

Richard F. Daines, M.D.
CommissionerJames W. Clyne, Jr.
Executive Deputy Commissioner

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To: Health Care Providers, Hospitals, Long Term Care Facilities, and Local Health Departments**From:** NYSDOH Division of Epidemiology

HEALTH ADVISORY:
**UPDATED CLINICAL GUIDANCE FOR HEALTH CARE PROVIDERS
FOR THE 2009-2010 INFLUENZA SEASON**

Please distribute to staff in the Departments of Critical Care, Emergency Medicine, Family Practice, Infection Control, Infectious Disease, Internal Medicine, Laboratory Medicine, Pediatrics, Pulmonary Medicine, and inpatient and outpatient units.

This advisory is for providers seeing patients outside of New York City. For guidance related to providers seeing patients in New York City, see the New York City Department of Health and Mental Hygiene (NYCDOHMH) Advisories at: www.nyc.gov/health/nycmed.

***This advisory includes updated clinical guidance recommendations.
Information that has been revised is highlighted.***

The New York State Department of Health (NYSDOH) is providing the following clinical guidance regarding the 2009-2010 influenza season and the ongoing pandemic of 2009 H1N1 influenza. This advisory updates earlier clinical guidance issued on October 26, 2009; this guidance is based on current information from the Centers for Disease Control and Prevention (CDC) and other sources, and will likely change as additional information becomes available. Please see the NYSDOH website at nyhealth.gov for detailed information on influenza surveillance and reporting, vaccination, infection control, and community mitigation measures.

The **major changes or additions** from previous advisories on 2009 H1N1 influenza are:

- Surveillance update on 2009 H1N1 influenza in New York State (NYS);
- Notice that the 2009 H1N1 influenza vaccine may now be administered to anyone who wishes to receive it;
- Updated oseltamivir dosing instructions for children younger than 1 year of age based on weight;
- Information regarding use of intravenous peramivir under a FDA-issued emergency use authorization (EUA);
- Information about the NYS Antiviral Distribution Program for uninsured and under-insured individuals;
- Clarification of treatment considerations for patients with illness longer than 48 hours;
- Information regarding new 2009 H1N1 influenza resources for obstetric care providers; and
- Information regarding 2009 H1N1 influenza in severely immunosuppressed patients.

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1. Influenza Surveillance Update

The NYSDOH is conducting enhanced surveillance to track influenza activity in NYS for the 2009-2010 influenza season. Since September 1, 2009, 2009 H1N1 influenza has been the predominant influenza strain seen across the state. As predicted, the 2009-2010 influenza season started much earlier than previous influenza seasons, with a sharp increase in all surveillance indicators during the month of October, a high peak of activity in early November, followed by a decline over the past 4 weeks. The November peak was higher than that seen in any previous influenza season to date, representing over a 300% increase in reported positive influenza laboratory tests and hospitalizations compared with the peak of a typical influenza season.

Active surveillance is being conducted at a network of hospitals across NYS. Data collected since October 1, 2009, reveals that among hospitalized patients, the majority have at least one underlying medical condition. The most common underlying medical condition among pediatric patients was asthma (66%), followed by neuromuscular disorder (11%), obesity (7%), chronic cardiovascular conditions (5%), diabetes mellitus (3%), other chronic lung disease (2%), and other chronic metabolic disease (1%). Among adult patients the most common underlying medical conditions were asthma (30%) and other chronic lung disease (30%), followed by diabetes mellitus (26%), chronic cardiovascular conditions (25%), obesity (23%), neuromuscular disorder (13%), other chronic metabolic conditions (12%), and morbid obesity (12%). Nearly all (98%) pediatric and adult patients recovered from their illness. Death occurred in 3 (1.5%) of 200 pediatric cases and 4 (2.7%) of 146 adult cases.

Providers should review regional and state influenza virus surveillance data weekly during the influenza season to determine which types of influenza (A or B) and subtypes of influenza A virus (2009 H1N1, seasonal H1N1 or seasonal H3N2) are currently circulating in their area. This information will help guide clinical management decisions, including the appropriate choice of antiviral medication(s) for empiric therapy. Current information on influenza surveillance data in NYS is available on the NYSDOH public website at: <http://www.nyhealth.gov/diseases/communicable/influenza/surveillance/2009-2010/> or on the NYSDOH Health Commerce System (HCS) at: <https://commerce.health.state.ny.us/hpn/hanweb/flu/sfhome.shtml>.

