
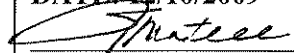


<b>COOK COUNTY DEPARTMENT OF PUBLIC HEALTH POLICY AND PROCEDURE MANUAL</b>		
<b>POLICY TITLE:</b> Guidelines for the Administration of Inactivated Influenza A (H1N1) Influenza Vaccine in CCDPH Clinics		<b>POLICY NUMBER:</b> 769-0929-09
<b>DATE OF ORIGIN:</b> 12.10.2009 <b>DATE LAST RENEWED OR REVISED:</b> <b>NEXT REVIEW:</b> 10.6.2010	<input type="checkbox"/> <b>CORE POLICY</b> <input checked="" type="checkbox"/> <b>SERVICE UNIT POLICY</b>	<b>RELATED POLICIES:</b> 770-0929-09 771-0929-09
<b>APPROVAL BY CHIEF OPERATING OFFICER</b>  _____ N/A _____ <b>DATE:</b>	<b>APPROVAL BY SERVICE UNIT DIRECTOR(S)</b>  _____  <b>DATE: 12/10/2009</b>  <b>DATE: 12.10.2009</b>	<b>PAGE</b> 1 of 5

## I. POLICY

In order to reduce morbidity and mortality from H1N1 influenza infection, the Cook County Department of Public Health (CCDPH) is working with local governmental agencies and emergency management authorities to make vaccine available to adult and pediatric patients who fall within the categories identified for vaccination in guidelines from the Illinois Department of Public Health (IDPH), Centers for Disease Control and Prevention (CDC), and Advisory Committee on Immunization Practices (ACIP) between October 1, 2009 through March 31, 2010.

This policy applies to the administration of Inactivated Influenza A (H1N1) 2009 Monovalent Vaccine, one type of H1N1 vaccine that will be available. Inactivated H1N1 vaccine will be administered in CCDPH managed clinics under the direction of the Chief Medical Officer and the Director of Integrated Health Services, or their designees. CCDPH Authorized Vaccinators shall adhere to this Policy and related Policy 770-0929-09, CCDPH Public Health Physician Standing Order applicable to the Administration of Inactivated Influenza A (H1N1) 2009 Monovalent Vaccine.

Patients presenting for H1N1 vaccination should be encouraged to receive seasonal influenza vaccination in addition to H1N1 influenza vaccination.

## II. SERVICE UNITS/AREAS/PERSONNEL AFFECTED

- A. Integrated Health Support Services Nursing Personnel
- B. Physicians, Dentists and Advanced Practice Nursing Personnel Reporting to the Chief Medical Officer
- C. Volunteers, Local Governmental Agency Personnel and Nurse Consultants to Licensed Daycare Centers who are working under the direction of the Cook County Department of Public Health in cooperation with the Cook County Emergency Management Agency.

## III. DEFINITIONS

- A. The categories of personnel identified in Section II above who are designated and approved by the CCDPH to administer vaccinations shall, during the performance of their vaccination duties pursuant to this policy, be referred to as "CCDPH Authorized Vaccinators."
- B. The persons receiving Inactivated Influenza A (H1N1) vaccine from CCDPH Authorized Vaccinators shall be referred to as "Patients."

- C. CCDPH Authorized Vaccinators shall administer the Inactivated Influenza A (H1N1) Vaccine to Patients in accordance with the attached Public Health Physician Standing Order and the provisions of Policy 770-0929-09 Guidelines for the Administration of Inactivated Influenza A H1N1 Vaccine (H1N1).

