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Comisión de Epidemiología

## NOTA TECNICA N 10

### Nueva Influenza A (H1N1) y embarazo. Parte II

A continuación les presentamos la segunda nota técnica sobre la nueva Influenza A (H1N1) y embarazo, el primer artículo de los CDC, enfatiza que las embarazadas en general, incluyendo a las infectadas con VIH, tienen mayor riesgo de complicaciones asociadas a la nueva Influenza A (H1N1), en tal sentido los CDC recomiendan tratamiento antiviral específico con Oseltamivir en toda mujer gestante con diagnóstico sospechoso, probable o confirmado de la nueva Influenza. Revisa además las complicaciones que se pueden presentar en estas pacientes y realiza recomendaciones sobre el amamantamiento. El segundo artículo del MMWR, presenta tres casos de Influenza A (H1N1) en mujeres embarazadas que ameritaron hospitalización y donde una de las gestantes falleció; en esta paciente tanto el diagnóstico como la terapéutica fueron realizados tardíamente.

Dra. Ana Carvajal

Comisión de Epidemiología

RSCMV

May 21, 2009 **Attention: HIV-infected pregnant women are at risk of potentially serious disease due to influenza viruses. The Centers**

**for Disease Control and Prevention (CDC) recommends that pregnant women, including HIV-infected pregnant women, with confirmed, probable, or suspected novel influenza A (H1N1) infection receive antiviral therapy with oseltamivir (Tamiflu).**

## **Pregnant Women and Novel Influenza A (H1N1): Considerations for Clinicians**

### **Summary**

Pregnancy raises risk for complications related to seasonal as well as pandemic influenza infections such as those caused by the novel influenza A (H1N1) virus. The CDC has recently summarized information about novel H1N1 infection during pregnancy and has issued preliminary treatment recommendations, shown below (May 7, 2009 4:35 PM ET URL: [http://www.cdc.gov/h1n1flu/clinician\\_pregnant.htm](http://www.cdc.gov/h1n1flu/clinician_pregnant.htm)).

Twenty cases of novel H1N1 (15 confirmed and 5 probable) in pregnant women have been reported in the U.S. as of May 10, 2009. Three women were hospitalized, and one of them died. Based on available data, the CDC recommends that pregnant women with confirmed, probable, or suspected novel H1N1 infection receive antiviral therapy with oseltamivir (Tamiflu; preferred for its systemic absorption) for 5 days. Therapy should be initiated as soon as possible, even if more than 48 hours have elapsed since symptom onset. Acetaminophen should also be administered, as fevers are associated with adverse maternal and fetal outcomes. Pregnant women who have had close contact with someone who has confirmed, probable, or suspected novel H1N1 infection should receive prophylaxis with either oseltamivir or zanamivir (Relenza) for 10 days.

Both the [Advisory Committee on Immunization Practices](#) and the [American College of Obstetricians and Gynecologists](#) recommend annual influenza vaccination for all pregnant women. However, because the 2008–2009 seasonal vaccine does not protect against novel H1N1, even vaccinated pregnant women with flu-like symptoms should be evaluated and treated. Although the safety and efficacy of oseltamivir during pregnancy have not been firmly established, the benefits of this antiviral drug are likely to outweigh the risks. Novel H1N1 seems to be resistant to amantadine and rimantadine, so these drugs should not be used in people with suspected novel H1N1 infection.

### **Background**

Human infections with a novel influenza A (H1N1) virus that is easily transmissible among humans were first identified in April 2009. The epidemiology and clinical presentations of these infections are currently under investigation. There are insufficient data available at this point to determine who at higher risk for complications of novel influenza A (H1N1) virus infection. However, it's reasonable to assume that the same age and risk groups who are at higher risk for

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seasonal influenza complications also should be considered at higher risk for novel influenza A (H1N1) complications.

