



# STATE OF NEW YORK DEPARTMENT OF HEALTH

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Troy, New York 12180-2299

March 5, 2007  
DPACS: 07-06

Dear Chief Executive Officer:

On November 2, 2006, a letter was sent to all hospitals regarding the immunization of hospital inpatients 65 years of age and older against influenza and pneumococcal disease. This letter is being written to advise facilities of clarifications to the previous letter and supersedes that letter. The changes include:

- Written consent using a consent form is not required for the use of non-patient specific standing orders. Therefore, verbal consent is acceptable.
- When using non-patient specific standing orders, the fact that verbal or written consent has been obtained must be documented. This information may be included in a documentation/consent form, or may be documented in a notation in the patient's medical record.
- A patient specific order may be authorized by the patient's treating practitioner at any time during the hospital stay. Such patient specific orders may be carried out under the general hospital consent and no separate verbal or written consent would be required.
- Clarification has been added to the attached non-patient specific standing order sample protocols specifying that both influenza and pneumococcal vaccines can be given if a history of vaccination is not available.

On July 26, 2006, Governor Pataki signed into law amendments to Public Health Law that will now require hospitals to offer vaccinations to patients 65 years of age or older who are admitted to the hospital (copy enclosed). The law became effective on October 24, 2006.

The law requires hospitals to adopt an immunization policy that meets the provisions outlined in this correspondence. In addition, the law authorizes hospitals to implement a non-patient specific standing order policy for eligible patients in accordance with the immunization policy approved by the hospital. Hospitals should take steps immediately to implement these requirements and to secure supplies necessary to meet patient needs. The provisions of the law are outlined below and it is not expected that separate regulations will be promulgated at this time.

## **Immunizations Required**

All immunizations given pursuant to this legislation should be in accord with the current recommendations of the Advisory Committee on Immunization Practices (ACIP). The current ACIP recommendations for pneumococcal vaccination date from 1997. Current ACIP recommendations for influenza vaccination are published each year prior to the start of influenza season.

- Influenza – Annually between September first and April first, all patients age sixty-five or older should be considered as candidates for vaccination against the influenza virus.

Current ACIP recommendations for influenza vaccination are found at <http://www.cdc.gov/mmwr/PDF/rr/rr5510.pdf>.

- Pneumococcal – All patients age sixty-five or older at any time of the year should be screened to identify those patients who are candidates for vaccination, including those patients who are candidates for a second dose. A second dose of pneumococcal vaccine is recommended if the patient received vaccine >5 years previously and was aged <65 years at the time of vaccination. Current ACIP recommendations are found at: <http://www.cdc.gov/mmwr/PDF/rr/rr4608.pdf>.

### **Affected Individuals**

- The law specifies that all patients age 65 or older admitted to the hospital should be considered a potential candidate for immunization against influenza and pneumococcal disease.
- The law applies to hospital inpatients and as such would not mandate a similar program for hospital outpatients whose length of stay at the facility is less than 24 hours. Hospitals may, however, expand the program to identify other at-risk populations to whom immunizations may be offered.
- The hospital is expected to adopt an immunization policy that includes a clinical protocol for screening patients to identify those patients who are candidates for immunization. All candidates determined suitable for vaccination should be offered immunizations against influenza virus and pneumococcal disease.

### **Determination of Suitability for Vaccination**

All persons eligible for vaccination by virtue of age and vaccination history should be deemed to be suitable for vaccination and offered vaccination, unless:

- The specific immunization is medically contraindicated for that individual according to the contraindications set forth in the ACIP recommendations or in the vaccine package insert.
- The patient confirms that he/she has received such vaccinations or is not in need of a second dose of vaccine against pneumococcal disease.

No patients should be vaccinated if the patient refuses the vaccine after being fully informed of the health benefits and risks of vaccination.

Each patient's record should include evidence that he/she has been screened to determine if he/she is a candidate for immunization. For patients who are not candidates for immunization, each patient's record should document the reason the vaccine was not administered to the patient.