2. Persons at High Risk for Complications from Influenza

Until further information is available, the same groups at increased risk of seasonal influenza-related complications are considered to be at increased risk for 2009 H1N1 influenza-related complications and include the following:

- Children <5 years, but especially children younger than 2 years old (see Section 7).
- Persons with the following underlying medical conditions:
 - Chronic pulmonary disease, including asthma;
 - Chronic cardiovascular (except isolated hypertension), renal, or hepatic disease;
 - Hematological disorders, including sickle cell disease;
 - Metabolic disorders, including diabetes;
 - Neurologic or neuromuscular disorders that increase the risk for aspiration or compromise the handling of respiratory secretions (e.g., cognitive dysfunction, spinal cord injuries, seizure disorders); or
 - Immunocompromising conditions, including HIV infection, leukemia, lymphoma, Hodgkin's disease, multiple myeloma, generalized malignancy, chronic renal failure, nephrotic syndrome; those receiving immunosuppressive chemotherapy (including corticosteroids); those who have received an organ or bone marrow transplant; and those who have central nervous system fluid leaks.
- Persons <19 years who are receiving long-term aspirin therapy for diseases such as rheumatoid arthritis or Kawasaki disease.
- Pregnant women and women up to 2 weeks postpartum (including following pregnancy loss).
- Residents of nursing homes and other chronic-care facilities.
- Adults ≥65 years.

3. Clinical Assessment

It is not possible to distinguish between seasonal influenza infection, 2009 H1N1 influenza infection, and infections with other respiratory viruses based solely on a patient's clinical presentation. Depending on the clinical test used, influenza testing may not be sensitive or timely enough to assist with initial patient management decisions. There is also the added challenge of differing antiviral resistance patterns of influenza strains, which affects the choice of antiviral treatment. Thus, providers will need to consider several factors when making initial patient management decisions, including:

- Current levels of both seasonal influenza and 2009 H1N1 influenza activity in the community;
- Results of any rapid influenza diagnostic testing, if performed;
- Severity of the patient's illness; and
- Presence of any underlying medical conditions that places the patient at higher risk for complications from influenza.

Clinical Presentation

Clinicians should consider 2009 H1N1 influenza or seasonal influenza infection in the differential diagnosis of any person presenting with an unexplained acute febrile respiratory illness, including:

- ILI (defined as a measured temperature ≥37.8°C [100°F] with cough or sore throat);
- Pneumonia and fever;
- Acute respiratory distress syndrome (ARDS) and fever; or
- Respiratory distress and fever.

Patients with 2009 H1N1 influenza infection are likely to present with symptoms similar to typical, seasonal ILI. In addition to fever, cough, and sore throat, patients with confirmed uncomplicated 2009 H1N1 influenza infection have reported chills, headache, rhinorrhea, shortness of breath, myalgias, fatigue, nausea, abdominal pain, and diarrhea. Providers should keep in mind that, as with seasonal influenza, infants, elderly adults, and persons with compromised immune systems may have atypical

presentations, such as presenting without a fever, sepsis-like syndrome, or an unexplained exacerbation of a chronic lung or heart condition. Algorithms for the triage of adults (>18 years) and children (≤18 years) with ILI are available on the CDC website at: <http://www.cdc.gov/h1n1flu/guidance/>.

4. Reporting Criteria

Community Case Reporting

Physician reporting is focused on patient deaths suspected to be influenza-associated. All physicians should report immediately by telephone to the local health department (LHD) any patient deaths meeting the following reporting criteria:

- Deaths among adult and pediatric patients involving an unexplained acute respiratory febrile illness.
- Deaths among adult and pediatric patients suspected or confirmed to have 2009 H1N1 influenza.
- Deaths among pediatric patients suspected or confirmed to be related to any type of influenza (2009 H1N1 influenza or seasonal influenza).

For all pediatric deaths, the LHD will coordinate with the coroner or medical examiner to facilitate appropriate follow-up, including an autopsy examination and submission of specimens for testing at the NYSDOH Wadsworth Center and/or CDC. The LHD may also request clinical information about the deceased patient for completion of a case report for submission to the NYSDOH. While autopsies may be requested, consent is generally required.

For adult deaths, there is no longer a need to conduct routine autopsies for influenza surveillance. The LHD may request clinical information about the deceased patient for completion of a case report for submission to the NYSDOH. Autopsy can be considered if the case presented with unusual disease processes (based on clinical judgment) prior to death. If an autopsy is done and reveals unusual pathologic findings, submission of specimens for further testing at the NYSDOH Wadsworth Center will be considered on a case-by-case basis.

