosuppressed or have altered or compromised immune status as a consequence of treatment with systemic corticosteroids, alkylating drugs, antimetabolites, radiation, or other immunosuppressive therapies

(B) Precautions

(1) Vaccine recipients should avoid close contact (e.g., within the same household) with immunocompromised individuals for at least 21 days.

(2) Do not administer live, intranasal influenza A (H1N1) vaccine until 48 hours after the cessation of antiviral therapy, and antiviral agents may not be administered until two weeks after administration of live, intranasal influenza A (H1N1) vaccine unless medically indicated.

(3) For patients with moderate to severe acute illness, postpone administration until after the acute phase (at least 72 hours) of febrile and/or respiratory illness.

(4) Live, intranasal influenza A (H1N1) vaccine may be given at the same time as other vaccines, EXCEPT seasonal live attenuated influenza vaccine (per CDC recommendations). However, if two live vaccines (e.g., MMR or chickenpox) are not given on the same day, they should be given at least four weeks apart.

(5) Caution should be exercised if live, intranasal influenza A (H1N1) vaccine is administered to nursing mothers.

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 developed 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) Schedule

(1) Vaccinations should be administered one time in children ≥ 14 years of age and adults.

(2) Vaccinations should be administered as soon as the vaccines become available.

(B) 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 2009 H1N1 influenza vaccine.

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

(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/strength/dose of the immunization, lot number and expiration date of the immunization, route of administration, and 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.

(C) 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*. If an *Epi-Pen* is to be used, at least three adult *Epi-Pens* 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

SEE REVERSE SIDE FOR PHYSICIAN AUTHORIZATION

Administration of the influenza A (H1N1) vaccine, under the direction of the physician who signed below, may be performed by the following individuals (Pharmacy interns may administer immunizations for influenza to individuals 18 years of age or older):

_____ _____ _____

_____ _____ _____

Administration of the influenza A (H1N1) 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 an annual basis, the activities of the health care providers administering the vaccine under this protocol.

Date: _____
*MUST BE RENEWED WITH PHYSICIAN EVERY YEAR

Physician Signature: _____

Physician Name: _____

Address: _____

City: _____ State: _____ Zip:_____

Medical License #: _____

Pharmacist in Charge:_____

Pharmacist in Charge Signature:_____

Date:_____Pharmacist in Charge License #_____

Pharmacy Name:_____

Pharmacy Address:_____

City_____ State_____ Zip_____

PHYSICIAN/BOARD OF HEALTH NOTIFICATION
Pharmacists must report administration of influenza A (H1N1) vaccines as required by the CDC, state and/or local health departments. Also, per Ohio law: 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.