



STATE OF NEW YORK DEPARTMENT OF HEALTH

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September 14, 2009

TO: All Medical Providers and Health Care Facilities

FROM: NYSDOH Bureau of Immunization

HEALTH ADVISORY: Novel H1N1 Influenza Vaccine Information
Please distribute to the Infection Control Department, Medical Director, Director of Nursing, Emergency Department, Employee Health, and all patient care areas

The purpose of this advisory is to provide information on the novel H1N1 influenza vaccine. Please keep in mind that this information is the best that is known at the time. Since this is a rapidly evolving situation, the information provided can change. Updates will be provided when new information is available.

Topics Covered:

1. Definitions
2. General Information on the Novel H1N1 Influenza Vaccine
3. The Timeline for Development of the Novel H1N1 Influenza Vaccine
4. Target Groups for Novel H1N1 Influenza Vaccine
5. Sites Where the Novel H1N1 Influenza Vaccine Will be Given
6. Methods of Distribution for the Novel H1N1 Influenza Vaccine
7. Insurance Coverage for Administration of the Novel H1N1 Influenza Vaccine
8. How Private Providers, Pharmacists, and Others Located Outside New York City Will Be Able to Register to Receive the Novel H1N1 Influenza Vaccine
9. Advantages of Using NYSIIS
- 10 Reporting Doses Administered
11. How Health Care Facilities will Be Able to Access the Novel H1N1 Influenza Vaccine
12. Vaccine Safety
13. Seasonal Influenza Vaccine
14. Pneumococcal Vaccine
15. New Regulations Requiring Influenza Vaccine in Certain Health Care Facilities
16. Volunteer Opportunities
17. Additional Information and Resources

1. Definitions

Novel H1N1 Influenza: The new influenza virus that started circulating in the United States in April 2009. Most of the population does not have immunity to this virus. This virus is causing a

worldwide pandemic. It has been called “swine flu” because part of its genetic make up originated in pigs.

Seasonal Influenza: The varying influenza viruses that circulate every year and infect up to 20% or more of the population. Seasonal influenza viruses generally circulate during the fall and winter.

Novel H1N1 Influenza Vaccine: The vaccine against the novel H1N1 influenza virus that is currently being developed.

Seasonal Influenza Vaccine: The influenza vaccine that is developed every year against the 3 influenza virus strains that are expected to cause disease that season.

2. General Information on the Novel H1N1 Influenza Vaccine

Novel H1N1 influenza vaccine is being produced by the same 5 manufacturers that produce seasonal influenza vaccine. This vaccine is expected to:

- Be formulated just like seasonal influenza vaccine but with a change in the influenza strain that is included;
- Contain only the novel H1N1 influenza strain;
- Be a licensed vaccine;
- Be available in both the injectable form and the nasal spray;
- Be available in limited quantities without thimerosal;
- Become available mid to late October, though some doses may be available as early as September;
- Require 1 or 2 doses, 3-4 weeks apart;
- Be provided at no cost by the Federal government;
- Be able to be given at the same time as seasonal influenza vaccine; and
- Be safe and effective.

3. The Timeline for the Development of Novel H1N1 Influenza Vaccine

The novel H1N1 influenza vaccine is currently being manufactured and is simultaneously undergoing clinical trials. The clinical studies will help to address the final dosage of antigen in the vaccine, the number of doses required, the interval between the doses, any safety concerns, antibody responses to the vaccine, and other clinical information. The information from the trials is expected to be available sometime in September.

The vaccine is expected to begin being available in mid October, though some amount of doses may become available in late September or early October. Discussions of which groups would be targeted to receive any doses that become available in September are under way. Though the early doses may be available before the results from the clinical trials are completed, the efficacy and safety profile of the new vaccine is expected to be very similar to seasonal influenza vaccine. The new vaccine is being produced by the same process as seasonal vaccine. Seasonal influenza vaccine already contains an H1N1 strain of the influenza virus. Nevertheless, the safety and efficacy studies that are underway are more extensive than what is usually done with the licensing of seasonal influenza vaccine.