Providers should also continue to report patients with milder ILI who are part of a community outbreak (especially patients who are from congregate facilities such as group homes and day care settings). A community outbreak is generally defined as a cluster of illness above baseline among epidemiologically linked cases. The LHD will determine if an investigation or further follow-up is indicated. If there are difficulties reaching the LHD, the provider should contact the NYSDOH. During business hours, call 518-473-4439; after hours, call 1-866-881-2809.

Health Care Facility Outbreak Reporting

In addition to the reporting criteria above, NYSDOH-regulated health care facilities must report to the NYSDOH any instance of nosocomial transmission of influenza, including:

- A single nosocomial case of confirmed influenza in a facility patient/resident or staff member
- Clusters of ILI among health care workers and patients/residents of a facility (defined as two or more cases on the same unit within 7 days)

Reports should be submitted via the Nosocomial Outbreak Reporting Application (NORA) system located on the Health Provider Network (HPN) at: <https://commerce.health.state.ny.us/hpn/infecontrol/forms.html>. The appropriate NYSDOH Regional Epidemiology office or NYCDOHMH office will follow-up with the facility making the report.

For questions regarding nosocomial reporting, please contact the appropriate NYSDOH Regional Epidemiology office as listed at: http://www.health.state.ny.us/professionals/diseases/reporting/communicable/infection/regional_epi_staff.htm or the NYCDOHMH Influenza Surveillance Coordinator at (212) 442-9050 or (212) 788-4150. To reach the NYSDOH after hours, call 1-866-881-2809.

5. Influenza Diagnostic Testing in Patients with Suspected Influenza

There are several types of laboratory diagnostic tests that can be used for detecting the presence of influenza viruses in respiratory specimens, including rapid influenza diagnostic tests (RIDTs), direct immunofluorescence assays (DFAs), viral culture, and nucleic acid amplification tests such as real-time reverse transcriptase-polymerase chain reaction (rRT-PCR). These tests differ in their sensitivity and specificity in detecting influenza viruses, the amount of time needed from specimen collection until results are available, and the tests' ability to distinguish between different influenza virus types and subtypes.

RIDTs have low to moderate sensitivity (range 10-70%) for both seasonal and 2009 H1N1 influenza compared to rRT-PCR. Thus, a negative rapid test result does not rule out influenza virus infection.

Clinicians should not withhold treatment based on a negative rapid test result. Since false negative results can occur, if clinical suspicion of influenza is high in a patient who tests negative by RIDT (or if RIDT is not offered), early, empiric antiviral therapy should be administered, if appropriate. (See Section 8 on antiviral treatment for further details). Additional information on the use of RIDTs is at: http://www.cdc.gov/h1n1flu/guidance/rapid_testing.htm.

Definitive testing for 2009 H1N1 requires rRT-PCR or viral culture. Testing is now available to NYS patients at several commercial and hospital laboratories, a list of which can be found at: http://www.health.state.ny.us/diseases/communicable/influenza/h1n1/health_care_providers/guidance/where_to_obtain_h1n1_testing.htm.

Public health laboratory testing for 2009 H1N1 influenza is reserved primarily for surveillance purposes, but is available for special clinical circumstances on a case-by-case basis, such as where antiviral susceptibility testing may be indicated (e.g., immunosuppressed patients, failure to respond to antiviral therapy, or development of illness while on antiviral therapy). Such cases should be reported to the LHD, where staff will review the case and discuss appropriate testing with the NYSDOH.

Patients hospitalized with an acute febrile respiratory illness

Providers should consider laboratory testing for influenza by commercially available tests (RIDT; DFA; rRT-PCR; or culture). **Providers should take into consideration the limitations of the diagnostic test used and antiviral treatment should not wait for laboratory confirmation of influenza.**

Since a negative RIDT or DFA test result does not exclude influenza virus infection, hospitalized patients with a negative RIDT or DFA result should have priority for further testing with a nucleic acid amplification test, such as rRT-PCR, if influenza infection is clinically suspected. Testing and treatment for bacterial pathogens and other respiratory viruses should be conducted as appropriate. In addition, patient deaths meeting the reporting criteria outlined in Section 4 should be reported to the LHD for possible further testing.

High-risk patients with milder influenza illness in the outpatient setting

Providers may also consider commercially available influenza testing for high-risk patients in the outpatient setting who have milder ILI symptoms if it will provide useful information that affects the care of these patients. Providers should take into consideration the limitations of the diagnostic test used.

