
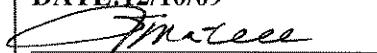


COOK COUNTY DEPARTMENT OF PUBLIC HEALTH POLICY AND PROCEDURE MANUAL		
POLICY TITLE: Guidelines for the Administration of Live Attenuated Influenza A (H1N1) Vaccine (LAIV-H1N1)		POLICY NUMBER: 771-0929-09
DATE OF ORIGIN: 10.6.2009 DATE LAST RENEWED OR REVISED: NEXT REVIEW: 10.6.2010	<input type="checkbox"/> CORE POLICY <input checked="" type="checkbox"/> SERVICE UNIT POLICY	RELATED POLICIES: 772-0929-09 769-0929-09
APPROVAL BY CHIEF OPERATING OFFICER _____ N/A _____ DATE:	APPROVAL BY SERVICE UNIT DIRECTOR(S)  _____ DATE: 12/10/09  DATE: 12.10.2009	PAGE 1 of 5

I. POLICY

In order to reduce morbidity and mortality from H1N1 influenza infection, the 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 and March 31, 2010.

This policy applies to the administration of Live Attenuated Influenza A (H1N1) Vaccine (LAIV-H1N1), one type of H1N1 vaccine that will be available. LAIV-H1N1 will be administered 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 772-0929-09 CCDPH - Public Health Physician Standing Order applicable to the Administration of Live Attenuated Influenza A (H1N1) Vaccine (LAIV-H1N1).

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 LAIV-H1N1 from a CCDPH Authorized Vaccinators shall be referred to as "Patients".

- C. CCDPH Authorized Vaccinators shall administer the LAIV-H1N1 to Patients in accordance with the attached Public Health Physician Standing Order and the provisions of Policy 772-0929-09 Guidelines for the Administration of Live Attenuated H1N1 Influenza Vaccine (LAIV-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 Live Attenuated Influenza A (H1N1) Vaccine (LAIV-H1N1)
1. Pregnancy
 2. Age less than 2 years or greater than 49 years of age
 3. Serious allergy to eggs (i.e. hives or anaphylactic reaction) or other components of the vaccine.
 4. Serious reactions to previous influenza vaccination.
 5. History of Guillain-Barré Syndrome.
 6. History of asthma or respiratory wheezing
 7. Chronic health conditions such as heart disease, lung disease, kidney disease, liver disease, metabolic disorders such as diabetes, anemia and other blood disorders.
 8. Acute febrile illness or other active infection.
 9. Active muscular or neurologic disorder such as cerebral palsy that can lead to breathing or swallowing problems.
 10. Vaccination with a live virus vaccine in the past 28 days including MMR (measles, mumps, rubella), Varicella (chicken pox), FluMist (live, attenuated seasonal influenza vaccine)
 11. Individuals under the age of 18 who are on Aspirin-containing therapy
 12. Receipt of antivirals 48 hours before administration of LAIV-H1N1
 13. Concomitant administration of FluMist (live, attenuated seasonal influenza vaccine)
 14. Weakened immune system/immunocompromised from conditions such as HIV/AIDS, cancer, leukemia, lymphoma, lupus.
 15. Less than 28 days have lapsed since the initial dose of H1N1 vaccine.
 16. Anyone in close contact with a person with a severely weakened immune system requiring care in a protected environment such as a bone marrow transplant unit.

E. Mode of Administration

LAIV-H1N1 will be supplied in pre-filled, single use sprayers for intranasal delivery of a single dose of vaccine.

F. LAIV-H1N1 Side Effects

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

1. **Mild side effects in children 2 to 17 years of age**

- a. Low grade fever (less than 100 degrees Fahrenheit)
- b. Rhinorrhea (runny nose), nasal congestion
- c. Cough
- d. Wheezing
- e. Pharyngitis (sore throat)
- f. Headache
- g. Muscle aches
- h. Abdominal pain or occasional vomiting or diarrhea

2. **Mild side effects in adults 18 to 49 years of age**

- a. Rhinorrhea (runny nose), nasal congestion
- b. Cough
- c. Chills
- d. Tiredness/weakness
- e. Pharyngitis (sore throat)
- f. Headache

3. **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

4. **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.

G. 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 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.

H. 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 clients of possible side effects and adverse reactions should be followed. Each client will be given the Live Attenuated Influenza A (LAIV-H1N1) Information Statement (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.

I. Management of Medical Questions During the Clinic Session

Questions regarding the administration of LAIV-H1N1 Vaccine during the clinic session will be referred to the CCDPH Charge Nurse for review.

1. If the CCDPH Charge Nurse cannot make a determination based on protocol, medical consultation will be obtained from Incident Command.
2. 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.

J. Additional Doses

1. Patients should be advised to receive a second dose of LAIV-H1N1 Vaccine 28 days after their first vaccination.
2. The second dose may be received from primary care providers, retail pharmacies, or regional CCDPH sites.
3. Ideally, the second dose should be the same type as the first vaccination.
4. CCDPH will not be reserving doses for the second vaccination.

K. Vaccine Administration:

1. Refer to the Policy 772-0929-09 CCDPH - Public Health Physician Standing Order applicable to the Administration of Live Attenuated Influenza A (H1N1) Vaccine (LAIV-H1N1).
2. Refer to the Emergency Protocol for management of medical emergencies.

L. Reporting Adverse Events

1. Client should be instructed to contact their primary care provider for advice and 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. Client should ask their primary care provider to report the reaction by filing a Vaccine Adverse Event Reporting System (VAERS) form or they can file a report through the website at www.vaers.hhs.gov or by calling 1-800-822-7967.

M. Storage

1. Vaccine should be stored between 2° and 8°C (36° and 46°F).
2. **Do not freeze.** Discard if the vaccine has been frozen.
3. Live Attenuated Influenza A (H1N1) Vaccine must be used prior to the expiration date on the sprayer label.

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 Live, Intranasal Manufactured by MedImmune, LLC located at <http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM182406.pdf>
- C. Vaccine Information Statement for 2009 H1N1 Influenza Vaccine (10/2/2009) located at <http://www.cdc.gov/vaccines/Pubs/vis/downloads/vis-laiv-h1n1.pdf>