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Interim Guidance—Pregnant Women and H1N1 (Swine Influenza): Considerations for Clinicians

May 1, 2009 12:25 AM ET

Background

Human infections with H1N1 (swine influenza) virus that is easily transmissible among humans were first identified in April 2009 with cases in the United States and Mexico. The epidemiology and clinical presentations of these infections are currently under investigation. There are insufficient data available at this point to determine who is at higher risk for complications of H1N1 (swine influenza) virus infection. However, in 1988 a previously healthy 32-year-old pregnant woman was hospitalized for pneumonia and died 8 days later after infection with another variant of swine influenza virus. Pregnant women are also known to be higher risk for seasonal influenza complications and during prior pandemics, and it is reasonable to assume that pregnant women are also at higher risk for H1N1 (swine influenza) 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 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 H1N1 (swine influenza) 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 H1N1 (swine influenza) virus infection should be tested (<http://www.cdc.gov/h1n1flu/specimencollection.htm>), 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 H1N1 (swine influenza).

Treatment and chemoprophylaxis

The currently circulating H1N1 (swine influenza) virus is sensitive to the neuraminidase inhibitor antiviral medications zanamivir and oseltamivir, but is resistant to the adamantane antiviral medications, amantadine and rimantadine. Pregnant women who meet

current [case-definitions](#) for confirmed, probable or suspected H1N1 (swine influenza) infection should receive empiric antiviral treatment. Pregnant women who are close contacts with persons with suspected, probable or confirmed cases of H1N1 (swine influenza) should receive antiviral chemoprophylaxis. These recommendations for treatment and chemoprophylaxis are the same ones used for others who are at higher risk of complications from influenza.

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 additional data on the benefits and risks of antiviral therapy in pregnant women become available.

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. However, no adverse effects have been reported among women who received oseltamivir or zanamivir during pregnancy or among infants born to women who have received oseltamivir or zanamivir. Pregnancy should not be considered a contraindication to oseltamivir or zanamivir use. Pregnant women might be at higher risk for severe complications from H1N1 (swine influenza), and the benefits of treatment or chemoprophylaxis with zanamivir or oseltamivir likely outweigh the theoretical risks of antiviral use. 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 and medication delivery system challenges 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.

Several studies have shown that fever during pregnancy is associated with an increased risk of birth defects and other adverse outcomes. For this reason, fever in pregnant women should be treated. Acetaminophen appears to be the best option for treatment of fever during pregnancy.

Other ways to reduce risk for pregnant women

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

Women who are breastfeeding can continue while receiving antivirals. However, women who are ill with H1N1 (swine influenza) should take steps to reduce the risk to their infants, such as frequent hand washing and possibly wearing a mask (see below). The risk for H1N1 (swine influenza) transmission through breast milk is unknown. However, reports of viremia with seasonal influenza infection are rare.

Efforts to identify the risk for pregnant women from H1N1 (swine influenza) during 2009 are underway. Enhanced surveillance for hospitalized patients with H1N1 (swine influenza) has been initiated. [Additional information about swine influenza is available](#)

Interim Guidance on Specimen Collection, Processing, and Testing for Patients with Suspected Swine-Origin Influenza A (H1N1) Virus Infection

April 30, 2009 12:15 PM EDT

Objective: To provide interim guidance on appropriate specimen collection, storage, processing, and testing for patients with suspected swine-origin influenza A (H1N1) virus infection.

Case Definitions

A *confirmed case* of S-OIV infection is defined as a person with an acute febrile respiratory illness with laboratory confirmed S-OIV infection at CDC by one or more of the following tests:

1. real-time RT-PCR
2. viral culture

[Case definitions for *probable and suspected* cases.](#)

Duration of viral shedding

The duration of shedding with swine-origin influenza A (H1N1) virus is unknown. Therefore, until data are available, the estimated duration of viral shedding is based upon seasonal influenza virus infection. Infected persons are assumed to be shedding virus and potentially infectious from the day prior to illness onset until resolution of fever. Infected persons should be assumed to be contagious up to 7 days from illness onset. Some persons who are infected might potentially shed virus and be contagious for longer periods (e.g. young infants, immunosuppressed, and immunocompromised persons).

Testing for swine-origin influenza A (H1N1) virus

Clinicians should consider testing suspected cases of swine-origin influenza A (H1N1), especially those with severe illness, by obtaining an upper respiratory specimen to test for swine-origin influenza A (H1N1) virus.

