



Questions & Answers: Antiviral Drugs, 2009-2010 Flu Season

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Antiviral Recommendations

Background

On September 22, 2009 CDC updated its recommendations for the use of influenza antiviral medicines to provide additional guidance for clinicians in prescribing antiviral medicines for treatment and prevention (chemoprophylaxis) of influenza during the 2009-2010 flu season. These recommendations are intended to help clinicians prioritize use of antiviral drugs for treatment and prevention of influenza. As in earlier antiviral recommendations posted on May 6, 2009 and updated on September 8, 2009, the priority for use of antiviral medications this season continues to be in people with more severe illness, such as people hospitalized with influenza, and people at increased risk of influenza-related complications. This document has been updated to provide additional clarification on several issues, including the increased risk for complications in young children, particularly children younger than 2 years of age.

As with any medical decision making, clinical judgment is an essential factor in making decisions about treatment with antiviral medications.

How is the new guidance different from the guidance that was issued on September 8, 2009?

The priority use for antiviral medications during the upcoming influenza season remains generally the same as outlined in the antiviral recommendations first posted on May 6, 2009 and updated on September 8, 2009; that is to prioritize use of these drugs for those patients who are severely ill (such as those who are hospitalized) and those patients who are ill with influenza-like illness and who are at higher risk for influenza related complications. New information in the updated guidance dated September 22, 2009 includes:

1. Additional context and guidance for clinicians regarding the risk for complications and treatment considerations for young and very young children.
2. Information regarding the oral dosing dispenser included in the Tamiflu® for Oral Suspension packaging and instructions to insure the units of measure on the prescription instructions match the dosing device are also included.
3. More information about the possible underlying physiological conditions that may be associated with neuromuscular and neurocognitive disorders that might contribute to the increased risk for influenza complications in persons with these types of disorders.

The updated recommendations continue to balance between providing clinicians the information and guidance needed to reach those at greatest risk with appropriate and timely treatment; to reduce the chances of antiviral resistance through inappropriate or unnecessary chemoprophylaxis; and yet to still recognize the overarching importance of clinical judgment in

making treatment and chemoprophylaxis decisions.

Who is prioritized for treatment with influenza antiviral drugs?

Most people ill with influenza will recover without complications.

Some people are at highest risk of influenza-related complications and are prioritized for treatment with influenza antiviral drugs this season. They include:

- People with more severe illness, such as those hospitalized with suspected or confirmed influenza

- People with suspected or confirmed influenza who are at higher risk for complications

 - Children younger than 2 years old

 - Adults 65 years and older

 - Pregnant women

 - People with certain chronic medical or immunosuppressive conditions

- People younger than 19 years of age who are receiving long-term aspirin therapy

Children 2 years 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 and who are not severely ill do not necessarily require antiviral treatment.

Children and adults presenting with suspected influenza who have symptoms of lower respiratory tract illness or clinical deterioration should also receive prompt empiric antiviral therapy, regardless of previous health or age.

Physicians may also decide not to treat some people in these groups and/or treat people who are not in these groups based on their clinical judgment.

Who is lower priority for treatment with influenza antiviral drugs?

Treatment with influenza antiviral drugs is generally not needed for people who are not at higher risk for complications or do not have severe influenza, such as those requiring hospitalization. However, any suspected influenza patient who presents with emergency warning signs (for example, difficulty breathing or shortness of breath) or signs of lower respiratory tract illness or worsening illness should seek medical care promptly receive antiviral therapy when indicated.

Doctors may treat some people who are not in a high risk group based on their clinical judgment. In addition, doctors also may decide that treatment is not needed for some who are in a high risk group based on their clinical judgment.

Which influenza antiviral drugs should be used for treatment this season?

At this time, treatment with oseltamivir (trade name Tamiflu®) or zanamivir (trade name Relenza®) is recommended for all people with suspected or confirmed influenza who require hospitalization.

When should health care providers start treatment with antiviral drugs?