Antiviral treatment should not wait for laboratory confirmation of influenza.

Patients with mild illness and not at high risk for complications from influenza

For these patients, influenza testing is usually not indicated because testing will not influence treatment decisions.

6. Patients with Mild Illness

Health care providers should advise people with mild influenza symptoms **not** to go to the emergency department. Patients with mild illness may not need to be seen in the office. These patients can be screened by phone, prescribed antiviral medications if indicated (e.g., if the patient is at high risk for influenza complications), given symptomatic treatment recommendations, and instructed to contact their health care provider if more serious symptoms develop or if no improvement **within 72 hours**.

Patients with mild illness should be provided with educational information about preventing influenza transmission and advised to stay home until at least 24 hours after they are free of fever (100° F [37.8°C]), or signs of a fever without the use of fever-reducing medications. Guidance for taking care of a sick person in the home can be found at: <http://www.cdc.gov/h1n1flu/homecare/>.

7. Antiviral Treatment for Influenza

Prompt, empiric antiviral treatment is **recommended** for:

- Patients **hospitalized** with confirmed or suspected influenza.
- Patients with suspected or confirmed influenza who are **severely ill** or who are **showing evidence of rapid clinical deterioration**. Signs and symptoms of severe illness due to suspected influenza are an indication for immediate treatment, regardless of previous health or age.
- Outpatients who are at **higher risk for influenza-related complications** (see Section 2 for a list of high-risk conditions). Clinical judgment should be used in deciding whether outpatients with risk factors for influenza-related complications require treatment.

Treatment should be started empirically based on clinical judgment as early as possible and providers should not wait for laboratory confirmation of influenza as treatment is most effective when started in the first 48 hours of illness. For patients with severe disease and/or who are at high risk for complications, treatment can be initiated at any point (even beyond 48 hours of illness), but is most effective earlier in the course of illness. Recommended duration of treatment is 5 days. Hospitalized patients with severe infection may require longer treatment courses.

Clinical judgment is an important factor in treatment decisions. Persons without any underlying medical conditions who present with an uncomplicated febrile illness can be considered for antiviral treatment if initiated within 48 hours after illness onset, but the benefits may be modest. However, any suspected influenza patient who presents with emergency warning signs (e.g., difficulty breathing or shortness of breath) or signs of lower respiratory tract illness should promptly receive antiviral therapy.

People who are already recovering from influenza do not need antiviral medications for treatment. Options for close follow-up should be carefully considered. Clinicians who prefer not to treat empirically should discuss signs and symptoms of worsening illness with such patients and arrange for follow-up at least by telephone.

Since no vaccine is 100% effective, a history of receipt of 2009 H1N1 vaccine or seasonal influenza vaccine does not rule out influenza infection. Early empiric treatment should be initiated for persons with suspected influenza, when indicated, regardless of the individual's influenza vaccination status. **People who are vaccinated with live attenuated influenza vaccines (LAIV) and who are given antiviral drugs within 48 hours before or up to 2 weeks after vaccination may not develop immunity and should be revaccinated.**

Infants and Young Children

Children younger than 2 years of age are at higher risk for influenza-related complications and have a higher rate of hospitalization compared to older children. Given this increased risk for hospitalization,

children younger than 2 years old are recommended for antiviral treatment. **The oseltamivir dosing instructions for children younger than 1 year of age recently changed to weight-based dosing. See Appendix 1, Table 2.**

Children 2 to 4 years old are more likely to require hospitalization or urgent medical evaluation for influenza compared with older children, although the risk is much lower than for children younger than 2 years old. Children aged 2 years to 4 years without high-risk conditions (see Section 2) and with mild illness do not necessarily require antiviral treatment. Health care providers should use clinical judgment to guide treatment decisions.

Choice of Antiviral Medication for Treatment

Health care providers need to make decisions about which antiviral medication to use for treatment by taking into consideration the influenza activity in NYS and the antiviral susceptibility patterns of the circulating strains. Evidence from the southern hemisphere suggests that 2009 H1N1 influenza virus will remain the dominant influenza strain this season. However, health care providers should review their regional and state influenza virus surveillance data weekly to determine which types (influenza A or B) and subtypes of influenza A virus (2009 H1N1 influenza, seasonal H1N1 influenza, or seasonal H3N2 influenza) are currently circulating in the area (See Section 1 for surveillance information).

The following recommendations are based on antiviral susceptibility patterns current as of December 2009.

