
Non-Patient Specific Order for Administering 2009 H1N1 Influenza Vaccine - Pharmacists

Purpose: To reduce morbidity and mortality from influenza virus infection by vaccinating all children and adults who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices.

Policy: Under these standing orders, a licensed pharmacist with a certificate of administration issued by the New York State (NYS) Department of Education, where allowed under state law, may vaccinate patients who meet any of the criteria below. Pharmacists must follow all pertinent NYS laws and regulations. Regulations specific to pharmacist administration of vaccines can be found at www.op.nysed.gov/part63.htm.

Procedure:

1. Unless local or state conditions and/or vaccine availability specify otherwise, identify children and adults in need of influenza A (H1N1) 2009 monovalent vaccination based on the following priority groups (group a, then b, then c):

a. Primary Target Groups

- i. Age 6 months through 24 years
- ii. Age 25 through 64 years with any of the following conditions: chronic pulmonary (including asthma), cardiovascular (excluding hypertension), renal, hepatic, cognitive, neurologic/neuromuscular, hematologic, or metabolic (e.g., diabetes) disorders; immunosuppression, including that caused by medications or HIV; long-term aspirin therapy (applies to a child or adolescent age 6 months through 18 years)
- iii. Being pregnant during the influenza season
- iv. All healthcare and emergency medical services personnel
- v. All adults, children, and teens who are household contacts or caregivers of infants younger than age 6 months.

b. All other (e.g., healthy) adults ages 25 through 64 years

c. Adults ages 65 years and older

2. *Screen all patients for contraindications and precautions to influenza vaccine:*

Contraindications:

- A severe reaction (e.g., anaphylaxis) after ingesting eggs, receiving a previous dose of influenza vaccine or being exposed to an influenza vaccine component.
- Do not give LAIV to anyone who has contact with a person who is severely immunosuppressed and requires care in a protective environment such as a bone marrow transplant unit, pregnant women; children younger than 2 years of age; children 2 years through 4 years of age who have experience wheezing within the past 12 months, based on a health care provider's statement; children or adults with any of the conditions described in 1.a.ii above; or to children or adults who received seasonal or H1N1 LAIV at any time within the preceding 4 weeks, including the date of the current visit.

Precautions:

- Moderate or severe acute illness with or without fever (until symptoms have abated).
- Taking prescription anti-influenza medications (until 48 hours after cessation of therapy).
- History of Guillain Barré syndrome.

3. *Provide all patients, or other person legally responsible when the patient is incapable of consenting to immunization administration, with a copy of the most current federal Vaccine Information Statement (VIS) before administering the immunization:* You must document in the patient's medication profile, the publication date of the VIS and the date it was given to the patient. Provide non-English speaking patients with a copy of the VIS in their native language, if available; these can be found at www.immunize.org/vis.

4. *Obtain consent for immunization:* You must inform each recipient of potential side effects and adverse reactions, orally and in writing, prior to immunization. You shall not administer the immunization unless the recipient is adequately informed and consents to the immunization. For recipients incapable of consenting to the administration of an immunization, before an immunization may be administered, either a person legally responsible for the recipient shall have given prior written consent to the immunization after having been informed in writing of potential side effects and adverse reactions, or a person legally responsible for the recipient is in attendance during the immunization and consents to the immunization after having been informed of potential side effects and adverse reactions.

5. *Advise on Adverse Events:* You must provide each patient with written instructions to call their primary care physician or seek care at the local emergency department if they have an adverse reaction to the vaccine.

6. *Administer Vaccine:* Administer injectable inactivated H1N1 vaccine intramuscularly in the vastus lateralis for infants (and toddlers lacking adequate deltoid mass) or in the deltoid muscle (for older children, and adults). Use a 22–25 g needle. Choose needle length appropriate to the person's age and body mass: infants 6 through 11 mos: 1"; 1 through 2 yrs: 1–1.3"; 3 yrs and older: 1–1.5". Give 0.25 mL for children 6–35 months and 0.5 mL for all others age 3 years and older (Note: A 5/8"

needle may be used for patients weighing less than 130 lbs (<60kg) for injection in the deltoid muscle *only* if the skin is stretched tight, subcutaneous tissue is not bunched, and the injection is made at a 90-degree angle.). Alternatively, healthy, non-pregnant persons ages 2 through 49 years may be given 0.2 mL of intranasal H1N1 LAIV; 0.1 mL is sprayed into each nostril while the patient is in an upright position. Give a second dose of H1N1 vaccine 4 weeks after the first dose to children 9 years of age and younger.