### **Immunization Policy**

Hospitals shall adopt an immunization policy for influenza and pneumococcal disease that includes but is not limited to:

- Procedures for the offering of immunizations against the influenza virus, between September first and April first, and pneumococcal disease during the admission or before discharge, to patients who are age sixty-five or older.
- A clinical protocol to identify those patients age sixty-five or older who are candidates for immunization. The protocol must include, but is not limited to, an assessment for contraindications to immunization. Facilities may expand the protocol to identify other at-risk populations to whom immunization should be offered.
- Provisions to notify all members of the hospital's medical staff of the immunization requirements, the option for a patient specific order for immunization, or, in the absence of a

patient specific order, the hospital's non-patient specific standing order policy for vaccination against influenza virus and pneumococcal disease for each admitted patient age sixty-five or older.

- Procedures for ensuring that individuals offered immunization or their representative receive information regarding the risks and benefits of vaccination. Vaccine Information Statements (VISs) developed by the Centers for Disease Control and Prevention (CDC), United States Health and Human Services, are required for this use and are found at the following websites: <http://www.cdc.gov/nip/publications/VIS/vis-facts.htm>  
<http://www.immunize.org/vis/>
- A non-patient specific standing order policy authorized by the hospital's medical director or other responsible physician that provides for a nursing assessment by a registered professional nurse to determine the suitability of the patient for immunization, including, but not limited to, an assessment for contraindications to immunization.
- A system for documenting patient refusals, medical contraindications and any post-vaccination adverse events, in the patient's record.
- A system for documenting vaccine administration. A certificate of immunization should be provided to the patient with the following information documented for the patient and in the patient's medical record:
  - Which immunizing agent and VIS was given
  - Date of publication of VIS
  - Date VIS was given to the patient
  - Name and title of person administering vaccine
  - Date of administration
  - Vaccine manufacturer and lot number

This information may be included in a documentation/consent form to meet patient needs.

- Provisions for ensuring that, in accordance with the New York State Education Department NYSED nursing practice regulations (<http://www.op.nysed.gov/immunguide.htm>), verbal or written consent has been obtained and is documented in the patients record, whenever vaccination is administered utilizing non-patient specific orders.
- Provisions to document in the patient's record that the vaccination was refused. The patient and/or the patient's representative may refuse immunization upon being fully informed as to the risks and benefits of the immunizing agent(s).

### **Patient Specific Orders**

- A patient specific order may be authorized by the patient's treating practitioner at any time during the hospital stay. Such patient specific orders may be carried out under the general hospital consent and no separate verbal or written consent would be required. It is expected that each patient or patient representative would receive documentation of immunization including the Vaccine Information Statements (VISs) developed by the Centers for Disease Control and Prevention (CDC).
- Patient specific orders indicating that the patient should not be vaccinated due to valid medical contraindications would take precedence over the hospital's non-patient specific standing order policy.

### **Non-Patient Specific Standing Orders**

- In the absence of a patient specific order, the law authorizes facilities to utilize non-patient specific standing orders for patients who have been assessed by a registered professional nurse

to determine the suitability of the patient for immunization, including, but not limited to, an assessment for contraindications to immunization.

- Non-patient specific standing orders for immunization should be used only with a clinical protocol implemented to identify those patients who are candidates for immunization. The policy for implementing non-patient specific standing orders and the clinical protocol must be authorized by the medical director or other responsible physician.
- Verbal or written consent must be documented when immunizations are administered in accordance with a non-patient specific order.

### **Vaccine Availability**

- The law allows the commissioner to waive these requirements if there is a shortage or delay in distribution of influenza and/or pneumococcal vaccine. If vaccines are not available due to shortages or unavailability, it should be noted in the patient's record why the vaccine was not offered.
- It is recognized that the influenza vaccine may not be readily available in early fall. In cases where the vaccine has not yet been received, the patient's record should note the reason the vaccine was not offered.

The requirements set forth in law support the recommendations of the CDC's Advisory Committee on Immunization Practices (ACIP), which constitute the standard of medical care. By providing seniors with the opportunity to receive vaccinations as inpatients, the immunization rate in New York will increase, thus reducing the significant risks posed by influenza and pneumococcal disease to this population.

