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To: Healthcare Providers, Hospitals, Laboratories, Local Health Departments

From: NYSDOH Bureau of Communicable Disease Control

HEALTH ADVISORY: UPDATE #5

NOVEL INFLUENZA A (H1N1) VIRUS INFECTION

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

The New York State Department of Health (NYSDOH) is providing this update regarding the ongoing epidemic of novel influenza A (H1N1) virus (previously referred to as swine-origin influenza virus) nationwide and in New York State (NYS). The guidance in this advisory is intended 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.

The changes in this advisory include:

- New information about the World Health Organization's decision to raise the worldwide pandemic alert level to Phase 6, indicating that a global pandemic is underway.
- Updated surveillance information about influenza activity in NYS which shows that influenza continues to circulate at levels that are higher than normal for this time of year and the predominant circulating strain is novel influenza A (H1N1).
- Updated information about patients who are at high risk for complications due to novel influenza A (H1N1) infection.
- Updated reporting criteria that focus on patients with severe illness, patients who are part of a community or healthcare facility outbreak, and deaths among persons with novel influenza A (H1N1) infection or an unexplained febrile respiratory illness.
- Decreased emphasis on laboratory testing of patients with milder influenza-like illness (ILI) who are at high risk for complications due to influenza.
- Increased emphasis on early, empiric antiviral treatment of hospitalized patients with acute febrile respiratory illness and patients with milder ILI who are at high risk for complications from influenza.
- Revised algorithm on the testing, treatment, reporting, and prophylaxis for patients with ILI. The revised algorithm contains additional information on reporting and prophylaxis.

This interim information is based on currently available information and will likely change as additional information becomes available. This update is current as of June 16, 2009, and should replace all previously released NYSDOH novel influenza A (H1N1) updates.

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1. Background

Since April 2009, the Centers for Disease Control and Prevention (CDC) has been working with the World Health Organization (WHO), state, city, and local officials to conduct an ongoing investigation of an outbreak of human cases of novel influenza A (H1N1) infection. This is a novel influenza A virus that has not been identified in people before, and human-to-human transmission of the virus appears to be ongoing into the summer months. As of June 12, 2009, over 17,800 confirmed and probable cases of novel influenza A (H1N1) infection have been reported in the United States.

On June 11, 2009, the WHO raised the worldwide pandemic alert level to Phase 6 in response to the ongoing global spread of the novel influenza A (H1N1) virus. A Phase 6 designation indicates that a global pandemic is underway. The decision to raise the pandemic alert level to Phase 6 was based on the spread of novel influenza A (H1N1) virus, not the severity of illness caused by the virus. It is not known at this time how severe this novel influenza A (H1N1) pandemic will be in terms of how many people infected will develop serious complications from infection. However, because novel influenza A (H1N1) is a new virus, many people may have little or no immunity against it, and illness may be more severe and widespread.

Influenza continues to circulate in NYS at levels that appear higher than normal for this time of year. The majority of the influenza viruses recently subtyped at the NYSDOH Wadsworth Center have been novel influenza A (H1N1) viruses, with much lower levels of seasonal influenza viruses detected. Of the 282 positive influenza specimens subtyped at Wadsworth Center between May 17 and June 6, 2009, 89% were novel influenza A (H1N1), 9% were seasonal influenza A (H3N2), 2% were seasonal influenza A (H1N1), and 0.4% were seasonal influenza B. A statewide weekly influenza surveillance report can be found 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 Novel Influenza A (H1N1)

It is not known at this time how severe novel influenza A (H1N1) will be in the general population as the pandemic evolves. However, early indications are that pregnancy and other previously recognized medical conditions that increase the risk of seasonal influenza-related complications, like asthma and diabetes, also appear to be associated with increased risk of complications from novel H1N1 virus infection as well.

Unlike what is seen for seasonal influenza, adults older than 64 years do not appear to be at increased risk of novel H1N1-related complications thus far in the outbreak. Also, the largest number of novel influenza A (H1N1) confirmed and probable cases have occurred in people between the ages of 5 and 24 years old. Studies are underway to see if individuals might have natural immunity to novel influenza A (H1N1) virus, depending on their age. Early reports indicate that no children and few adults younger than 60 years old have existing antibody to the novel influenza A (H1N1) virus; however, about one-third of adults older than 60 may have antibodies against this virus. It is unknown how much, if any, protection may be afforded against the novel influenza A (H1N1) by any existing antibody.