7. *Recommendations for Future Vaccines:* Notify the patient that the influenza vaccine must be taken annually. If patient is in one of the recommended groups for pneumococcal vaccine, suggest that they receive it. The recommended groups can be found at www.cdc.gov/vaccines/pubs/acip-list.htm. Notify the parents or guardians of those 9 years of age or younger to have their children return after 28 days to receive a second dose.
8. *Document each patient's vaccine administration information and follow up with the following or in the following places:*
 - a. **Patient medication profile:** Record the recipient's name, date, address of administration, administering pharmacist, immunization agent, manufacturer and lot number. If vaccine was not given, record the reason(s) for non-receipt of the vaccine (e.g., medical contraindication, patient refusal).
 - b. **Immunization Record Card:** You must provide a signed immunization record card with this information.
 - c. **Patient's primary care physician:** With the consent of the recipient or a person legally responsible when the recipient is incapable of consenting, communicate this information to the recipient's primary health care practitioner, if one exists, within one month of the administration of such immunization. Such communication may be transmitted in electronic format. In the event that a pharmacist administers influenza vaccine at a Point of Dispensing (POD) overseen or approved by the New York State Department of Health or the local health department, this requirement is waived only if the patient's information is submitted into the New York State Immunization Information System (NYSIIS) or the New York City Immunization Registry.
 - d. **New York State Department of Health (NYSDOH):**
 - Administration of the 2009 H1N1 influenza vaccine must be reported by age group, absent any individually identifiable information to the NYSDOH weekly.
 - Identifying information must be submitted to the New York State Immunization Information System (NYSIIS) or New York City Immunization Registry (CIR) if the patient is less than 18 years old. More information about NYSIIS is available at www.nyhealth.gov/prevention/immunization/information_system and CIR at www.nycwebsite.gov.
 - e. **Vaccine Adverse Event Reporting System (VAERS):** Report all adverse reactions to influenza vaccine to VAERS. Contact VAERS through www.Vaers.hhs.gov or (800) 822-7967. VAERS report forms are available at www.vaers.hhs.gov.
9. *Advise patient on importance of having a primary care provider:* More information can be found on the NYSDOH website, http://www.health.state.ny.us/prevention/immunization/having_a_medical_home.htm. This requirement is waived only when influenza vaccine is administered at a POD.
10. *Be prepared for management of a medical emergency related to the administration of vaccine:* Have a written emergency medical protocol available, as well as equipment and medications, including emergency anaphylaxis treatment agents, related syringes and needles available at the location at which immunizations will be administered.

This policy and procedure shall remain in effect for all the patients of the pharmacist(s) listed here from the effective date stated below until rescinded or until June 30, 2009.

Pharmacist Name(s) and License Number(s)

Name of Issuing Physician or Certified Nurse Practitioner: _____

License Number: _____

Signature: _____ Effective date: _____

Non-Patient Specific Order for Medical Management of Vaccine Reactions in Adult Patients

All vaccines have the potential to cause an adverse reaction. In order to minimize adverse reactions, patients should be carefully screened for precautions and contraindications before vaccine is administered. Even with careful screening, reactions may occur. These reactions can vary from trivial and inconvenient (e.g., soreness, itching) to severe and life threatening (e.g., anaphylaxis). If reactions occur, staff should be prepared with procedures for their management. The table below describes procedures to follow if various reactions occur.

Reaction	Symptoms	Management
Localized	Soreness, redness, itching, or swelling at the injection site	Apply a cold compress to the injection site. Consider giving an analgesic (pain reliever) or antipruritic (anti-itch) medication.
	Slight bleeding	Apply an adhesive compress over the injection site
	Continuous bleeding	Place thick layer of gauze pads over site and maintain direct and firm pressure; raise the bleeding injection site (e.g., arm) above the level of the patient's heart.
Psychological fright and syncope (fainting)	Fright before injection is given	Have patient sit or lie down for the vaccination
	Extreme paleness, sweating, coldness of the hands and feet, nausea, light-headedness, dizziness, weakness, or visual disturbances	Have patient lie flat or sit with head between knees for several minutes. Loosen any tight clothing and maintain an open airway. Apply cool, damp cloths to patient's face and neck.
	Fall, without loss of consciousness	Examine the patient to determine if injury is present before attempting to move the patient. Place patient flat on back with feet elevated.
	Loss of consciousness	Check the patient to determine if injury is present before attempting to move the patient. Place patient flat on back with feet elevated. Call 911 if patient does not recover immediately.
Anaphylaxis	Sudden or gradual onset of generalized itching, erythema (redness), or urticaria (hives); angioedema (swelling of the lips, face or throat); severe bronchospasm (wheezing); shortness of breath; shock; abdominal cramping; or cardiovascular collapse.	See "Emergency Medical Protocol for Management of Anaphylactic Reactions in Adults" on the next page for detailed steps to follow in treating anaphylaxis.