Preferred respiratory specimens: The following should be collected as soon as possible after illness onset: nasopharyngeal swab/aspirate or nasal wash/aspirate. If these specimens cannot be collected, a combined nasal swab with an oropharyngeal swab is acceptable. For patients who are intubated, an endotracheal aspirate should also be collected. Specimens should be placed into sterile viral transport media (VTM) and immediately placed on ice or cold packs or at 4°C (refrigerator) for transport to the laboratory. Recommended infection control guidance is available for [persons collecting clinical specimens in clinics and other clinical settings](#) and [laboratory personnel](#).

Swabs

Ideally, swab specimens should be collected using swabs with a synthetic tip (e.g. polyester or Dacron®) and an aluminum or plastic shaft. Swabs with cotton tips and wooden shafts are not recommended. Specimens collected with swabs made of calcium alginate are not acceptable. The swab specimen collection vials should contain 1-3ml of viral transport medium (e.g. containing, protein stabilizer, antibiotics to discourage bacterial and fungal growth, and buffer solution), such M4RT or the [BD Universal Viral Transport System](#).

Storing Clinical Specimens: All respiratory specimens should be kept at 4°C until they can be placed at -70°C. If a -70°C freezer is not available, specimens should be kept at 4°C, preferably no longer than 1 week.

Shipping clinical specimens: Clinical specimens should be shipped on dry ice in appropriate packaging.

All specimens should be labeled clearly and include information requested by your state public health laboratory. Suspected case specimens shipped from the state public health laboratory to CDC should include all information required for seasonal influenza surveillance isolate or specimen submission.

Recommended Tests

Real-time RT-PCR for influenza A, B, H1, H3 at a State Health Department Laboratory is recommended. Currently, swine-origin influenza A (H1N1) virus will test positive for influenza A and negative for H1 and H3 by real-time RT-PCR. If reactivity of real-time RT-PCR for influenza A is strong (e.g. Ct \leq 30) it is more suggestive of a novel influenza A virus. Confirmation as swine-origin influenza A (H1N1) virus is performed at CDC currently, but may be available in state public health laboratories soon.

Other influenza tests

Rapid influenza antigen test: Also, these tests have unknown sensitivity and specificity to detect human infection with swine-origin influenza A (H1N1) virus in clinical specimens, and have suboptimal sensitivity to detect seasonal influenza viruses. Therefore, a negative rapid test could be a false negative and should not be assumed a final diagnostic test for swine-origin influenza infection.

Immunofluorescence (DFA or IFA): These tests can distinguish between influenza A and B viruses. A patient with a positive for influenza A by immunofluorescence may meet criteria for a suspected case. However, it is not possible to differentiate from seasonal influenza A viruses. Immunofluorescence depends upon the quality of a clinical specimen, operator skills, and has unknown sensitivity and specificity to detect human infection with swine-origin influenza A (H1N1) virus in clinical specimens. Therefore, a negative immunofluorescence could be a false negative and should not be assumed a final diagnostic test for swine-origin influenza infection.

Viral culture: Isolation of swine-origin influenza A (H1N1) virus is diagnostic of infection, but may not yield timely results for clinical management. A negative viral culture does not exclude infection with swine-origin influenza A (H1N1) virus.

Interim Guidance on Case Definitions to be Used For Investigations of Swine-Origin Influenza A (H1N1) Cases*

April 30, 2009 10:00 AM ET

This document provides interim guidance for state and local health departments conducting investigations of human cases of swine-origin influenza A (H1N1) virus (S-OIV). The following case definitions are for the purpose of investigations of suspected, probable, and confirmed cases of S-OIV infection.

Acute febrile respiratory illness is defined as a measured temperature 100 degrees Fahrenheit and recent onset of at least one of the following: rhinorrhea or nasal congestion, sore throat, or cough.

Case Definitions for Infection with Swine-origin Influenza A (H1N1) Virus (S-OIV)

A **confirmed case** of S-OIV infection is defined as a person with an acute febrile respiratory illness with laboratory confirmed S-OIV infection at CDC by one or more of the following tests:

1. real-time RT-PCR
2. viral culture

A **probable case** of S-OIV 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 S-OIV infection is defined as a person with acute febrile respiratory illness with onset

- within 7 days of close contact with a person who is a confirmed case of S-OIV infection, or
- within 7 days of travel to community either within the United States or internationally where there are one or more confirmed cases of S-OIV infection, or

- resides in a community where there are one or more confirmed cases of S-OIV infection.
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