Evidence that influenza can be more severe in pregnant women comes from observations during previous pandemics and from studies among pregnant women who had seasonal influenza. An excess of influenza-associated excess deaths among pregnant women were reported during the pandemics of 1918–1919 and 1957–1958. Adverse pregnancy outcomes have been reported following previous influenza pandemics, with increased rates of spontaneous abortion and preterm birth reported, especially among women with pneumonia. Case reports and several epidemiologic studies conducted during interpandemic periods also indicate that pregnancy increases the risk for influenza complications for the mother and might increase the risk for adverse perinatal outcomes or delivery complications.

#### **Clinical presentation**

Pregnant women with novel influenza A (H1N1) virus would be expected to present with typical acute respiratory illness (e.g., cough, sore throat, rhinorrhea) and fever or feverishness. Many pregnant women will go on to have a typical course of uncomplicated influenza. However, for some pregnant women, illness might progress rapidly, and might be complicated by secondary bacterial infections including pneumonia. Fetal distress associated with severe maternal illness can occur. Pregnant women who have suspected novel influenza A (H1N1) virus infection should be tested, and specimens from women who have unsubtypeable influenza A virus infections should have specimens sent to the state public health laboratory for additional testing to identify novel influenza A (H1N1).

#### **Treatment and chemoprophylaxis**

The currently circulating novel influenza A (H1N1) virus is sensitive to the neuraminidase inhibitor antiviral medications zanamivir (Relenza ) and oseltamivir (Tamiflu ), but is resistant to the adamantane antiviral medications, amantadine (Symmetrel ) and rimantadine (Flumadine ). Pregnant women who meet current case-definitions for confirmed, probable or suspected novel influenza A (H1N1) infection should receive empiric antiviral treatment. Pregnant women who are close contacts with persons with suspected, probable or confirmed cases of novel influenza A (H1N1) should receive chemoprophylaxis.

As is recommended for other persons who are treated, antiviral treatment with zanamivir or oseltamivir should be initiated as soon as possible after the onset of influenza symptoms, with benefits expected to be greatest if started within 48 hours of onset, based on data from studies of seasonal influenza. However, some data from studies on seasonal influenza indicate benefit for hospitalized patients even if treatment is started more than 48 hours after onset. Recommended duration of treatment is five days, and for chemoprophylaxis is 10 days. Oseltamivir and zanamivir treatment and chemoprophylaxis regimens recommended for pregnant women are the same as those recommended for adults who have seasonal influenza. Recommendations for use of antivirals for pregnant women might change as data on antiviral susceptibilities become available.

One of the more well-studied adverse effects of influenza is its associated hyperthermia. Studies have shown that maternal hyperthermia during the first trimester doubles the risk of neural tube defects and may be associated with other birth defects and adverse outcomes. Limited data suggest that the risk for birth defects associated with fever might be mitigated by antipyretic medications or multivitamins that contain folic acid. Maternal fever during labor has been shown to be a risk factor for adverse neonatal and developmental outcomes, including neonatal seizures, encephalopathy, cerebral palsy, and neonatal death. Even though distinguishing the

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effects of the cause of fever from the hyperthermia itself is difficult, fever in pregnant women should be treated because of the risk that hyperthermia appears to pose to the fetus. Acetaminophen appears to be the best option for treatment of fever during pregnancy, although data on even this common exposure are also limited.

Pregnancy should not be considered a contraindication to oseltamivir or zanamivir use. Pregnant women might be at higher risk for severe complications from novel influenza A (H1N1), and the benefits of treatment or chemoprophylaxis with zanamivir or oseltamivir likely outweigh the theoretical risks of antiviral use. Oseltamivir and zanamivir are "Pregnancy Category C" medications, indicating that no clinical studies have been conducted to assess the safety of these medications for pregnant women. Because of the unknown effects of influenza antiviral drugs on pregnant women and their fetuses, oseltamivir or zanamivir should be used during pregnancy only if the potential benefit justifies the potential risk to the embryo or fetus. Although a few adverse effects have been reported in pregnant women who took these medications, no relation between the use of these medications and those adverse events has been established. Because of its systemic activity, oseltamivir is preferred for treatment of pregnant women. The drug of choice for prophylaxis is less clear. Zanamivir may be preferable because of its limited systemic absorption; however, respiratory complications that may be associated with zanamivir because of its inhaled route of administration need to be considered, especially in women at risk for respiratory problems.