- The neuraminidase inhibitors, oseltamivir or zanamivir should be used to treat individuals with 2009 influenza A (H1N1), influenza A (H3N2), or influenza B.
 - For the treatment of pregnant women and women who are up to 2 weeks postpartum (regardless of pregnancy outcome), oseltamivir is preferred due to its systemic activity.
- Zanamivir should be used to treat individuals with seasonal influenza A (H1N1).
 - Rimantadine can be used for patients who cannot receive zanamivir (e.g., patient is <7 years old, has chronic underlying pulmonary disease, or cannot use the zanamivir inhalation device), or if zanamivir is unavailable.
 - Amantadine can be substituted for rimantadine if rimantadine is unavailable.
- Zanamivir or a combination of oseltamivir and rimantadine should be used if:
 - The patient's subtype information is not available **and** multiple influenza strains are circulating including seasonal influenza A (H1N1), or
 - Influenza surveillance information is not available or unknown.
 - Use of zanamivir or combination therapy with oseltamivir and rimantadine will provide effective treatment against all possible circulating influenza viruses.

See Appendix 1 for antiviral medication dosing recommendations, Appendix 2 for antiviral drug sensitivities of influenza strains that may circulate during the 2009-2010 influenza season, and Appendix 3 for a summary table of recommendations for the selection of antiviral medications based on influenza surveillance data.

Note that zanamivir is not recommended for patients with underlying pulmonary disease, such as asthma or chronic obstructive pulmonary disease. Some experts recommend the use of increased (doubled doses) of oseltamivir for some severely ill patients, although there are no published data on its effectiveness. Dosages of some antiviral medications may need to be adjusted for persons age 65 years and older, persons with impaired renal function, or persons with liver disease. Clinicians should consult the package insert of each antiviral medication for additional dosing information, contraindications/warnings/precautions, and adverse effects.

A third neuraminidase inhibitor, peramivir, formulated for intravenous (IV) administration is an investigational product currently being evaluated in clinical trials. The FDA issued an EUA for treatment with peramivir of hospitalized patients with 2009 H1N1 influenza who have potentially life-threatening suspected or laboratory-confirmed infection.

- Peramivir IV is available through the CDC upon request of a licensed physician at: <http://www.cdc.gov/h1n1flu/eua/peramivir.htm>.
- Under the EUA, treatment of adult patients with IV peramivir is approved only if:
 1. The patient has not responded to either oral or inhaled antiviral therapy;
 2. Drug delivery by a route other than IV is not expected to be dependable or is not feasible;
 - or
 3. The clinician judges IV therapy is appropriate due to other circumstances.
- Treatment of pediatric patients is approved if either of the first two criteria apply (see www.cdc.gov/h1n1flu/eua/peramivir.htm).

8. Antiviral Chemoprophylaxis for Influenza

Post-exposure prophylaxis can be considered for persons who are at high risk for influenza complications and who had close contact with a person with influenza during the ill person's infectious period (defined as 1 day prior to onset of symptoms until 24 hours after fever ends). (See Section 2 for a list of high-risk conditions.) When chemoprophylaxis is indicated, antiviral medication should be initiated as soon as possible following the exposure and should continue for 10 days following the last known exposure to influenza. Chemoprophylaxis generally is not recommended if more than 48 hours have elapsed since the last contact with an infectious person. Patients given post-exposure chemoprophylaxis should be informed that the chemoprophylaxis lowers but does not eliminate the risk of influenza and that protection stops when the medication course is stopped. Patients receiving chemoprophylaxis should be encouraged to seek medical evaluation as soon as they develop a febrile respiratory illness that might indicate influenza.

Early Treatment as an Alternative to Chemoprophylaxis

As an alternative to chemoprophylaxis, health care providers may choose to counsel exposed people at higher risk of influenza complications about the signs and symptoms of influenza and advise them to immediately contact their health care provider if signs or symptoms develop. Health care providers should use clinical judgment regarding situations where early recognition of illness and treatment might be an appropriate alternative. Providers may choose to give the exposed patient a prescription for an influenza antiviral and may want to request that the patient contact the provider if signs or symptoms of influenza develop, obtain antiviral medications as quickly as possible, and start treatment.

Choice of Antiviral Medication for Chemoprophylaxis

Persons who are candidates for post-exposure chemoprophylaxis should be provided with medications most likely to be effective against the influenza virus that is the cause of the close contact's illness, if known. Health care providers should also be aware of state influenza activity and antiviral susceptibility patterns of the circulating strains (see *Choice of Antiviral Medication* in Section 7).