The exact amount of novel H1N1 vaccine that will become available in September or October is not known yet. However, some predictions are being made. The latest information available from the Centers for Disease Control and Prevention says that about 45 million doses will be available first as a “bolus” over several weeks in October. Then vaccine will be produced at a rate of 20 million doses per week.

4. Target Groups for Novel H1N1 Influenza Vaccine

The Advisory Committee on Immunization Practices (ACIP) met on July 29, 2009, and made recommendations on who should receive the novel H1N1 influenza vaccine and in what order they should receive it.

Here are some of the considerations regarding the epidemiology of novel H1N1 influenza that were used to create the target groups and the order in which they are to be vaccinated:

- Which groups had the most severe illness and risk for complications during the novel H1N1 outbreak earlier this year;
- Which groups had the greatest frequency of illness during the novel H1N1 outbreak;
- Contribution of particular groups to the overall burden of severe illness;
- Protection of healthcare system functions;
- Reduction of societal impact; and
- Potential for indirect protection of more vulnerable contacts.

Phase I: The following groups of people are the first target for the novel H1N1 influenza vaccine:

- Pregnant women;
- Household contacts and caregivers of infants younger than 6 months of age;
- Health care personnel and emergency medical services personnel;
- Children, adolescents, and young adults ages 6 months through 24 years of age; and
- Adults 25 through 64 years of age with a medical condition that makes them at high risk for complications of influenza.

If the initial supply of novel H1N1 influenza vaccine is limited either nationally or on a local basis and there is not enough vaccine to cover the groups above, then the following groups of people will be recommended to receive this vaccine:

- Pregnant women;
- Household contacts and caregivers of infants younger than 6 months of age;
- Health care personnel and emergency medical services personnel who have direct patient contact;
- Children 6 months through 4 years of age; and
- Children and adolescents 5 through 18 years of age with a medical condition that makes them at high risk for complications of influenza;

Phase II: Once it has been shown that there is enough vaccine to immunize the groups above, the next target group is:

- All adults from 25 through 64 years of age.

Phase III: Once it has been shown that there is enough vaccine to immunize the group above, the next target group is:

- All adults 65 years of age and older.

For more information on target groups and to see the rationale behind the recommendations, please visit the ACIP website at: <http://www.cdc.gov/vaccines/recs/provisional/default.htm>.

Please note: these target groups are somewhat different than those groups that are recommended for seasonal influenza vaccine. For information on recommendations for seasonal influenza vaccine, please see the Prevention and Control of Seasonal Influenza with Vaccines, MMWR July 31, 2009 / 58(RR08);1-52 at: <http://www.cdc.gov/MMWR/preview/mmwrhtml/rr5808a1.htm>.

5. Sites Where the Novel H1N1 Influenza Vaccine Will be Given

Planning is underway to deliver the novel H1N1 influenza vaccine in the quickest and broadest way possible. It is important to consider the sites where target groups are seen for medical care. Different communities may have different sites available. The following sites may offer the novel H1N1 influenza vaccine:

- Medical provider offices;
- Hospital outpatient clinics and community health centers;
- Local health department clinics (immunization or mass dispensing clinics);
- Pharmacies;
- School-based clinics;
- College and university health centers;
- Health care facilities; and
- Medical practices located in certain occupational sites.

The NYSDOH will be coordinating the sites that will be available in cooperation with each local health department.

6. Methods of Distribution for the Novel H1N1 Influenza Vaccine

Vaccine distribution will occur under the control of the NYSDOH for all counties outside of New York City. Vaccine will be distributed through a central distributor that is under contract with the Centers for Disease Control and Prevention (CDC). The NYSDOH will direct the central distributor, McKesson, to deliver vaccine to sites in New York State. The exact number of sites that will be available to New York State is not known yet, but is expected to be around 3,000. In New York City, the New York City Department of Health and Mental Hygiene will assume responsibility for directing the distribution of vaccine.

