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**New York State Department of Health (NYSDOH)
Clinical Guidance for Assessment, Testing, and Treatment of
Novel Influenza A (H1N1) Virus in Children
May 27, 2009**

Please note: This guidance 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.

All children <5 years (and especially those <2 years) and children ≥ 5 years with chronic medical conditions are at increased risk for complications from seasonal influenza. Preliminary information suggests children with chronic medical conditions, especially asthma, are at increased risk for complications from novel influenza A (H1N1) infection. Thus, until further information becomes available, the same age and risk groups who are at higher risk for seasonal influenza complications should be considered at higher risk for novel influenza A (H1N1) complications.

Chronic medical conditions that place children at high risk include:

- Pulmonary conditions (including asthma)
- Cardiovascular conditions (except hypertension)
- Chronic kidney and liver disease
- Hematological disorders (including sickle cell disease)
- Neurologic conditions (including intellectual and developmental disability, cerebral palsy, spinal cord injuries, seizure disorders, or other neuromuscular disorders)
- Metabolic disorders (including diabetes mellitus)
- Immunosuppression (including that caused by medications or HIV/AIDS)
- Pregnancy
- Long-term aspirin therapy for chronic disorders

Clinical Assessment

Clinicians should consider novel influenza A (H1N1) virus in the differential diagnosis of any child presenting with fever (a measured temperature $\geq 37.8^{\circ}\text{C}$ [100°F]) and influenza-like illness (cough or sore throat).

Patients with confirmed uncomplicated novel influenza A (H1N1) disease have experienced fever, chills, headache, cough, sore throat, rhinorrhea, shortness of breath, myalgias, arthralgias, fatigue, vomiting, or diarrhea. The estimated incubation period is unknown but is likely to range from 1-7 days, and more likely 1-4 days.

Infants and very young children with influenza may not present with typical symptoms of cough or other respiratory symptoms. Often, their only symptoms may be fever and/or lethargy. The presence of influenza in the community should heighten clinical diagnostic suspicion. **In high-risk children, early recognition of possible influenza-like illness and rapid initiation of presumptive antiviral treatment are highly recommended, regardless of pending influenza testing results.**

Local Testing Recommendations

The following pediatric patients should be tested locally for influenza A by commercially available rapid antigen testing or immunofluorescence (DFA or IFA):

- Children hospitalized for acute febrile respiratory illness (fever and influenza-like illness (ILI), pneumonia, ARDS, or respiratory distress).
- Non-hospitalized children who have ILI and who are at high-risk for severe disease.

Because influenza testing takes time and the rapid test for influenza is not sensitive for the detection of seasonal or novel influenza A (H1N1), providers should initiate early, empiric antiviral treatment for all hospitalized pediatric patients with acute febrile respiratory illness. In addition, providers should initiate early antiviral treatment for patients who are at high risk for complications from influenza with less severe illness who are being treated as outpatients with ILI (see section below on antiviral treatment for further details).

Confirmatory Testing Criteria

Currently in New York State, 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 health department and approved for testing in advance of specimen submission.

The following pediatric patients should be reported to the local health department to determine whether testing for novel influenza A (H1N1) is indicated:

- All children hospitalized with acute febrile respiratory illness (fever and ILI, pneumonia, ARDS, or respiratory distress) who test positive for influenza A or who test positive for influenza but typing is not available.
- All children hospitalized with acute febrile respiratory illness who test influenza negative or are not tested but are highly suspicious for novel influenza A (H1N1).
- Children with ILI who are part of a cluster (especially children who are from congregate facilities such as group homes, day care settings, camps, and pediatric long-term care facilities).

Mild Illness

Pediatric patients with mild illness AND who have no underlying medical conditions that place them at higher risk of complications from influenza need not 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. Those patients with mild illness should be provided with educational information about preventing influenza transmission and advised to be kept home from school or daycare for 7 days after symptom onset or until they are symptom-free for 24 hours, whichever is longer. For typical clinical management purposes, **pediatric 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. Pediatric patients with serious illness should be further evaluated; the most appropriate setting for the evaluation of a severely ill pediatric patient may be the hospital emergency room. Do **NOT** send patients to an emergency department unless you believe hospital admission may be warranted.

Antiviral Treatment for Novel Influenza A (H1N1) Virus

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

1. All children hospitalized with suspected novel influenza A (H1N1) virus.
2. All children <5 years with suspected mild or severe infection with novel influenza A (H1N1) virus.
3. Children ≥5 years with suspected mild or severe infection with novel influenza A (H1N1) virus AND who are high risk for influenza complications. In particular, providers should keep in mind that children 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 contraindicated in patients with underlying pulmonary disease, such as asthma. Antiviral treatment recommendations for seasonal influenza may differ and can be found at: <http://www.cdc.gov/flu/professionals/antivirals/index.htm>.