#### IV. PROCEDURE

- A. Priority Groups for H1N1 vaccination – Level 1. If there are sufficient amounts of Influenza A (H1N1) vaccine, persons falling within the following priority groups identified in accordance with CDC criteria may be administered H1N1 vaccination:
1. Pregnant women
  2. Infants/children/young adults aged 6 months to 24 years of age
  3. Caretakers of infants less than 6 months of age
  4. Individuals aged 25 through 64 years of age with chronic medical conditions.
  5. Healthcare workers and emergency service personnel.
- B. Priority Groups for H1N1 vaccination – Level 2. If there are limited amounts of Influenza A (H1N1) vaccine, persons falling within the following priority groups identified in accordance with CDC criteria may be administered H1N1 vaccination:
1. Pregnant women
  2. Infants/children 6 months to 4 years of age
  3. Caretakers of infants less than 6 months of age
  4. Children aged 5 through 18 years of age with chronic medical conditions.
  5. Healthcare workers with direct patient contact.
- C. Groups for H1N1 vaccination – Level 3. If there are sufficient amounts of influenza A (H1N1) vaccine and priority groups have had access to H1N1 vaccination, all other persons not included in Priority Groups for Level 1 and Level 2 may be administered H1N1 vaccination including:
1. Healthy individuals aged 25 through 64 years of age.
  2. Individuals 65 and over.
- D. Contraindications to Inactivated Influenza A (H1N1) Vaccination by CCDPH  
Persons with the following conditions will not be immunized with H1N1 influenza vaccine and should be referred to their primary care physician for management:
1. Serious allergy to eggs (i.e. hives or anaphylactic reaction) or other components of the vaccine.
  2. Serious reactions to previous influenza vaccination.
  3. History of Guillain-Barré Syndrome.
  4. Acute febrile illness or other active infection.
  5. Sensitivity to thimerosal (a mercury derivative used as a preservative in some H1N1 vaccine).
  6. Less than 28 days have lapsed since the initial dose of H1N1 vaccine.
- E. How H1N1 Influenza Virus will be Supplied
1. Single-dose pre-filled syringe or vial
    - a. 0.25 mL single dose syringe without preservative, manufactured by:
      - i. Sanofi-Pasteur
    - b. 0.50 mL single dose syringe without preservative, manufactured by:
      - i. CSL
      - ii. Sanofi-Pasteur
    - c. 0.50 mL single dose vial without preservative, manufactured by:
      - i. Sanofi-Pasteur
    - d. 0.50 mL single dose syringe with thimerosal, manufactured by:
      - i. Novartis

2. Multi-dose vials
  - a. Contain a small amount of thimerosal as a preservative
  - b. 5 mL vial with 10 doses/vial, manufactured by:
    - i. CSL
    - ii. Novartis
    - iii. Sanofi-Pasteur

F. Determination of Vaccine Type

1. Different products have been licensed based on age groups:
2. The following table identifies the product licensed by age:

Age	Product	Dose	Route
6 – 35 months of age	Sanofi Pasteur	0.25 mL	Intramuscular
36 months – 9 years of age	Sanofi Pasteur	0.50 mL	Intramuscular
4 – 9 years of age	Novartis	0.50 mL	Intramuscular
10 – 17 years of age	Sanofi Pasteur	0.50 mL	Intramuscular
	Novartis	0.50 mL	Intramuscular
18 years of age and older	CSL	0.50 mL	Intramuscular
	Sanofi Pasteur	0.50 mL	Intramuscular
	Novartis	0.50 mL	Intramuscular

G. Inactivated Influenza A Influenza (H1N1) Vaccine Side Effects

Note: The risk of H1N1 Influenza vaccine causing serious harm or death is extremely small. However, a vaccine like any medicine may rarely cause serious problems such as severe allergic reactions.

1. **Mild side effects** – Usually begin *soon after the injection* and usually last *one to two days* after the immunization.
  - a. Low grade fever (less than 100 degrees Fahrenheit)
  - b. Erythema (redness) and tenderness at the site of injection
  - c. Headache
  - d. Malaise
  - e. Muscle aches (myalgia)
  - f. Nausea
  - g. Fainting (mainly in adolescents)
2. **Life-threatening allergic reactions** – Are very rare and usually occur within *a few minutes to a few hours* after the immunization and are more likely to occur in persons with a severe allergy to eggs.
  - a. Difficulty breathing
  - b. Hoarseness
  - c. Wheezing
  - d. Paleness
  - e. Weakness
  - f. Fast heartbeat
  - g. Dizziness
3. **Guillain-Barré syndrome** - Normally, about one person per 100,000 people per year will develop Guillain-Barré syndrome (GBS), an illness characterized by fever, nerve damage, and muscle weakness. In 1976, vaccination with the swine flu vaccine was associated with development of GBS.