7. Insurance Coverage for Administration of the Novel H1N1 Influenza Vaccine

The novel H1N1 influenza vaccine itself and supplies to administer it will be provided without charge by the Federal government. It is expected that the cost of vaccine administration will be covered by most health insurance, and Medicaid and Medicare will cover it. For those who do not have health insurance or whose insurance will not cover the administration fee, the fee may be charged to the patient, unless the provider waives it. In addition, funding is available so that local health departments can work to assure that those who are uninsured can get vaccinated. A provider, pharmacist, or local health department may charge an administration fee. Local health departments cannot turn someone away if he or she cannot afford the administration fee.

Vaccination of school-aged children, under the general direction of local health departments, will most likely occur in schools in many areas of the state, paid for with federal funding. Overall guidance for reimbursement for novel H1N1 vaccination clinics in schools will be forthcoming from both the CDC and the NYSDOH.

8. How Private Providers, Pharmacists, and Others Located Outside New York City Will Be Able to Register to Receive the Novel H1N1 Influenza Vaccine

Details about receiving vaccine are still being worked out. Vaccine distribution will be managed by the NYSDOH with assistance from a variety of sources. Many providers and pharmacists will be receiving novel H1N1 vaccine directly through CDC's central distributor, McKesson Specialties. Some providers and pharmacists may receive vaccine from their local health department or from the NYSDOH. A website is available for providers and pharmacists to register interest in receiving vaccine (see below). It is not yet clear if all providers who express interest will be able to access vaccine.

To obtain H1N1 vaccine in New York City, contact the NYC Department of Health and Mental Hygiene at <http://www.nyc.gov/html/doh/html/cir/a03c.html> or call 212-676-2323.

Requirements for Receiving Vaccine

All medical providers and pharmacists that are interested in receiving vaccine must do the following:

- Register your interest in receiving H1N1 vaccine with the NYSDOH vaccine program by going to the registration website at: <https://hcsteamwork1.health.state.ny.us/pub/>.
- Sign a provider agreement that is in the process of development;
- Agree to report weekly all doses administered by age group and
- Agree to report all vaccine inventory to NYSDOH as required.

Providers that Will Vaccinate Patients Less Than 19 Years of Age

New York State Law requires that all vaccinations of pediatric patients (less than 19 years of age) be entered into the New York State Immunization Information System (NYSIIS), the state's immunization registry. All providers that are interested in receiving novel H1N1 influenza monovalent vaccine for use in pediatric patients (less than 19 years of age) must complete three steps. These can be completed by accessing this website:

<https://hcsteamwork1.health.state.ny.us/pub/>.

1. Establish a NYSDOH Health Commerce System (HCS) account

- The Health Commerce System (HCS) (also referred to as the Health Provider Network or the HPN) is a secure web-based system designed by the NYSDOH

specifically for electronically exchanging health-related data and information between health care providers and NYSDOH.

- Note: this is the same account that physicians use to order prescription pads and update their Physician Profile; all physicians should have an account.
- Completing the on-line HCS application request form will bring the user to the H1N1 vaccine pre-registration form and the HCS application information will pre-populate appropriate fields to expedite the H1N1 vaccine pre-registration process.

2. Pre-register interest in receiving H1N1 vaccine with the NYSDOH vaccine program

- This pre-registration process is designed for you to express interest only and does not obligate you to receive/administer vaccine nor does it guarantee you will receive vaccine if supplies are limited. Users with a current HCS account can use their log in id to pre-populate the vaccine pre-registration form and expedite the process. Once your registration is received and the remaining details of the vaccination campaign have been finalized, you will be contacted by the vaccine program to sign the formal provider agreement that has been supplied by the Federal government, agreeing to appropriately store and handle the vaccine, to give vaccines only to the CDC targeted groups, and to report vaccine usage.

3. Establish access in the New York State Immunization Information System (NYSIIS), also known as the immunization registry (see attached fact sheet).

- NYSIIS participation is required by NYS law for providers who immunize children less than 19 years of age. Participating in training establishes a NYSIIS user account.
- 47 electronic health record/billing vendors are approved to automatically upload immunization information into NYSIIS.
- The website above provides additional information on an online orientation to NYSIIS and training opportunities for new users.

Local Health Departments do not have to register with the NYSDOH to receive vaccine.