Until further information is available, the same groups at increased risk of seasonal influenza-related complications are considered to be at increased risk for novel H1N1-related complications. These high-risk groups include:

- Children <5 years.
- Persons with the following underlying medical conditions:
 - Chronic pulmonary disease, including asthma;
 - Chronic cardiovascular (except 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; or
 - Immunosuppression, including that caused by medications or by HIV.
- Persons <19 years who are receiving long-term aspirin therapy for diseases such as rheumatoid arthritis or Kawasaki disease.
- Pregnant women.
- Residents of nursing homes and other chronic-care facilities.
- Adults ≥65 years (the classification of this group as high risk for novel H1N1-related complications may be subject to change based on accumulating epidemiologic information).

3. *Clinical Assessment*

In all clinical settings, patients should be screened for signs and symptoms of febrile respiratory illness at the initial point of contact, and these patients should be promptly segregated and assessed. Clinicians should consider novel influenza A (H1N1) infection in the differential diagnosis of any person presenting with an unexplained acute febrile respiratory illness, including influenza-like illness (defined as a measured temperature $\geq 37.8^{\circ}\text{C}$ [100°F] with cough or sore throat), or fever and: pneumonia, acute respiratory distress syndrome (ARDS), or respiratory distress. See page 10 for an algorithm that summarizes the following reporting, testing, treatment and prophylaxis recommendations for patients with influenza-like illness (ILI) in NYS.

Patients with novel influenza A (H1N1) infection are likely to present with symptoms of typical ILI. In addition to fever, cough and sore throat, patients with confirmed uncomplicated novel influenza A (H1N1) infection have reported chills, headache, rhinorrhea, shortness of breath, myalgias, fatigue, and to a lesser extent, 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 (due to inability to mount a fever response), hypothermia, or sepsis-like syndrome.

It is expected that most patients will recover uneventfully from novel influenza A (H1N1) infection. However, for some patients, illness may progress rapidly and may be complicated by pneumonia or ARDS. Preliminary data from the CDC has shown that most of the patients with novel influenza A (H1N1) infection who developed pneumonia have had findings consistent with viral pneumonia, rather than a secondary bacterial infection.

4. Reporting Criteria

Community Case Reporting

Now that novel influenza A (H1N1) activity has been documented in regions throughout NYS, public health surveillance efforts are focused on patients with severe illness or those who are part of an outbreak in a defined group (see below). Physicians should report immediately by telephone to the local health department (LHD) any patients meeting the following reporting criteria:

- Patients hospitalized with an acute febrile respiratory illness (ILI; fever and: pneumonia, ARDS, or respiratory distress).
- Patients with milder ILI who are part of a community outbreak (especially patients who are from congregate facilities such as group homes, day care settings, camps). A community outbreak is generally defined as a cluster of illness above baseline among epidemiologically linked cases.
- Unexplained deaths involving an unexplained acute respiratory febrile illness.
- Deaths among patients confirmed to have novel influenza A (H1N1).

The LHD will determine if testing for novel influenza A (H1N1) is indicated (see section below on novel influenza A (H1N1) confirmatory testing criteria). 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.

Healthcare Facility Outbreak Reporting

In addition to the reporting criteria above, any healthcare facility outbreak of suspected novel influenza A (H1N1) infection should be reported directly to the NYSDOH. During business hours, call the NYSDOH Regional Epidemiologist; after hours, call 1-866-881-2809. See page 8 for definitions related to a healthcare facility outbreak.

5. Influenza Laboratory Testing Recommendations

Laboratory testing for influenza by commercially available tests (rapid antigen testing [EIA], immunofluorescence [DFA or IFA], or PCR) is *strongly recommended* for patients hospitalized with an acute febrile respiratory illness (ILI; fever and: pneumonia, ARDS, or respiratory distress). These patients should also be reported to the LHD to assess the need for novel influenza A (H1N1) testing at a public health laboratory (see section below on novel influenza A (H1N1) confirmatory testing for further details). Providers may also consider commercially available influenza testing for certain high-risk patients in the outpatient setting who have mild ILI symptoms.

Laboratory testing for influenza by commercially available tests may help inform decisions regarding the management of patients with an acute febrile respiratory illness. However, providers should be aware that the sensitivity of rapid testing is poor for both seasonal and novel influenza A (H1N1). Negative results do not rule out influenza in patients with compatible illness. However, a positive influenza A test at this time is likely to be novel H1N1 infection, although seasonal influenza A viruses continue to be identified. Immunofluorescence and PCR testing are more sensitive than rapid testing, but are usually only available through commercial diagnostic laboratories and thus results are often not immediately available.