Table 1. Antiviral medication dosing recommendations for treatment or chemoprophylaxis of novel influenza A (H1N1) infection. (Table extracted from [IDSA guidelines for seasonal influenza.](#))

Agent, Group	Treatment		Chemoprophylaxis
<b>Oseltamivir (Tamiflu)</b>			
<b>Adults</b>	75-mg capsule twice per day for 5 days		75-mg capsule once per day
<b>Children ≥ 12 months</b>	15 kg or less	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
	<b>Zanamivir</b>		
<b>Adults</b>	Two 5-mg inhalations (10 mg total) twice per day	Two 5-mg inhalations (10 mg total) once per day	Two 5-mg inhalations (10 mg total) once per day
<b>Children</b>	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)	Two 5-mg inhalations (10 mg total) once per day (age, 5 years or older)

**Other ways to reduce risk for pregnant women**

There is no vaccine available yet to prevent novel influenza A (H1N1); however, the risk for novel influenza A (H1N1) might be reduced by taking steps to reduce the chance of being exposed to respiratory infections. These actions include frequent hand washing, covering coughs, and having ill persons stay home except to seek medical care, and minimize contact with others in the household. Additional measures that can limit transmission of a new influenza strain include voluntary home quarantine of members of households with

confirmed or probable novel influenza A (H1N1) cases, reduction of unnecessary social contacts, and avoidance whenever possible of crowded settings. If used correctly, facemasks and respirators may help reduce the risk of getting influenza, but they should be used along with other preventive measures, such as avoiding close contact and maintaining good hand hygiene. A respirator that fits snugly on the face can filter out

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small particles that can be inhaled around the edges of a facemask, but compared with a facemask it is harder to breathe through a respirator for long periods of time.

#### **Breastfeeding considerations**

Infants who are not breastfeeding are particularly vulnerable to infection and hospitalization for severe respiratory illness. Women who deliver should be encouraged to initiate breastfeeding early and feed frequently. Ideally, babies should receive most of their nutrition from breast milk. Eliminate unnecessary formula supplementation, so the infant can receive as much maternal antibodies as possible.

If a woman is ill, she should continue breastfeeding and increase feeding frequency. If maternal illness prevents safe feeding at the breast, but she can still pump, encourage her to do so. The risk for novel influenza A (H1N1) transmission through breast milk is unknown. However, reports of viremia with seasonal influenza infection are rare.

Expressed milk should be used for infants too ill to feed at the breast. In certain situations, infants may be able to use donor human milk from a HMBANA-certified milk bank.

Antiviral medication treatment or prophylaxis is not a contraindication for breastfeeding.

Instruct parent and caretakers on how to protect their infant from the spread of germs that cause respiratory illnesses like novel influenza A (H1N1):

- Wash adults' and infants' hands frequently with soap and water, especially after infants place their hands in their mouths.
- Keep infants and mothers as close together as possible and encourage early and frequent skin-to-skin contact between mothers and their infants.
- Limit sharing of toys and other items that have been in infants' mouths. Wash thoroughly with soap and water any items that have been in infants' mouths.
- Keep pacifiers (including the pacifier ring/handle) and other items out of adults' or other infants' mouths prior to giving to the infant.
- Practice cough and sneeze etiquette.

#### **Citation**

Centers for Disease Control and Prevention (CDC). Novel influenza A (H1N1) virus infections in three pregnant women — United States, April–May 2009. *MMWR Morb Mortal Wkly Rep* 2009 May 15; 58:497. (URL: <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm58d0512a1.htm>).