9. Other Treatment and Prophylaxis Issues

Oseltamivir-Resistant 2009 H1N1 Influenza

To date, there have been sporadic reports of persons with oseltamivir-resistant 2009 H1N1 influenza virus infection. These reports have typically occurred among persons who developed illness while receiving oseltamivir for chemoprophylaxis or immunocompromised patients with influenza who were being treated. Since these reports are rare, the CDC's interim recommendations for the treatment and chemoprophylaxis of 2009 H1N1 influenza have not changed and oseltamivir continues to be an option. Inappropriate use of oseltamivir for chemoprophylaxis could contribute to the increased development of oseltamivir resistance among 2009 H1N1 influenza viruses. Antiviral agents for chemoprophylaxis

should be used judiciously; chemoprophylaxis should be reserved for persons at high risk for influenza complications who have been exposed to a person with influenza.

Severely Immunosuppressed Patients

CDC recently released clinical guidance for clinicians regarding 2009 H1N1 influenza in severely immunosuppressed patients, including information on clinical issues, vaccination, diagnostic testing, antiviral treatment, and antiviral resistance. This guidance can be found at: http://www.cdc.gov/h1n1flu/immunosuppression/index.htm?s_cid=ccu122109_immunosuppression_e

NYS Antiviral Distribution Program for Uninsured and Under-Insured Individuals

Effective December 7, 2009, the NYSDOH, in cooperation with pharmacy and other healthcare partners, has activated a program to provide affordable antiviral medications to members of the public that otherwise could not afford its retail cost. This effort involves the distribution of antiviral medication to retail pharmacies, certain federally qualified health centers, and a limited number of other health clinics within the 57 counties of NYS (outside of NYC). Uninsured and under-insured patients who are deemed by a clinician to require antiviral treatment (oseltamivir or zanamivir) for influenza may acquire these medications at no charge with the exception of a \$5.00 dispensing fee. Individuals that cannot afford this fee may request that it be waived. Detailed information about this program is available at: http://www.nyhealth.gov/diseases/communicable/influenza/h1n1/public/free_antiviral_medicines/2009-12-04_h1n1_antivirals_notice_to_provider.htm.

Pregnant Women

CDC has updated resources for obstetric care providers specific to 2009 H1N1 influenza in pregnant women which can be found at: http://www.cdc.gov/h1n1flu/clinician_pregnant.htm. CDC has also established a support line (404-368-2133) staffed 24 hours/7 days to provide clarification on CDC guidance for pregnant women via telephone consultation with board-certified obstetricians.

An algorithm for the assessment and treatment of pregnant women with ILI is available on the American College of Obstetricians and Gynecologists (ACOG) website at: <http://www.acog.org/departments/resourceCenter/2009H1N1TriageTreatment.pdf>.

10. Influenza Vaccination

Seasonal Influenza Vaccination

Providers are strongly encouraged to vaccinate their patients with seasonal flu vaccine as soon as possible, especially those who are at high risk for influenza complications. The usual seasonal influenza viruses are still expected to cause illness this winter and spring; vaccinating patients with seasonal vaccine is not only an important prevention strategy, it may help reduce the overall burden on the health care system during the influenza season. Information on seasonal influenza vaccine can be found at: <http://www.cdc.gov/flu/professionals/acip/index.htm>

2009 H1N1 Influenza Vaccination

When it first became available in October 2009, the CDC recommended five priority groups for vaccination. These groups included:

- Pregnant women;
- People who live with or care for children younger than 6 months of age;
- Health care and emergency medical services personnel;
- Persons between the ages of 6 months and 24 years old; and
- People ages of 25 through 64 years of age who are at higher risk for complications from 2009 H1N1 infection because of chronic health disorders or compromised immune systems.

As of December 10, 2009, NYS suspended the requirement that the 2009 H1N1 influenza vaccine be restricted to the ACIP priority groups. Therefore, the 2009 H1N1 influenza vaccine can now be administered to anyone who wishes to receive it. Health care providers should still focus on the priority groups, but providers should not pass up an opportunity to vaccinate anyone who wishes to receive it if vaccine is available.

The H1N1 vaccine is as safe and effective as the ordinary seasonal flu vaccine and is developed using the same process as seasonal vaccine. Flu vaccines have consistently had excellent safety records in recent decades, as documented in multi-year studies. The CDC issued a report December 4 on the safety of the H1N1 vaccines that found no substantial differences between the safety of the H1N1 vaccines and that of seasonal flu vaccines (see: <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5848a4.htm>). Public health officials continue to emphasize that getting the vaccine is much safer than getting the flu.