Due to these laboratory testing limitations, providers should not rely on influenza test results and should initiate early, empiric antiviral treatment for all hospitalized patients with suspected novel influenza A (H1N1). In addition, providers should initiate early antiviral treatment for outpatients who are at high risk for complications from influenza (see section below on antiviral treatment for further details).

6. Novel Influenza A (H1N1) Confirmatory Testing Criteria

Currently in NYS, only public health laboratories can perform the testing needed to **confirm** novel influenza A (H1N1). Testing for novel influenza A (H1N1) will only be conducted on specimens from

patients who have been reported to the local or State health department and approved for testing in advance of specimen submission. Testing for novel influenza A (H1N1) is currently prioritized for patients who are hospitalized and/or part of a community or healthcare facility outbreak. The LHD and NYSDOH will work closely with hospitals and providers to determine which specimens should be submitted to a public health laboratory for confirmatory testing.

7. *Patients with Mild Illness*

Patients with mild illness AND who have no underlying medical conditions that place them at higher risk of complications from influenza may not need to be seen in the office. These patients or their parents can be screened by phone, given symptomatic treatment recommendations, and instructed to contact their physician for any signs of worsening severity of illness. For typical clinical management purposes, patients with mild illness who have no underlying medical conditions should NOT be tested for influenza because screening tests will not influence treatment decisions.

Exposure to novel influenza A (H1N1) virus alone is not an indication for hospital or emergency room referral. Patients with serious illness should be further evaluated; the most appropriate setting for the evaluation of a severely ill patient may be the hospital emergency room. Do **NOT** send patients to an emergency department unless you believe hospital admission may be warranted.

Patients with mild illness should be provided with educational information about preventing influenza transmission and advised to stay home for 7 days after symptom onset or until they are symptom-free for 24 hours, whichever is longer. Guidance for taking care of a sick person in the home can be found at: http://www.cdc.gov/h1n1flu/guidance_homecare.htm.

8. *Antiviral Treatment for Novel Influenza A (H1N1) Virus*

Antiviral treatment is **recommended** for the following patients:

- Patients hospitalized with confirmed, probable or suspected novel influenza A (H1N1) virus infection.
- Patients with milder presentations of suspected novel influenza A (H1N1) virus infection AND who are at high risk for influenza complications. In particular, providers should keep in mind that persons with asthma are at high risk for complications due to influenza and should receive early antiviral treatment with oseltamivir.

Antiviral treatment with zanamivir or oseltamivir should be initiated as soon as possible (ideally within 48 hours) after the onset of symptoms. For patients with severe disease, treatment can be initiated at any point, but is most effective earlier in the course of illness. Recommended duration of treatment is 5 days. Novel influenza A (H1N1) is sensitive (not resistant) to the neuraminidase inhibitors, oseltamivir and zanamivir, and resistant (not sensitive) to the adamantanes, amantadine and rimantadine. Note that zanamivir is not recommended for patients with underlying pulmonary disease, such as asthma or chronic obstructive pulmonary disease. See Tables 1 and 2 on page 9 for novel influenza A (H1N1) antiviral medication dosing recommendations.

These antiviral recommendations are based on current influenza surveillance information that indicates very little seasonal influenza is circulating in NYS at this time. Antiviral treatment recommendations for seasonal influenza may differ and can be found at: <http://www.cdc.gov/flu/professionals/antivirals/index.htm>.

Clinical judgment is an important factor in treatment decisions. Persons with suspected novel influenza A (H1N1) infection who present with an uncomplicated febrile illness typically do not require treatment unless they are at higher risk for influenza complications. For most of these patients without any underlying medical conditions, the benefits of using antivirals may be modest.

9. Antiviral Chemoprophylaxis for Novel Influenza A (H1N1) Virus

Post-exposure prophylaxis *should be considered* for the persons who are at high risk for influenza complications and who had close contact with a person with confirmed, probable, or suspected novel influenza A (H1N1) virus infection. When chemoprophylaxis is indicated, either oseltamivir or zanamivir should be initiated as soon as possible following the exposure and should continue for **10 days** following the last known exposure to novel influenza A (H1N1) virus infection. Note that zanamivir is not recommended for patients with underlying pulmonary disease, such as asthma or chronic obstructive pulmonary disease. See Tables 1 and 2 on page 9 for novel influenza A (H1N1) antiviral medication dosing recommendations.