Any questions regarding this letter may be directed to the Department's Immunization Program at (518) 473-4437 or the Division of Primary and Acute Care Services at (518) 402-1003.

Sincerely,



Guthrie S. Birkhead, M.D., M.P.H.  
Director  
Center for Community Health



Martin J. Conroy  
Director  
Division of Primary & Acute Care Services

# Sample Clinical Protocol for Administering Pneumococcal Vaccine to Adults

## Purpose

To reduce morbidity and mortality from pneumococcal disease by vaccinating all patients who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices.

## Policy

Utilizing this clinical protocol, the hospital has implemented a non-patient specific standing order policy that would allow eligible nurses to vaccinate patients who meet any of the criteria below.

## Procedure

1. Identify adults in need of vaccination with 23-valent pneumococcal polysaccharide vaccine (PPV23) based on the following criteria:

Age 65 years or older with no or unknown history of prior receipt of PPV23

- a. Age 18–64 years with no or unknown history of prior receipt of PPV23 and any of the following conditions:
  - i. chronic cardiovascular disease (e.g., congestive heart failure, cardiomyopathies)
  - ii. chronic pulmonary disease (e.g., emphysema or chronic obstructive pulmonary disease [not asthma])
  - iii. diabetes mellitus, alcoholism, chronic liver disease (cirrhosis), or cerebrospinal fluid leaks
  - iv. functional or anatomic asplenia (e.g., sickle cell disease, splenectomy)
  - v. immunosuppressive conditions (e.g., HIV infection, leukemia, congenital immunodeficiency, Hodgkin's disease, lymphoma, multiple myeloma, generalized malignancy) \*
  - vi. immunosuppressive chemotherapy (e.g., alkylating agents, antimetabolites, long-term systemic corticosteroids) \*
  - vii. organ or bone marrow transplantation \*
  - viii. chronic renal failure or nephrotic syndrome
  - ix. candidate for or recipient of cochlear implant

2. Identify adults in need of a second and final dose of PPV23 if five or more years have elapsed since the previous vaccination and the patient is:

Age 65 years or older and received prior PPV23 vaccination when less than age 65 years

- a. At highest risk for serious pneumococcal infection and/or likely to have a rapid decline in pneumococcal antibody levels (i.e., categories iv. - viii. above)

3. Screen all patients for contraindications and precautions to PPV23 vaccine.

**Contraindications:** a history of a serious reaction (e.g., anaphylaxis) after a previous dose of PPV23 or to a vaccine component. For a list of vaccine components, go to [www.cdc.gov/nip/publications/pink/appendices/a/excipient.pdf](http://www.cdc.gov/nip/publications/pink/appendices/a/excipient.pdf)

- a. **Precautions:** a moderate or severe acute illness with or without fever

**4. Unknown Vaccination History:** Every attempt should be made to locate a patient's immunization record, however, pneumococcal vaccination should not be withheld in the absence of an immunization record. A verbal history of vaccination from the patient is acceptable to determine immunization status. It is not recommended that those immunized with pneumococcal vaccine after 65 years of age receive a second vaccine.

5. Provide all patients with a copy of the most current federal Vaccine Information Statement (VIS). Although not required by federal law, it is prudent to document in the patient's medical record or office log, 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](http://www.immunize.org/vis)

6. Administer 0.5 mL PPV23 vaccine either IM (22–25g, 1–2" needle) or SC (23–25g, 5/8–3/4" needle).
7. Document each patient's vaccine administration information and follow up in the following places:
  - a. **Medical chart:** Record the date the vaccine was administered, the manufacturer and lot number, the vaccination site and route, and the name and title of the person administering the vaccine. If vaccine was not given, record the reason(s) for non-receipt of the vaccine (e.g., medical contraindication, patient refusal). According to New York State Education Department NYSED nursing practice regulations (<http://www.op.nysed.gov/immunguide.htm>), written consent must be obtained whenever vaccination is administered utilizing non-patient specific orders.
  - b. **Personal immunization record card:** Record the date of vaccination and the name/location of the administering clinic.
  - c. **Patient's primary care provider:** According to NYSED regulations referenced above, documentation of the patient's vaccination must be shared with the patient's primary care provider.
8. Be prepared for management of a medical emergency related to the administration of vaccine by having a written emergency medical protocol available, as well as equipment and medications.
9. Report all adverse reactions to PPV23 to the federal Vaccine Adverse Event Reporting System (VAERS) at [www.vaers.org](http://www.vaers.org) or by calling (800) 822-7967. VAERS report forms are available at [www.vaers.org](http://www.vaers.org)