Once the decision to administer antiviral treatment is made, treatment with zanamivir or

oseltamivir should be initiated as soon as possible after the onset of symptoms. Evidence for benefits from antiviral treatment in studies of seasonal influenza is strongest when treatment is started within 48 hours of illness onset. However, some studies of oseltamivir treatment of hospitalized patients with seasonal influenza have indicated benefit, including reductions in mortality or duration of hospitalization even for patients whose treatment was started more than 48 hours after illness onset.

When treatment is indicated, health care providers generally should not wait for laboratory confirmation of influenza to begin treatment with antiviral drugs because laboratory testing can delay treatment and because a negative rapid test for influenza does not rule out influenza. The sensitivity of rapid influenza diagnostic tests can range from 10-70% for 2009 H1N1 virus.

What can health care providers do to reduce delays in antiviral treatment?

Clinicians can take several actions to reduce delays in antiviral treatment initiation. These include:

1. Informing people at higher risk for influenza complications of the signs and symptoms of influenza and the need for them to get treated early.
2. Ensuring quick access to telephone consultation and clinical evaluation for these patients as well as patients who report severe illness.
3. Considering empiric treatment of patients at higher risk for influenza complications based on telephone contact if hospitalization is not indicated and if this will substantially reduce delay before treatment is initiated.

What actions should health care providers take when waiting for influenza test results?

When treatment is indicated, health care providers should consider empiric treatment while influenza test results are pending, if the clinicians decided to test, especially if there will be a significant delay before testing can be performed. Once the decision to administer antiviral treatment is made, treatment with oseltamivir or zanamivir should be initiated as soon as possible after the onset of symptoms.

How long should patients receive treatment with antiviral drugs?

The recommended duration of treatment is five days. However, hospitalized patients with severe infections might require longer treatment courses.

When should clinicians prescribe antiviral drugs for prevention of influenza?

Pre-exposure antiviral chemoprophylaxis should only be used in limited circumstances, and in consultation with local medical or public health authorities. Certain people at ongoing occupational risk for exposure (health care personnel, public health workers, or first responders who are working in communities with influenza A H1N1 outbreak), especially those at higher risk for complications of influenza, should carefully follow guidelines for appropriate personal protective equipment to prevent influenza exposure to influenza. Health care workers at high risk of influenza-related complications who cannot minimize exposure may consider temporary reassignment.

Who should receive antiviral drugs for prevention of influenza?

Antiviral chemoprophylaxis generally should be reserved for people at higher risk for influenza-related complications who have had contact with someone likely to have been infected with influenza. As an alternative to chemoprophylaxis, clinicians can also choose to counsel people at higher risk for influenza-related complications about the early signs and symptoms of influenza and advise them to immediately contact a health care provider for evaluation and possible early treatment if clinical signs or symptoms develop.

Post-exposure antiviral chemoprophylaxis with either oseltamivir or zanamivir can be considered for health care personnel, public health workers, or first responders who have had a recognized, unprotected close contact exposure to a person with confirmed, probable, or suspected 2009 H1N1 or seasonal influenza during that person's infectious period. However, use of recommended PPE and other administrative controls (e.g. having health care personnel stay home from work when ill, and triaging for identification of potentially infectious patients) should be used to reduce the need for post-exposure chemoprophylaxis among health care workers. As an alternative to chemoprophylaxis, health care personnel who have occupational exposures, can also be counseled about the early signs and symptoms of influenza, and advised to immediately contact their healthcare provider for evaluation and possible early treatment if clinical signs or symptoms develop.

Should antiviral agents be used for post exposure chemoprophylaxis in healthy individuals?

Antiviral agents are discouraged for prevention of illness in healthy children or adults based on potential exposure in community, school, camp or other settings. In addition, there are no safety data regarding long term or frequent use of antiviral agents in children, and limited data for healthy adults.

Which antiviral drugs should health care providers prescribe for chemoprophylaxis of 2009 H1N1?

For antiviral chemoprophylaxis of 2009 H1N1 influenza virus infection, either oseltamivir or zanamivir are recommended. Currently, circulating 2009 H1N1 viruses are susceptible to oseltamivir and zanamivir, but resistant to amantadine

What is the recommended duration for antiviral chemoprophylaxis if used following exposure to someone with influenza?