Providers should take into account the patient's infectious period when making decisions regarding antiviral prophylaxis. The infectious period for persons infected with the novel influenza A (H1N1) virus is assumed to be similar to seasonal influenza. With seasonal influenza, studies have shown that people may be able to transmit infection beginning one day before they develop symptoms to up to 7 days after they get sick or 24 hours after resolution of symptoms, whichever is longer. Children, especially younger children, may be infectious for longer periods. However, for this guidance, the *infectious period* is defined as one day before until 7 days after the case's onset of illness. If the contact occurred with a case whose illness started more than 7 days before contact with the person under consideration for antivirals, then chemoprophylaxis may not be indicated.

10. Infection Control Recommendations

Due to evidence that novel influenza A (H1N1) is comparable to seasonal influenza in its spectrum of illness and transmission pattern and does not appear to be causing unusual mortality compared to seasonal influenza, NYSDOH continues to recommend that infection control measures for novel influenza A (H1N1) be similar to those taken for seasonal influenza, with exceptions noted below. NYSDOH guidance in healthcare settings differs from current CDC guidance. However, NYSDOH guidance is consistent with the most current scientific evidence available and is consistent with that distributed by the NYCDOHMH and other state health departments.

Efforts to maximize adherence to recommendations for seasonal influenza, including meticulous respiratory hygiene and cough etiquette, should be practiced in all medical facilities. This includes the placement of a surgical facemask on all patients with febrile respiratory illness in all patient settings, in order to reduce the spread of the virus to health care workers and patients. These infection control recommendations apply to ALL patients with influenza, including confirmed or probable novel influenza A (H1N1), or with febrile respiratory illness.

Inpatient settings and hospital emergency departments

- Healthcare facilities should establish mechanisms to screen patients for signs and symptoms of febrile respiratory illness at any point of entry to the facility. Continue to advise patients with fever and acute respiratory symptoms, such as cough or sore throat, to notify the triage nurse immediately. Patients with these complaints should be placed in a single room with closed door if possible, or asked to wait at least 3-6 feet away from other people. The patient should be asked to wear a surgical mask as tolerated and to perform hand hygiene.
- Use STANDARD and DROPLET precautions for routine medical care of patients with confirmed or probable novel influenza A (H1N1), or febrile respiratory illness. Negative pressure airborne infection isolation rooms (AIIRs) and N95 respirators are no longer recommended for routine patient care for patients with novel influenza A (H1N1) or febrile respiratory illness.
- Aerosol-generating procedures (e.g., nebulized treatments, bronchoscopy, intubation and extubation, and deep open tracheal suctioning) should be performed, when feasible, in a

- negative pressure AIIR. Fit-tested N95 respirators and eye protection (goggles or face shield) should be worn by health care personnel performing these procedures.
- Any patient with febrile respiratory illness should be placed in a private room for medical care whenever possible.
 - Patients should wear a surgical facemask when outside their room or when being transferred.
 - Healthcare workers examining, caring for, or obtaining nasal, nasopharyngeal or pharyngeal specimens from patients with probable or confirmed novel influenza A (H1N1) or febrile respiratory illness should wear a surgical facemask.
 - **Hand hygiene is absolutely essential** and should be performed before and after patient care, and before donning and after removal of a surgical facemask. Fit-tested N95 masks and eye protection (goggles or face shields) are *not* necessary *except* for aerosol-generating procedures as described above.
 - Nebulized treatments for patients with febrile respiratory illness should be provided in a private room with closed door if at all possible or 6 feet apart at a minimum if a private room is not available. If private rooms are limited, reserve the private rooms for patients with febrile respiratory disease. If no private room is available, use a curtain or other barrier between patients who are in the same room when performing nebulized treatments.
 - Visitors should be asked to perform hand hygiene before entering and after exiting the patient's room and advised to wear a surgical facemask while in the room with the patient.

Clinics, medical offices or other ambulatory care settings

- Patients with febrile respiratory illness in outpatient settings should be asked to wear a surgical facemask, as tolerated, upon entry, while waiting, and while being examined and cared for.
- Staff who have close contact, including examining or providing direct medical care for the patient with febrile respiratory illness, should wear a surgical facemask and gloves, and should put the facemask on ideally before entering the room.
- Staff should be instructed to perform hand hygiene and put their facemask on first followed by gloves. When patient care is complete, remove gloves first then facemask, and perform hand hygiene.
- If a nasopharyngeal swab or other respiratory specimen is being collected, the patient should be instructed to remove the facemask briefly for specimen collection, then replace the mask as soon as the specimen is obtained.
- Meticulous hand hygiene should be performed before and after removal of PPE and before and after patient care.