Pregnant Women and Novel Influenza A (H1N1): Considerations for Clinicians

## **Novel Influenza A (H1N1) Virus Infections in Three Pregnant Women --- United States, April--May 2009**

CDC first identified cases of respiratory infection with a novel influenza A (H1N1) virus in the United States on April 15 and 17, 2009 (1). During seasonal influenza epidemics and previous pandemics, pregnant women have been at increased risk for complications related to influenza infection (2--5). In addition, maternal influenza virus infection and accompanying hyperthermia place fetuses at risk for complications such as birth defects and preterm birth (6). As part of surveillance for infection with the novel influenza A (H1N1) virus, CDC initiated surveillance for pregnant women who were infected with the novel virus. As of May 10,

a total of 20 cases of novel influenza A (H1N1) virus infection had been reported among pregnant women in the United States, including 15 confirmed cases and five probable cases.\* Among the 13 women from seven states for whom data are available, the median age was 26 years (range: 15--39 years); three women were hospitalized, one of whom died. This report provides preliminary details of three cases of novel influenza A (H1N1) virus infection in pregnant women. Pregnant women with confirmed, probable, or suspected novel influenza A (H1N1) virus infection should receive antiviral treatment for 5 days. Oseltamivir is the preferred treatment for pregnant women, and the drug regimen should be initiated within 48 hours of symptom onset, if possible. Pregnant women who are in close contact with a person with confirmed, probable, or suspected novel influenza A (H1N1) infection should receive a 10-day course of chemoprophylaxis with zanamivir or oseltamivir.

## Case Reports

**Patient A.** On April 15, a woman aged 33 years at 35 weeks' gestation with a 1-day history of myalgias, dry cough, and low-grade fever was examined by her obstetrician-gynecologist. She had been in relatively good health and had been taking no medications other than prenatal vitamins, although she had a history of psoriasis and mild asthma. The patient had not recently traveled to Mexico. Rapid influenza diagnostic testing performed in the physician's office was positive.

On April 19, she was examined in a local emergency department, with worsening shortness of breath, fever, and productive cough. She experienced severe respiratory distress, with an oxygen saturation of approximately 80% on room air and a respiratory rate of approximately 30 breaths per minute. A chest radiograph revealed bilateral nodular infiltrates. The patient required intubation and was placed on mechanical ventilation. On April 19, an emergency cesarean delivery was performed, resulting in a female infant with Apgar scores of 4 at 1 minute after birth and of 6 at 5 minutes after birth; the infant is healthy and has been discharged home. On April 21, the patient developed acute respiratory distress syndrome (ARDS). The patient began receiving oseltamivir on April 28. She also received broad-spectrum antibiotics and remained on mechanical ventilation. The patient died on May 4.

On April 25, a nasopharyngeal swab specimen collected from patient A indicated an unsubtypable influenza A strain by real-time reverse transcription--polymerase chain reaction (rRT-PCR) at the San Antonio Metro Health Laboratory. The specimen was forwarded to the Virus Surveillance and Diagnostic Branch Laboratory, Influenza Division, CDC, where testing was inconclusive for novel influenza A (H1N1) virus. On April 30, a repeat nasopharyngeal specimen was collected, which was positive by rRT-PCR for novel influenza A (H1N1) virus at CDC.

**Patient B.** A previously healthy woman aged 35 years at 32 weeks' gestation was seen at a local emergency department on April 20 with a 1-day history of shortness of breath, fever, cough, diarrhea, headache, myalgias, sore throat, and inspiratory chest pain. She was febrile (101.6°F [38.7°C]), with a heart rate of 128 beats per minute, respiratory rate of 22 breaths per minute, and oxygen saturation of >97% on room air. A chest radiograph was normal. Rapid influenza diagnostic testing was negative. The patient received a parenteral nonsteroidal anti-inflammatory medication, acetaminophen, and inhaled albuterol and was discharged home. She was evaluated the following day in her obstetrician-gynecologist's office, where a nasopharyngeal swab sample was collected and sent for rRT-PCR testing. The patient received antibiotics, anti-nausea medication, acetaminophen, and an inhaled corticosteroid. The patient recovered fully, and her pregnancy is proceeding normally.