9. Advantages of Using NYSIIS

NYSIIS provides a number of advantages for providers of novel H1N1 monovalent influenza vaccine: 1) automatically generates the federally mandated weekly vaccine usage reports, 2) monitors vaccine inventory to enable prompt reordering, 3) generates reminder lists and letters for the second influenza vaccine dose, if required, 4) provides a legal record of the vaccination, 5) enables correct ascertainment of prior influenza vaccine history if patients receive some influenza vaccine doses (seasonal and/or monovalent H1N1) at other provider sites, and 6) enables NYSDOH to more closely monitor possible vaccine adverse events.

10. Reporting Doses Administered and Vaccine Inventory

All vaccinators will be required to report the number of doses administered and their current inventory to the NYSDOH on a weekly basis. The doses administered will be reported according to the age of the recipient. For those vaccinators who are using NYSIIS to record vaccinations given, the report of doses administered and inventory can be generated easily by using reports that are available in NYSIIS. For those who are not using NYSIIS, an alternative method of reporting is being developed by the NYSDOH.

11. How Health Care Facilities Will Be Able to Access Novel H1N1 Influenza Vaccine

All health care personnel and emergency medical service providers are within the initial target groups for vaccination with the novel H1N1 influenza vaccine. All hospitals will receive an allocation of the vaccine for use in the facility. Other health care facilities will also be able to receive vaccine and should follow the procedures outlined above and make sure they have the required accounts set up.

12. Vaccine Safety

Though the novel H1N1 influenza vaccine is manufactured in the same manner as seasonal influenza vaccine, special measures are being taken to ensure its safety. Studies will be conducted by the CDC and vaccine manufacturers to monitor for Guillain Barre Syndrome and any unusual adverse events. New York State will also carefully monitor reports of Guillain Barre Syndrome in the state.

The Vaccine Adverse Events Recording System (VAERS) will be used to accept reports of adverse events after vaccination. The NYSDOH will receive reports from the CDC on any adverse events that occur in New York State on a regular basis. If an adverse event is suspected, it should be reported directly to VAERS by calling 1-800-822-7967 or by going to www.vaers.hhs.gov

13. Seasonal Influenza Vaccine

Seasonal influenza vaccine is already becoming available from several manufacturers. Seasonal influenza vaccine should be given to all eligible and interested persons as soon as it becomes available. This is true every year, but, is especially true this influenza season. Seasonal influenza viruses may circulate at the same time as the novel H1N1 influenza virus. Seasonal influenza vaccine use will help to decrease illness and to preserve all important societal functions.

Seasonal influenza disease will probably overlap with novel H1N1 influenza disease, and seasonal influenza vaccination will overlap with novel H1N1 influenza vaccination. To avoid confusion, it is important to keep up-to-date on the latest influenza information and to use communication messages developed by the CDC and the NYSDOH for your health care personnel, patients, and the public.

Some providers may encounter temporary difficulties ordering seasonal influenza vaccine. According to CDC, this is a temporary situation which occurs every year due to double booking of vaccine orders by providers. As vaccine orders start to be filled, double bookings are released and vaccine becomes available. Even with some manufacturing difficulties, the projections are 114-115 million doses of seasonal vaccine this year, which exceeds the amount of 113 million doses last year (when millions of doses went unused).

Providers looking to order additional vaccine should be encouraged to use the supplies that they have now and continue to look for additional flu vaccine for purchase in the coming weeks. To assist providers in finding flu vaccine, the National Influenza Vaccine Summit supports IVATS, the Influenza Vaccine Availability Tracking System, which provides information about vaccine manufacturers and distributors with vaccine available for purchase. IVATS can be found at: <http://www.preventinfluenza.org/ivats/>. The information in IVATS is updated throughout the influenza vaccination season.