All medical providers that would like to order vaccine must be registered. To register please go to the NYSDOH website and follow the H1N1 links to the registration page. If you are already registered, please call the NYSDOH Vaccine Call Center at 1-800-KID-SHOT (or 1-800-543-7468) to place an order on your assigned day.

11. Pneumococcal Vaccination

During influenza outbreaks, pneumococcal vaccines may be useful in preventing secondary pneumococcal infections and reducing illness and death. Currently, two vaccines are available for prevention of pneumococcal disease, a 23-valent pneumococcal polysaccharide vaccine (PPSV23) and a 7-valent pneumococcal conjugate vaccine (PCV7).

CDC's ACIP recommends a single dose of PPSV23 for all people 65 years and older and for persons 2 to 64 years of age with certain high-risk conditions. A single revaccination at least five years after initial vaccination is recommended for: 1) people 65 years and older who were first vaccinated before age 65 years, and 2) people at highest risk, such as those who have no spleen, and those who have HIV infection, AIDS, or malignancy. Patients who have existing indications for PPSV23 should continue to be vaccinated according to current ACIP recommendations. PPSV23 may be administered on the same day as any of the influenza vaccines. Use of PPSV23 among people without current indications for vaccination is not recommended at this time.

PCV7 is recommended for all children up to 59 months of age. Health care providers should continue to vaccinate this population according to current ACIP recommendations. For more information about recommendations for use of pneumococcal vaccines, please see: http://www.cdc.gov/h1n1flu/guidance/ppsv_h1n1.htm.

12. Additional Information

The NYSDOH will provide updated guidance as information and recommendations become available. For additional information on this evolving situation, please refer to the following websites:

- New York State Department of Health: nyhealth.gov
- New York City Department of Health and Mental Hygiene: nyc.gov/flu
- U.S. Department of Health and Human Services (manager): flu.gov
- Centers for Disease Control and Prevention: <http://cdc.gov/h1n1flu/>
- National Library of Medicine: <http://sis.nlm.nih.gov/enviro/swineflu.html>
- Infectious Diseases Society of America: <http://www.idsociety.org/Content.aspx?id=14220>
- World Health Organization: <http://www.who.int/en/>

Influenza Antiviral Medication Dosing Recommendations

Table 1: Antiviral medication dosing recommendations for adults and children 12 months of age and older

Agent, group		Treatment (5 days)	Chemoprophylaxis (10 days)
Neuraminidase inhibitors			
Oseltamivir			
Adults		75 mg capsule twice per day	75 mg capsule once per day
Children (age 12 months or older) by weight	≤15 kg	60 mg per day divided into 2 doses	30 mg once per day
	15-23 kg	90 mg per day divided into 2 doses	45 mg once per day
	24-40 kg	120 mg per day divided into 2 doses	60 mg once per day
	>40 kg	150 mg per day divided into 2 doses	75 mg once per day
Zanamivir			
Adults		Two 5 mg inhalations (10 mg total) twice per day	Two 5 mg inhalations (10 mg total) once per day
Children		Two 5 mg inhalations (10 mg total) twice per day (age, 7 years or older)	Two 5 mg inhalations (10 mg total) once per day (age, 5 years or older)
Adamantanes¹			
Rimantadine²			
Adults		200 mg per day, either as a single daily dose or divided into 2 doses	200 mg per day, either as a single daily dose or divided into 2 doses
Children (age, 1-9 years)		6.6 mg/kg per day (maximum, 150 mg per day) divided into 2 doses	5 mg/kg per day once daily, not to exceed 150 mg
Children (age, 10 years and older)		200 mg per day, either as a single daily dose or divided into 2 doses	200 mg per day, either as a single daily dose or divided into 2 doses
Amantadine			
Adults		200 mg per day, either as a single daily dose or divided into 2 doses	200 mg per day, either as a single daily dose or divided into 2 doses
Children (age, 1-9 years)		5-8 mg/kg per day divided into 2 doses or as a single daily dose (maximum, 150 mg per day)	5-8 mg/kg per day divided into 2 doses or as a single daily dose (maximum, 150 mg per day)
Children (age, 10-12 years)		200 mg per day divided into 2 doses	200 mg per day divided into 2 doses

(Table 1 adapted from Infectious Diseases Society of America guidelines for seasonal influenza)

¹ Adamantanes should be used only in situations where seasonal H1N1 influenza infection or exposure is suspected.