This policy and procedure shall remain in effect for all patients of the \_\_\_\_\_ clinic until rescinded or until \_\_\_\_\_ (date).

Medical Director's signature: \_\_\_\_\_ Effective date: \_\_\_\_\_

\* Guidance regarding vaccination of individuals with altered immunocompetence can be found in the Centers for Disease Control and Prevention. General Recommendations on Immunization: recommendations of the Advisory Committee on Immunization Practices and the American Academy of Family Physicians. MMWR 2002; 51 (No.RR-2): page 22. Also available at: <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5102a1.htm>

# Sample Clinical Protocol for Administering Influenza Vaccine to Adults

## Purpose

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

## Policy

Utilizing this clinical protocol, the hospital has implemented a non-patient specific standing order policy that would allow eligible nurses to vaccinate patients who meet any of the criteria below.

## Procedure

1. Identify adults in need of influenza vaccination based on meeting any of the following criteria:
  - a. Age 50 years or older (all adults age 65 years and older admitted to the hospital between September 1<sup>st</sup> and April 1<sup>st</sup> must be considered candidates for influenza vaccine, as per New York State Public Health Law)
  - b. Have any of the following conditions:
    - chronic disorder of the pulmonary or cardiovascular system, including asthma
    - chronic metabolic disease (e.g., diabetes), renal dysfunction, hemoglobinopathy, or immunosuppression (e.g., caused by medications, HIV) that has required regular medical follow-up or hospitalization during the preceding year
    - any condition that compromises respiratory function or the handling of respiratory secretions or that can increase the risk of aspiration (e.g., cognitive dysfunction, spinal cord injury, seizure disorder or other neuromuscular disorder)
    - will be pregnant during the influenza season
  - c. Residence in a nursing home or other chronic-care facility that houses persons of any age who have chronic medical conditions. NYS PHL mandates these patients be screened and vaccinated annually, therefore vaccination history should be obtained from the facility.
  - d. In an occupation or living situation that puts one in proximity to persons at high risk, including
    - a healthcare worker, caregiver, or household member in contact with person(s) at high risk of developing complications from influenza
    - a household contact or out-of-home caretaker of a child age 0–59 months
  - e. Wish to reduce the likelihood of becoming ill with influenza
2. Screen all patients for contraindications and precautions to influenza vaccine:
  - a. **Contraindications:** serious reaction (e.g., anaphylaxis) after ingesting eggs or after receiving a previous dose of influenza vaccine or an influenza vaccine component. For a list of vaccine components, go to [www.cdc.gov/nip/publications/pink/appendices/b/excipient-table-2.pdf](http://www.cdc.gov/nip/publications/pink/appendices/b/excipient-table-2.pdf) Do not give live attenuated influenza vaccine (LAIV) to pregnant women, immunosuppressed persons, or anyone over the age of 49 years. Use of inactivated influenza vaccine is preferred over LAIV for close contacts of severely immunosuppressed persons during periods when the immunocompromised person requires a protective environment.

**Precautions:** moderate or severe acute illness with or without fever

**3 Unknown Vaccination History:** If a patient does not know whether or when he or she has received an influenza vaccination, every attempt should be made to obtain the patient's immunization record. If this is not possible, influenza vaccination may be considered because the risk of complications from influenza disease is high in this group and the immune response will not be impaired with a second dose.