All staff working in hospital or medical office settings should be instructed NOT to work if they are ill. If they become ill while working, they should be instructed to cease patient care and go home immediately and follow their facility's employee health policies. While waiting to go home, they should be asked to wear a surgical facemask and to sit away from other staff and patients.

11. 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: <http://www.nyhealth.gov>
- New York City Department of Health and Mental Hygiene: www.nyc.gov/health/nycmed
- Centers for Disease Control and Prevention: <http://www.cdc.gov/flu/swine/investigation.htm>
- National Library of Medicine: <http://sis.nlm.nih.gov/enviro/swineflu.html>
- World Health Organization: <http://www.who.int/en/>

Definitions

Illness Definitions:

An *influenza-like illness (ILI)* is defined as an illness characterized by a documented fever $\geq 37.8^{\circ}\text{C}$ ($\geq 100^{\circ}\text{F}$) and cough and/or sore throat in the absence of another cause.

An *acute febrile respiratory illness* is defined as an illness characterized by an influenza-like illness; or fever and: pneumonia, acute respiratory distress syndrome (ARDS), or respiratory distress in the absence of another cause.

Novel Influenza A (H1N1) Case Definitions:

A *confirmed case* of novel influenza A (H1N1) infection is defined as a person with an acute febrile respiratory illness with laboratory confirmed novel influenza A (H1N1) infection by real-time RT-PCR and/or viral culture.

A *probable case* of novel influenza A (H1N1) infection is defined as a person with an acute febrile respiratory illness who is positive for influenza A, but negative for H1 and H3 by influenza RT-PCR.

A *suspected case* of novel influenza A (H1N1) infection is defined as a person with an unexplained acute febrile respiratory illness (influenza-like illness; or documented fever $\geq 37.8^{\circ}\text{C}$ [$\geq 100^{\circ}\text{F}$] and: pneumonia, ARDS, or respiratory distress in the absence of another cause).

Cluster or Outbreak Definitions by Type of Location:

A *healthcare facility (HCF) outbreak* is defined as follows:

- For long-term care facilities only
 - Two or more cases of acute febrile respiratory illness or a single laboratory confirmed/probable case of novel influenza A (H1N1) in a resident
- For all other healthcare settings
 - Acute febrile respiratory illness in a patient or healthcare worker after known HCF-setting exposure to a confirmed, probable, or suspect case of novel influenza A (H1N1) and no other exposures (e.g., community exposures) that would place them in the suspect case category.
 - Laboratory confirmed/probable test result in a HCF patient whose onset of acute febrile respiratory illness is seven or more days AFTER admission to the hospital.

A *community outbreak* is generally defined as a cluster of illness above baseline among epidemiologically linked cases.

Novel Influenza A (H1N1) Antiviral Medication Dosing Recommendations

Table 1: Novel influenza A (H1N1) antiviral medication dosing recommendations for adults and children \geq 12 months (table from Infectious Disease Society of America guidelines for seasonal influenza)

