Influenza A (H1N1) Immunization Protocol

NAME AND STRENGTH OF VACCINE TO BE USED

Age Group	Influenza A (H1N1) 2009 Monovalent Vaccine	Dosage	Number of doses required	Route
≥14 years	Manufacturers: CSL, Novartis, Sanofi Pasteur	0.5 mL	1	IM
≥18 years	Manufacturers: CSL, Novartis, Sanofi Pasteur, ID Biomedical	0.5 mL	1	IM

INTENDED AUDIENCE AND PATIENT POPULATION

(A) Pregnant Women

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

(C) Healthcare and emergency medical services personnel

(D) All people from 6 months through 24 years of age

(E) Persons aged 25-64 years old who have health conditions associated with higher risk of medical complications from influenza

(1) Persons who have chronic pulmonary (including asthma), cardiovascular (except hypertension), renal, hepatic, hematologic or metabolic disorders (including diabetes mellitus)

(2) Persons who have immunosuppression (including immunosuppression caused by medications or by HIV)

(3) Persons who have any condition (e.g., cognitive dysfunction, spinal cord injuries, seizure disorders, or other neurologic/neuromuscular disorders) that can compromise respiratory function or the handling of respiratory secretions or that can increase the risk of aspiration

(F) 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 & Prevention (CDC).

(G) Once demand for vaccine among younger age groups is being met, vaccination should be expanded to all persons aged ≥65 years or as recommended by CDC.

PRECAUTIONS AND CONTRAINDICATIONS

(A) Contraindications

(1) Severe allergic reaction to a previous influenza vaccination or any vaccine component

(2) Hypersensitivity to eggs or to other components of the vaccine (see package insert)

(3) Moderate to severe acute illness (do not vaccinate until symptoms abate)

(4) A history of Guillain-Barré syndrome (GBS) within 6 weeks following a previous dose of influenza vaccine is considered to be a precaution for use of Influenza A (H1N1) 2009 Monovalent Vaccine. The decision to give the vaccine should be based on careful consideration of the potential benefits and risks.

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. 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 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. Those with documented immunoglobulin E (IgE)-mediated hypersensitivity to eggs, including those who have occupational asthma or other allergic responses should consult a physician before receiving the influenza vaccine.

ADMINISTRATION

(A) Schedule

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

(2) Vaccinations should be given as soon as vaccine becomes 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 inactivated 2009 H1N1 influenza vaccine.

(3) 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 obese patients, a 1½ -inch needle will be used.

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

(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 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

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.

(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 promptly (within hours opposed to days after exposure). If HIV infection is not prevented, early treatment of initial HIV infection may lessen the severity of symptoms and delay AIDS onset. No medications are FDA approved for prevention. Zidovudine and lamivudine plus a protease inhibitor (indinavir or nelfinavir) are recommended.

(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 7 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.