Duration of antiviral chemoprophylaxis *post-exposure* is 10 days after the last known exposure.

What is the treatment of choice for pregnant women with suspected or confirmed 2009 H1N1 infection?

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. Pregnancy should not be considered a contraindication to oseltamivir or zanamivir use. Because of its systemic activity, oseltamivir is preferred for treatment of pregnant women.

General Information on Antiviral Drugs

What are influenza antiviral drugs?

Influenza antiviral drugs are prescription drugs (pills, liquid, or inhaler) that decrease the ability of flu viruses to reproduce. While getting a flu vaccine each year is the first and most important step in protecting against flu, antiviral drugs are a second line of defense in the prevention and treatment of flu.

What are the treatment benefits of influenza antiviral drugs?

For treatment, antiviral drugs should be started within 2 days after becoming sick. When used this way, these drugs can reduce the severity of flu symptoms and shorten the time you are sick by 1 or 2 days. They may also prevent serious flu complications. Some studies of oseltamivir treatment of hospitalized patients with seasonal influenza have indicated benefit, including reductions in mortality or duration of hospitalization even for patients whose treatment was started more than 48 hours after illness onset.

Antiviral drugs may be especially important for people who are very sick (hospitalized) or people who are sick with the flu and who are at increased risk of serious flu complications, such as pregnant women, young children and those with chronic health conditions.

How effective are antiviral drugs at preventing the flu?

When used to prevent the flu, antiviral drugs are about 70% to 90% effective against susceptible viruses (i.e., viruses that are not resistant to the antiviral medication). It's important to remember that flu antiviral drugs are not a substitute for getting a flu vaccine.

What side effects can occur with influenza antiviral drugs?

Side effects differ for each drug. If an antiviral drug has been prescribed for you, ask your doctor to explain how to use the drug and any possible side effects. Health care professionals prescribing flu antiviral drugs should alert patients about adverse events that can occur. For more information about side effects, see [Antiviral Drugs: Summary of Side Effects](#).

Antiviral Drugs and Children

Can children take antiviral drugs?

Yes. The two drugs recommended for use against influenza (including 2009 H1N1) this season can be used in children.

Oseltamivir (Tamiflu®) is approved by the Food and Drug Administration (FDA) for use in children 1 year of age or older. In addition, in July 2009, the FDA issued an [Emergency Use Authorization \(EUA\)](#) for the use of Tamiflu  ® in pediatric patients younger than 1 year of age.

Zanamivir (Relenza®), is approved for treatment in children 7 years and older, but is licensed only for use in people **without** underlying respiratory or heart disease, including people with asthma.

What kind of antiviral drugs are available for children?

Oseltamivir (Tamiflu®) comes in an oral suspension (liquid) for children. It also comes in capsules at children's dosages. Zanamivir (Relenza®) is an inhaled powder that comes with a disk inhaler.

What are the recommendations for the use of antiviral drugs in young children?

The September 22, 2009 updated interim recommendations for the use of antiviral drugs provides additional clarification regarding the increased risk for flu-related complications for young children. Children younger than 2 years old should be considered for early empiric treatment with the antiviral drug oseltamivir if they have suspected or confirmed flu.

Hospitalization data available found that children younger than 2 years old were at increased risk for flu-related complications compared to older populations. During April through August 2009, hospitalization rates for lab-confirmed 2009 H1N1 influenza in children younger than 2 years old was 2.5 times higher than the rates for children 2 years to 4 years old. In studies of seasonal influenza, the risk for hospitalization is also highest for infants, with the risk decreasing as a child gets older.

Given this increased risk for hospitalizations, children younger than 2 years are generally recommended for antiviral treatment. Children ages 2 years to 4 years old without high risk conditions and who are not severely ill do not necessarily need antiviral treatment. While children 2 years to 4 years old are more likely to require hospitalizations or urgent medical care for influenza compared with older children, this risk is much lower than the risk for children younger than 2 years old. Providers should use clinical judgment to guide treatment decisions for healthy children.

What if the pediatric oral suspension (liquid formulation) is not available and the child cannot swallow a capsule?