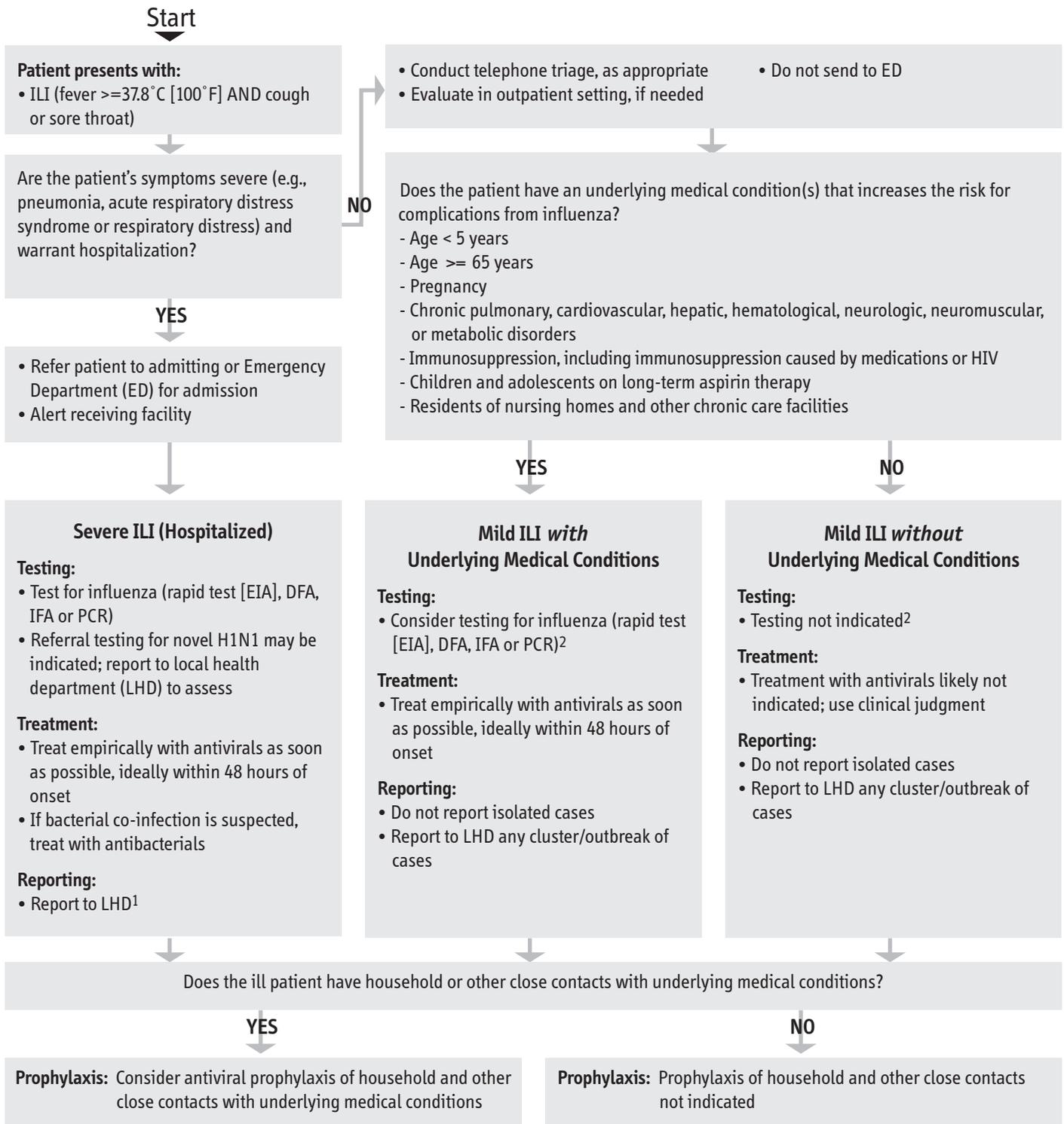
Agent, group		Treatment (5 days)	Chemoprophylaxis (10 days)
Oseltamivir			
Adults		75 mg capsule twice per day	75 mg capsule once per day
Children (age 12 months or older*) by weight	\leq 15 kg	60 mg per day divided into 2 doses	30 mg once per day
	15-23 kg	90 mg per day divided into 2 doses	45 mg once 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)

Table 2: Novel influenza A (H1N1) antiviral medication dosing recommendations for children $<$ 12 months*

Agent, group		Treatment (5 days)	Chemoprophylaxis (10 days)
Oseltamivir			
Children (age $<$ 12 months)	$<$ 3 months	12 mg twice daily	Not recommended unless situation judged critical due to limited data on use in this age group
	3-5 months	20 mg twice daily	20 mg once daily
	6-11 months	25 mg twice daily	25 mg once daily

* Oseltamivir use for children $<$ 12 months old was recently approved by the U.S. Food and Drug Administration (FDA) under an Emergency Use Authorization (EUA) and dosing for these children is age-based. Healthcare providers should be aware of the lack of data on safety and dosing when considering oseltamivir use in a seriously ill young infant with confirmed novel influenza A (H1N1) or who has been exposed to a confirmed case of novel influenza A (H1N1), and carefully monitor infants for adverse events when oseltamivir is used.

Testing, Treatment, Reporting and Prophylaxis Decision Algorithm for Patients with Influenza-Like Illness (ILI) in New York State



¹Also report any unexplained deaths involving an acute febrile respiratory illness or any deaths among patients with confirmed novel H1N1 infection.

²If the case is part of a community outbreak, the LHD may request specimens for novel H1N1 testing.