² Rimantadine has not been approved by the US Food and Drug Administration (FDA) for treatment of influenza of children, but published data exist on safety and efficacy in the pediatric population.

Clinicians should consult the package insert of each antiviral medication for specific dosing information, approved indications and ages, contraindications/warnings/precautions, and adverse effects.

Table 2: Oseltamivir medication dosing recommendations for children less than 12 months of age¹

Agent, group		Treatment (5 days)	Chemoprophylaxis (10 days)
Oseltamivir			
Children (age 0 to <12 months)	<3 months ²	3 mg/kg/dose twice daily	Not recommended unless situation judged critical due to limited data on use in this age group
	3 to < 12 months ³	3 mg/kg/dose twice daily	3 mg/kg/dose once per day

Source: <http://www.fda.gov/downloads/Drugs/DrugSafety/InformationbyDrugClass/UCM153546.pdf>

¹ Oseltamivir use for children < 12 months old was approved in April 2009 by the U.S. Food and Drug Administration (FDA) under an Emergency Use Authorization (EUA) in response to the 2009 H1N1 influenza outbreak. Dosing for children <12 months is weight-based. Health care providers should be aware of the lack of data on safety and dosing when considering oseltamivir use in young infants, and carefully monitor infants for adverse events when oseltamivir is used.

² Current weight-based dosing recommendations are not intended for premature infants. Premature infants may have slower clearance of Tamiflu due to immature renal function, and doses recommended for full term infants may lead to very high drug concentrations in this age group. Very limited data from a cohort of premature infants receiving an average dose of 1.7 mg/kg twice daily demonstrated drug concentrations higher than those observed with the recommended treatment dose in term infants (3 mg/kg twice daily). Observed drug concentrations were highly variable among premature infants. These data are insufficient to recommend a specific dose of Tamiflu for premature infants.

³ Weight-based dosing is preferred. However, if weight is not known, dosing by age for treatment (give two doses per day) or prophylaxis (give one dose per day) of influenza in full-term infants younger than 1 year of age may be necessary:

0-3 months (treatment only) = 12 mg (1 mL of 12 mg/mL commercial suspension) twice daily
 3-5 months (treatment) = 20 mg (1.6 mL of 12 mg/mL of commercial suspension) twice daily
 3-5 months (prophylaxis) = 20 mg (1.6 mL of 12 mg/mL of commercial suspension) once daily
 6-11 months (treatment) = 25 mg (2 mL of 12 mg/mL commercial suspension) twice daily
 6-11 months (prophylaxis) = 25 mg (2 mL of 12 mg/mL commercial suspension) once daily

Antiviral drug sensitivities of influenza strains expected to circulate during the 2009-2010 influenza season

Influenza Strain (2009-2010)	Amantadine (Symmetrel) Rimantadine (Flumadine)	Oseltamivir (Tamiflu)	Zanamivir (Relenza)
Seasonal influenza A (H1N1) virus (A/Brisbane/59/2007)	Susceptible	Resistant	Susceptible
2009 influenza A (H1N1) virus	Resistant	Susceptible	Susceptible
Seasonal influenza A (H3N2) virus (A/Brisbane/10/2007)	Resistant	Susceptible	Susceptible
Seasonal influenza B (B/Brisbane 60/2008, Victoria lineage)	Not effective	Susceptible	Susceptible

Source: American Academy of Pediatrics Committee on Infectious Diseases:
Recommendations for Prevention and Control of Influenza in Children, 2009-2010

Appendix 3

Interim recommendations for the selection of antiviral medications using viral surveillance data¹

Influenza virus(es) in the community	Preferred medication(s)
2009 influenza A (H1N1) and/or Influenza A (H3N2) and/or Influenza B	Oseltamivir or Zanamivir
Seasonal influenza A (H1N1)	Zanamivir or Rimantadine ²
Multiple influenza types/subtypes, <u>including seasonal H1N1</u> , are circulating or Surveillance data unknown or not available	Zanamivir or Combination oseltamivir and rimantadine ²

¹If rapid influenza diagnostic testing is performed and is positive for influenza B, infection with influenza B virus is likely. Treatment with either oseltamivir or zanamivir is appropriate, regardless of other circulating strains in the community.

²Amantadine can be substituted for rimantadine, but has increased risk of adverse events.

Clinicians should consult the package insert of each antiviral medication for specific dosing information, approved indications and ages, contraindications/warnings/precautions and adverse effects.