- 4 Provide all patients with a copy of the most current federal Vaccine Information Statement (VIS). You must document in the patient's medical record or office log, 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](http://www.immunize.org/vis)

- 5 Administer 0.5 mL of injectable trivalent inactivated influenza vaccine (TIV) IM (22–25g, 1–1½" needle) in the deltoid muscle. Alternatively, healthy persons ages 5–49 years without contraindications may be given 0.5 mL of intranasal LAIV; 0.25 mL is sprayed into each nostril while the patient is in an upright position.
  
- 6 Document each patient's vaccine administration information and follow up in the following places:
  - a. **Medical chart:** Record the date the vaccine was administered, the manufacturer and lot number, the vaccination site and route, and the name and title of the person administering the vaccine. If vaccine was not given, record the reason(s) for non-receipt of the vaccine (e.g., medical contraindication, patient refusal). According to New York State Education Department (NYSED) nursing practice regulations (<http://www.op.nysed.gov/immunguide.htm>), written consent must be obtained whenever vaccination is administered utilizing non-patient specific standing orders.
  
  - b. **Personal immunization record card:** Record the date of vaccination and the name/location of the administering clinic.
  
  - c. **Patient's primary care provider:** According to the NYSED regulations referenced above, documentation of the patient's vaccination must be shared with the patient's primary care provider.
  
- 7 Be prepared for management of a medical emergency related to the administration of vaccine by having a written emergency medical protocol available, as well as equipment and medications.
  
- 8 Report all adverse reactions to influenza vaccine to the federal Vaccine Adverse Event Reporting System (VAERS) at [www.vaers.hhs.gov](http://www.vaers.hhs.gov) or (800) 822-7967. VAERS report forms are available at [www.vaers.hhs.gov](http://www.vaers.hhs.gov)

This policy and procedure shall remain in effect for all patients of the \_\_\_\_\_  
(name of practice or clinic) until rescinded or until \_\_\_\_\_ (date).

Medical Director's signature: \_\_\_\_\_ Effective date: \_\_\_\_\_

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§ 2805-h. Immunizations. 1. Immunizations against poliomyelitis, mumps, measles, diphtheria and rubella. (a) It shall be the duty of the administrative officer or other person in charge of each hospital to inquire of each person in its care under the age of eighteen, or of a person in parental relation to such person, whether all necessary immunizations have been received for poliomyelitis, mumps, measles, diphtheria and rubella and, if not, to make available such immunizations and a certificate or certificates of such immunizations.

(b) This subdivision shall not apply to children whose parent, parents, or guardian are bona fide members of a recognized religious organization whose teachings are contrary to the practices herein required.

(c) If any physician licensed to practice medicine in this state certifies that such immunization may be detrimental to a child's health, the requirements of this section shall be inapplicable until such immunization is found no longer to be detrimental to the child's health.

2. Immunizations against influenza and pneumococcal. (a) Annually between September first and April first, it shall be the duty of the administrative officer or other person in charge of each general hospital to offer each admitted person age sixty-five or older vaccination against influenza virus. Such officer or person need not offer the vaccination to persons who have already received such vaccine or for whom it is otherwise inappropriate.

(b) It shall be the duty of the administrative officer or other person in charge of each general hospital to offer vaccination against pneumococcal disease to each admitted person age sixty-five or older in the hospital's care. Such officer or person need not offer the vaccination to people who have already received it, are not in need of a booster, or for whom it is otherwise inappropriate.

(c) Each general hospital shall adopt an influenza and pneumococcal immunization policy which shall include, but not be limited to, the following: procedures for identifying persons age sixty-five or older and at the discretion of the facility other individuals at risk; procedures for the offering of immunization against influenza virus, between September first and April first, and pneumococcal disease upon admission or discharge to persons age sixty-five or older; procedures for ensuring that individuals offered immunization or their guardian receive information regarding the risks and benefits of vaccination; a standing order policy approved by the medical director or other

appropriate physician which shall include, but not be limited to, an assessment for contra-indications; and a system for documenting vaccine administration, medical contra-indications, patient refusals and any post-vaccination adverse events.

(d) The commissioner may waive the requirements of this subdivision due to a shortage of influenza and/or pneumococcal vaccine.