Patient B had been in Mexico during the 3 days preceding her arrival at the emergency department. Several family members in Mexico and the United States had recently been ill with influenza-like illness, and her sister had been hospitalized for pneumonia during the preceding week. Testing of the nasopharyngeal swab specimen from patient B collected on April 21 was identified as an unsubtypable influenza A strain by rRT-

PCR testing at the Naval Health Research Laboratory in San Diego. Additional testing at CDC confirmed infection with novel influenza A (H1N1) virus.

**Patient C.** On April 29, a woman aged 29 years at 23 weeks' gestation was experiencing cough, sore throat, chills, subjective fever, and weakness of 1 day's duration and was seen at the family practice clinic where she had been receiving prenatal care. The patient had a history of asthma but was not taking any asthma medications. Her son, aged 10 years, reportedly had similar symptoms the week before the onset of her symptoms. Another son, aged 7 years, had become ill on the same day as his mother and accompanied her to the clinic. At the clinic, the younger son was coughing vigorously and was asked to put on a mask by office staff members. Rapid influenza diagnostic testing in the family practice clinic of a nasopharyngeal sample from patient C was positive. The woman was prescribed oseltamivir, which she began taking later the same day. Her symptoms are resolving without complications, and her pregnancy is proceeding normally.

Patient C had not traveled to Mexico recently. Her son aged 7 years also was prescribed oseltamivir on April 29 but was not tested for influenza. The physician who evaluated patient C was also pregnant (13 weeks' gestation). The physician began chemoprophylaxis with oseltamivir and has remained asymptomatic.

A nasopharyngeal swab collected from patient C on April 29 was identified as an unsubtypable influenza A strain by the Washington State Public Health Laboratory. Additional testing at CDC confirmed infection with novel influenza A (H1N1) virus.

**Reported by:** *V Fonseca, MD, M Davis, R Wing, MD, Texas Dept of State Health Svcs. P Kriner, MPH, K Lopez, MD, Imperial County Public Health Dept; PJ Blair, PhD, D Faix, MD, Naval Health Research Center, San Diego, California. G Goldbaum, MD, H Bruce, MPH, M Nelson, MD, Snohomish County Health District; AA Marfin, MD, Washington State Dept of Health. DJ Jamieson, MD, K MacFarlane, Div of Reproductive Health, National Center for Chronic Disease Prevention and Health Promotion; SA Rasmussen, MD, MA Honein, PhD, Div of Birth Defects and Developmental Disabilities, National Center on Birth Defects and Developmental Disabilities; L Finelli, DrPH, T Uyeki, MD, D Gross, DVM, A Fiore, MD, Influenza Div, National Center for Immunization and Respiratory Diseases; SJ Olsen, PhD, National Center for Preparedness, Detection, and Control of Infectious Diseases; DL Swerdlow, MD, EJ Barzilay, MD, M Menon, MD, CE O'Reilly, PhD, National Center for Zoonotic, Vector-Borne, and Enteric Diseases; N Dharan, MD, MK Patel, MD, EIS officers, CDC.*

#### **Editorial Note:**

This report provides preliminary details on three cases of novel influenza A (H1N1) virus infection in pregnant women. Additional information on these cases and other pregnant women with this infection is being compiled by CDC based on reports from state health departments. The three pregnant women described in this report all initially had symptoms of acute febrile respiratory illness similar to the clinical symptoms in nonpregnant women with the infection; one patient (patient A) developed ARDS and died. The most frequently reported symptoms among nonpregnant patients with novel influenza A (H1N1) virus infection have been fever, cough, and sore throat (1).

Although data are insufficient to determine who is at highest risk for complications of novel influenza A (H1N1) virus infection, seasonal influenza epidemics (2,3) and previous influenza pandemics (4,5) have shown that pregnant women generally are at higher risk for influenza-associated morbidity and mortality compared with women who are not pregnant. The increased risk of complications is thought to be related to several physiologic changes that occur during pregnancy, including alterations in the cardiovascular, respiratory, and immune systems (7). Pregnant women with underlying medical conditions such as asthma are at particularly high risk for influenza-related complications (2). Because pregnant women are at increased risk for influenza complications, the Advisory Committee on Immunization Practices and the American College of Obstetricians and Gynecologists have recommended that women receive the trivalent inactivated influenza vaccine (8).