For additional information on seasonal influenza vaccine, please see <http://www.cdc.gov/flu/> and www.health.state.ny.us

14. Pneumococcal Vaccine

Secondary bacterial pneumonia is the most common complication of influenza. For this reason it is important that all those who are recommended to receive the pneumococcal vaccine get immunized as soon as possible. Young infants usually receive all the pneumococcal conjugate vaccine (PCV) doses by the time they are 15 months of age, though children up to 59 months of age can be vaccinated. Persons 2 years of age and up can also receive the pneumococcal polysaccharide vaccine (PPSV) if they have the following:

- Chronic illness,
- Anatomic or functional asplenia
- An immunocompromising condition,
- HIV infection,
- Environments or settings with increased risk,
- Cochlear implant.

In addition, all persons aged 65 years and older should get one PPSV.

For more information on pneumococcal disease please visit the CDC website at <http://www.cdc.gov/vaccines/vpd-vac/pneumo/default.htm>.

15. New Regulations Requiring Influenza Vaccine in Certain Health Care Facilities

New regulations have been passed by the State Hospital Review and Planning Council (SHRPC) that require all health care personnel in hospitals, diagnostic and treatment centers, long term home health care programs, AIDS home care programs, home care service agencies, and hospices to be immunized against influenza disease each year. Mandating the novel H1N1 influenza vaccine will depend on several factors including whether it is approved as a licensed vaccine, whether there is adequate supply, and any Federal requirements surrounding the vaccine.

It is important that all health care personnel be immunized with both the seasonal influenza vaccine and the novel H1N1 influenza vaccine in order to allow the health care system to function smoothly in the face of increased illness from influenza this fall and winter. The regulation is now available at <http://www.nyhealth.gov/nysdoh/phforum/nycrr10.htm>.

16. Volunteer Opportunities

The novel H1N1 influenza vaccine campaign will require tremendous resources to assure that every New Yorker has access to vaccination. Volunteers of all sorts, both medical and non-medical will be needed to assist at vaccination sites. If you or your members are interested in

volunteering with a local health department, state health department or Medical Reserve Corp program, please go to www.nyhealth.gov/ServNY to enroll.

17. Additional Information and Resources

Additional information and resources on seasonal influenza and novel H1N1 influenza can be found at the following websites:

Global, National, State and City Resources

World Health Organization: Global alert and response, guidance documents, FAQ's etc.
<http://www.who.int/csr/disease/swineflu/en/index.html>

U.S. Government Swine, Avian and Pandemic Flu Information - One-stop access
From the U.S. Department of Health and Human Services
<http://www.flu.gov/>

CDC Novel H1N1: Clinical guidance
<http://www.cdc.gov/h1n1flu/clinicians/>

CDC Novel H1N1: Vaccination guidance for state, local and territorial health officials
<http://www.cdc.gov/h1n1flu/vaccination/statelocal/>

Food and Drug Administration (FDA): Use of Influenza Medicines and Diagnostic Testing Information

<http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm150305.htm>

New York State Department of Health: H1N1 Guidance
<http://www.nyhealth.gov/diseases/communicable/influenza/h1n1/>

New York State Office of Homeland Security
<http://www.security.state.ny.us/preparedness/index.html>

New York State Department of Insurance: Information on Vaccine Insurance Requirements
http://www.ins.state.ny.us/health/ih_hreqimmun.htm

New York City Department of Health and Mental Hygiene
<http://www.nyc.gov/html/doh/html/cd/cd-h1n1flu.shtml>

Clinical Information, Literature Reviews and Updates

New England Journal of Medicine:
<http://h1n1.nejm.org/?emp=marcom>

Center for Infectious Disease Research & Policy [Academic Health Center](http://www.cidrap.umn.edu/) -- [University of Minnesota](http://www.cidrap.umn.edu/)
<http://www.cidrap.umn.edu/>

American Medical Association

<http://www.ama-assn.org/ama/pub/physician-resources/medical-science/infectious-diseases/topics-interest/novel-influenza-a-h1n1.shtml>

American Academy of Pediatrics

<http://www.aap.org/advocacy/releases/may09swineflu.htm>

American Academy of Family Physicians

<http://www.aafp.org/online/en/home/clinical/disasterprep/swine-flu.html>

American College of Obstetricians and Gynecologists: Resource List

http://www.acog.org/departments/dept_notice.cfm?recno=20&bulletin=4866