Emergency Medical Protocol for Management of Anaphylactic Reactions in Adults

SUPPLIES NEEDED

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| <ul style="list-style-type: none"> <input type="checkbox"/> Aqueous epinephrine 1:1000 (i.e., 1 mg/mL) dilution, in ampoules, vials of solution, or prefilled syringes, including epinephrine autoinjectors (e.g., EpiPen). If EpiPens are stocked, at least three EpiPens (0.30 mg) should be available <input type="checkbox"/> Diphenhydramine (Benadryl) injectable (50mg/mL solution) and 25 mg or 50 mg capsules or tablets and syrup (12.5 mg/5mL suspension) <input type="checkbox"/> Syringes: 1-3 cc, 22-25g, 1", 1.5", and 2" needles for epinephrine and diphenhydramine (Benadryl) <input type="checkbox"/> Wristwatch with second hand | <ul style="list-style-type: none"> <input type="checkbox"/> Adult Airways (small, medium and large) <input type="checkbox"/> Sphygmomanometer (adult and extra-large cuffs) and stethoscope <input type="checkbox"/> Adult size pocket mask with one-way valve <input type="checkbox"/> Alcohol swabs <input type="checkbox"/> Tourniquet <input type="checkbox"/> Tongue Depressors <input type="checkbox"/> Flashlight with extra batteries (for examination of the mouth and throat) <input type="checkbox"/> Cell phone or access to an on-site phone |
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Treatment in Adults

1. If itching and swelling are confined to the injection site where the vaccination was given, observe patient closely for the development of generalized symptoms.
2. If symptoms are generalized, activate the emergency medical system (EMS; e.g., call 911) and notify the on-call physician. This should be done while a second person assesses the airway, breathing, circulation and level of consciousness of the patient.
3. Administer aqueous epinephrine 1:1000 dilution intramuscularly, 0.01 mL/kg/dose (adult dose ranges from 0.3mL to 0.5mL, with maximum single dose of 0.5mL).
4. In addition, for systemic anaphylaxis, administer diphenhydramine either orally or by intramuscular injection; the standard dose is 1-2 mg/kg, up to 100mg maximum single dose.
5. Monitor the patient closely until EMS arrives. Perform cardiopulmonary resuscitation (CPR), if necessary, and maintain airway. Keep patient in supine position (flat on back) unless he or she is having breathing difficulty. If breathing is difficult, patient's head may be elevated, provided blood pressure is adequate to prevent loss of consciousness. If blood pressure is low, elevate legs. Monitor blood pressure and pulse every 5 minutes.
6. If EMS has not arrived and symptoms are still present, repeat dose of epinephrine every 10-20 minutes for up to 3 doses, depending on patient's response.
7. Record all vital signs, medications administered to the patient, including the time, dosage, response, and the name of the medical personnel who administered the medication, and other relevant clinical information.
8. Notify the patient's primary care physician.
9. *Document each patient's vaccine administration information and follow up in the following places:*
 - a. **Patient medication profile:** Record the recipient's name, date, address of administration, administering pharmacist, anaphylaxis treatment agent, manufacturer and lot number. A copy of this standing order and protocol shall also be maintained in the patient medication profile for patients who receive the anaphylaxis treatment agent. In the event that a patient medication profile is not required, record this information on a separate form retained by the pharmacist who administered the anaphylaxis treatment agent.
 - b. **Local emergency medical system or provider of equivalent follow-up care and the patient's primary care physician (PCP):** Report the name of the agent used for anaphylaxis, when it was administered, the dosage strength, and route of administration.

Sources: 1. American Academy of Pediatrics. Passive Immunization. In: Pickering LK, ed. Red Book: 2006 Report of the Committee on Infectious Diseases. 27ed. Elk Grove Village, IL: American Academic of Pediatrics; 2006: 64-66
2. American Pharmacists Association, Grabenstein JD, *Pharmacy-Based Immunization Delivery*, 2002
3. *Got Your Shots? A Providers Guide to Immunizations in Minnesota*, Second Edition, Minnesota Department of Health, 2001:80-82

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License Number: _____
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