#### H. Management of Emergencies

1. CCDPH Charge staff will carry an Emergency Kit supplied by CCDPH for the management of emergencies including anaphylactic/allergic reactions following the established Cook County Department of Public Health Medical Emergency Protocol.
2. Vaccinations cannot be administered without an Emergency Kit being available at the administration location.
3. A telephone will be available in the immediate clinic area for activation of the Emergency Medical System (EMS).
4. The telephone number of the nearest EMS will be available for immediate use whenever patients are receiving vaccinations from CCDPH.

#### I. Consent Forms

1. Written informed consent for Influenza A (H1N1) Vaccine will be obtained prior to vaccination.
2. Each person to receive the vaccination will be screened for contraindications by the vaccinator.
3. The vaccinator will determine if vaccine can be administered based on the protocol and type of vaccine to be administered based on contraindications.
4. The standard practice of advising patients of possible side effects and adverse reactions should be followed. Each patient will be given the Influenza A (H1N1) Vaccine Information Statements (VIS) prior to vaccination.
5. The original Influenza A (H1N1) Vaccine Consent will be maintained by CCDPH. A copy of the Influenza A (H1N1) Vaccine Consent may be retained by the school or daycare center with authorization from the person receiving the vaccination and a copy will be given to the parent/guardian/patient.

#### J. Management of Medical Questions During the Clinic Session

1. Questions regarding the administration of H1N1 Vaccine during the clinic session will be referred to the CCDPH Charge Nurse for review.
2. If the CCDPH Charge Nurse cannot make a determination based on protocol, medical consultation will be obtained from Incident Command.
  - a. A physician will be designated by Incident Command to respond to all questions occurring during vaccination clinic hours.
3. All consultations and decision will be documented by the CCDPH Charge Nurse under Comments on the Influenza A H1N1 Consent Form.

#### K. Additional Doses

1. Infants/children under 10 years of age will require two doses of vaccine to confer maximum immunity.
2. The second dose should be given 28 days after the first.
3. The second dose may be received from primary care providers, retail pharmacies, or regional CCDPH sites.
4. Ideally, the second dose should be the same type as the first vaccination.
5. CCDPH will not be reserving doses for the second vaccination.

#### L. Vaccine Administration:

1. Refer to the Policy 770-0929-09 for the standing orders on the administration of Inactivated Influenza A (H1N1) Vaccine.
2. Refer to the Emergency Protocol for management of medical emergencies.

#### M. Reporting Adverse Events

1. In all cases, Patients should contact their primary care providers if they become ill after receiving Influenza A (H1N1) vaccine and should describe the following:
  - a. What happened
  - b. When it happened (including date and time)
  - c. When vaccination was given
  - d. What type of vaccine was given (injectable or nasal spray)
2. Patient should ask their primary care provider to report the reaction by filing a Vaccine Adverse Event Reporting System (VAERS) form or by filing an electronic report through the website at [www.vaers.hhs.gov](http://www.vaers.hhs.gov) or by calling 1-800-822-7967.

#### N. Storage

1. Vaccine should be stored between 2° and 8°C (36° and 46°F).
2. Between uses, return the multi-dose vial to the recommended storage conditions between 2° and 8°C (36° and 46°F).
3. Opened multi-dose vaccine should be labeled with the date that the vial is opened and used within 30 days of opening. Discard if the vaccine has not been used within 30 days of opening.
4. **Do not freeze.** Discard if the vaccine has been frozen.
5. Vaccine should not be used after the expiration date. Discard if the vaccine has expired.

#### V. REFERENCES

- A. Use of Influenza A (H1N1) 2009 Monovalent Vaccine, Recommendations of the Advisory Committee on Immunization Practices (ACIP), 2009. MMWR 2009; 58 (early release); 1-8 Located at <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr58e0821a1.htm>
- B. Package insert for Influenza A (H1N1) 2009 Monovalent Vaccine manufactured by Sanofi Pasteur, Inc. located at <http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM182404.pdf>
- C. Package insert for Influenza A (H1N1) 2009 Monovalent Vaccine manufactured by Novartis Vaccines and Diagnostics, Ltd. located at <http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM182242.pdf>
- D. Package insert for Influenza A (H1N1) 2009 Monovalent Vaccine manufactured by CSL Limited located at
- E. Vaccine Information Statement located at <http://www.cdc.gov/h1n1flu/vaccination/slv/pdf/vis-h1n1-prelicensure.pdf>.