Table 1: Summary of testing and treatment recommendations for pediatric patients with suspect novel influenza A (H1N1) virus

	Mild Illness		Severe Illness	
	TEST?	TREAT?	TEST?	TREAT?
High-risk medical conditions that increase complications of influenza	YES	Recommended	YES	Recommended
NO high-risk medical conditions that increase complications of influenza	TEST?	TREAT?	TEST?	TREAT?
	NO	Clinical judgment	YES	Recommended

Antiviral Chemoprophylaxis for Novel Influenza A (H1N1) Virus

Prophylaxis for children >3 months is **recommended** for the following patients:

1. All children <5 years who are close contacts of a person with confirmed probable, or suspected novel influenza A (H1N1) virus.
2. Children ≥5 years who are high risk for influenza complications and who are close contacts of a person with confirmed, probable, or suspected novel influenza A (H1N1) virus. In particular, providers should keep in mind that children with asthma are at high risk for complications due to influenza.

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 contraindicated in patients with underlying pulmonary disease, such as asthma. Antiviral chemoprophylaxis recommendations for seasonal influenza may differ and can be found at: <http://www.cdc.gov/flu/professionals/antivirals/index.htm>.

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.

Table 2: Novel influenza A (H1N1) virus antiviral medication dosing recommendations
(Table extracted from Infectious Disease Society of America guidelines for seasonal influenza)

Agent, group	Treatment (5 days)		Chemoprophylaxis (10 days)
Oseltamivir			
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			
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 3: Novel influenza A (H1N1) virus 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 FDA under an Emergency Use Authorization (EUA).

Emergency Use Authorization (EUA)

The Food and Drug Administration (FDA) has authorized use of oseltamivir for young children under EUA procedures. In addition, the EUA also allows the use of oseltamivir and zanamivir at later time points (i.e., patients who are symptomatic for **more than 2 days**) and/or in patients **sick enough to require hospitalization (severe illness)**.

When a national emergency is declared by the Secretary of the United States Department of Health and Human Services (DHHS), the FDA Commissioner can authorize the use of an unapproved medical product or an unapproved use of a licensed medical product. Once issued, an EUA is active for one year but may be terminated earlier if the DHHS Secretary determines that it is no longer needed. EUA requirements include record keeping, distribution of information sheets to providers and patients, and adverse event reporting. EUA procedures are described in the FDA draft guidance “Emergency Use Authorization of Medical Products” available on the FDA website at: www.fda.gov/cber/gdlns/emerase.pdf.

Oseltamivir use for children <12 months old was approved by the FDA under an 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 seriously ill young infants and carefully monitor infants for adverse events when oseltamivir is used.

Adverse Reactions to Antiviral Therapy

Health care professionals and consumers may report serious adverse events (side effects) with the use of these products or product quality problems to the FDA’s MedWatch Adverse Event Reporting program by calling 1-800-FDA-1088 or online at: <https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm> or by submitting a MedWatch Form 3500 (available at: http://www.fda.gov/medwatch/safety/FDA-3500_fillable.pdf) via mail to MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787 or fax to 1-800-FDA-0178.

Advice to Parents

Advice for parents with ill children

Parents should be instructed to get medical care immediately if their child shows any of the following signs:

- difficulty breathing, grunts or retractions of the skin over the ribs with inhalation
- purple or blue discoloration of the lips
- vomiting and is unable to keep liquids down
- a lack of tears when they cry
- seizures / convulsions
- decreased alertness or becomes lethargic and floppy

For symptomatic relief, aspirin and aspirin containing compounds should not be used because of their association with Reye Syndrome in the setting of influenza infection. Acetaminophen or a pediatric non-steroidal anti-inflammatory medication may be used instead. Nursing mothers (when well or ill) should continue to nurse the ill child.

Persons caring for an infected young child should keep their children home from school and daycare and limit the child's contact with others (including children) to decrease the spread of the illness. Children should be kept home for 7 days after their symptoms began or until they are symptom-free for 24 hours, whichever is longer. Additional guidance for care of ill persons at home can be found on the Centers for Disease Control and Prevention (CDC) website at: http://www.cdc.gov/h1n1flu/guidance_homecare.htm.

Advice for parents of well children who are at high-risk for complications from influenza infection

In communities with high levels of novel influenza A (H1N1) activity, parents of non-ill children who are at high risk of complications from influenza infection should consider keeping their child away from crowded settings and public gatherings.