The novel influenza A (H1N1) virus that is circulating is susceptible to the neuraminidase inhibitor antiviral medications, oseltamivir and zanamivir (1). In randomized, placebo-controlled trials among outpatients, these medications have reduced the severity and duration of symptoms of seasonal influenza if started within 48 hours of illness onset, and limited data from observational studies among hospitalized patients with seasonal influenza indicate that oseltamivir can reduce mortality, even when started >48 hours after illness onset (8). In addition, oseltamivir and zanamivir have been highly effective in preventing seasonal influenza if used shortly after exposure to the disease (8). Little information is available on the safety or effectiveness of these medications when used during pregnancy (9,10). However, considering the limited information available and the known risks for influenza complications during pregnancy, any potential risk to a fetus likely is outweighed by the expected benefits of influenza antiviral treatment for this novel virus. Thus, CDC interim guidance indicates that pregnant women with confirmed, probable, or suspected novel influenza A (H1N1) virus infection should receive antiviral treatment for 5 days.<sup>†</sup>

Although zanamivir can be used in pregnancy, oseltamivir is preferred for treatment of pregnant women because of its systemic absorption (10). Theoretically, higher systemic absorption might suppress influenza viral loads more effectively in sites other than the respiratory system (e.g., placenta) and might provide better protection against mother-child transmission. Similar to the recommendation for nonpregnant persons who are treated, oseltamivir treatment should be initiated as soon as possible, ideally within 48 hours of onset of symptoms. In addition, any pregnant woman hospitalized with confirmed, probable, or suspected novel influenza A (H1N1) virus infection should receive oseltamivir, even if >48 hours have elapsed since illness onset (8). Beginning treatment as early as possible is critical. In addition, treating fevers in pregnant women with acetaminophen is important because maternal hyperthermia has been associated with various adverse fetal and neonatal outcomes (6).

In all clinical settings, including settings that provide care for pregnant women, 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. Outpatient clinical settings and labor and delivery units should develop and implement procedures for handling patients with respiratory illness and friends or family members who might accompany them. Pregnant women who are in close contact with a person who has a confirmed, probable, or suspected case should receive a 10-day course of chemoprophylaxis with zanamivir or oseltamivir. For chemoprophylaxis in pregnant patients, a preferred anti-influenza medication has not been determined. Although zanamivir might have the benefit of more limited systemic absorption (9), respiratory symptoms such as coughing or severe nasal congestion might limit its usefulness because of its inhaled route of administration. The pregnant physician caring for patient C began chemoprophylaxis soon after exposure.

Because of the increased risk for severe complications, the public health response to outbreaks of novel influenza A (H1N1) virus should include considerations specific to pregnant women. Interim guidance on issues specific to pregnant women and the novel influenza A (H1N1) virus is available at [http://www.cdc.gov/h1n1flu/clinician\\_pregnant.htm](http://www.cdc.gov/h1n1flu/clinician_pregnant.htm). Additional information regarding novel influenza A (H1N1) virus is available at <http://www.cdc.gov/h1n1flu>. Clinicians should report cases of novel influenza A (H1N1) virus infection in pregnant women to their state or local health departments or CDC.

### **Acknowledgments**

The findings in this report are based, in part, on contributions by S Munday, MD, M Rios, MD, Imperial County Public Health Dept; P Kammerer, MD, C Myers, PhD, and T Hawksworth, Naval Health Research Center, San Diego, California.

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\* Case definitions available at <http://www.cdc.gov/h1n1flu/casedef.htm>.

† Guidance available at [http://www.cdc.gov/h1n1flu/clinician\\_pregnant.htm](http://www.cdc.gov/h1n1flu/clinician_pregnant.htm).

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