In the absence of oral suspension (liquid formulation) of Tamiflu® for pediatric patients who cannot swallow capsules, the children's doses of Tamiflu® capsules may be opened and mixed with sweetened liquids such as regular or sugar-free chocolate syrup.

What if there is no oral suspension (liquid formulation) and there are no pediatric doses of Tamiflu® capsules available?

In the absence of both oral suspension and pediatric capsules of Tamiflu®, there is another option to meet the need for a pediatric prescription of Tamiflu®. Adult dose (75 mg) capsules can be compounded by a health care professional to create a pediatric formulation.

Compounding is the mixing of drugs by a health care professional to fit the unique needs of a patient. The FDA has a statement on their website at

<http://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm100228.htm> to

remind health care providers and pharmacists of the FDA-approved instructions for the emergency compounding of an oral suspension from Tamiflu® 75mg capsules as described in the FDA approved manufacturer package insert for oseltamivir (Tamiflu®). Compounding an oral suspension from Tamiflu® 75mg capsules provides an alternative oral suspension when commercially manufactured oral suspension formulation is not readily available.

What are the side effects of antiviral drugs in children?

Reported side effects of **oseltamivir** are nausea and vomiting. Among children treated with oseltamivir in clinical studies, 14% had vomiting, compared with 8.5% of children getting a "placebo." (A placebo is an inactive substance that looks the same as, and is given in the same way as, a drug in a clinical trial.) Nausea and vomiting might be less severe if oseltamivir is taken with food. In addition, there have been reports of self-injury or delirium among persons

with influenza who take oseltamivir. Most of these reports have been in teenagers from Japan, and it is still not certain whether oseltamivir or the influenza virus was responsible for these behavior changes. The U.S. Food and Drug Administration advises that people taking either of the two medications recommended for influenza (oseltamivir and zanamivir) be monitored closely for abnormal behavior.

Side effects from **zanamivir** have been reported in fewer than 5% of people participating in clinical trials and have been reported at the same rate in people receiving zanamivir as those being given a “placebo.” Reported side effects have included diarrhea, nausea, sinusitis, nasal signs and symptoms, bronchitis, cough, headache, dizziness, and ear, nose, and throat infections. Also, zanamivir should not be used in people with underlying respiratory disease, including asthma.

What are the benefits of antiviral treatment in children?

Antiviral drugs work best if started soon after getting sick (within two days of symptoms starting.) Antiviral drugs can make flu symptoms milder and can shorten the duration of illness. Early treatment of influenza with antiviral drugs also has been shown to reduce the incidence of ear infections and the need for antibiotics in children between the ages of 1 and 12 years old. Studies in adults show that treatment with antiviral drugs may reduce more serious flu-related complications like pneumonia and hospitalizations. While no such studies have been done on children, antiviral drugs may be similarly helpful for reducing more serious flu-related complications in children. Treatment with influenza antiviral drugs could be particularly important for children at high risk of flu-related complications, including children younger than 2 years old and children of any age with chronic health conditions like asthma, diabetes, or heart or lung disease. This season, antiviral drugs are being prioritized for hospitalized patients (including children) and high risk patients who are sick with the flu.

What do other experts say about antiviral drugs and children?

The American Academy of Pediatrics (AAP) recommends antiviral drugs to treat influenza in children who are at higher risk of serious flu-related complications and who have moderate-to-severe influenza. These children in particular may benefit from a decrease in the duration of their symptoms. For more information on the AAP recommendations, visit <http://www.pediatrics.org/cgi/content/full/119/4/852> .

Influenza

What are the symptoms of seasonal influenza or 2009 H1N1 influenza?

The symptoms of seasonal and 2009 H1N1 influenza include fever, cough, sore throat, runny or stuffy nose, body aches, headache, chills and fatigue. Some people may also have vomiting and diarrhea. Some people may be infected with the flu, including 2009 H1N1, and have respiratory symptoms without a fever.

Who is at higher risk of influenza related complications?

Groups at higher risk for influenza related complications from 2009 H1N1 are similar to those at higher risk for seasonal influenza complications and include: children younger than 5 years old (risk is highest in children younger than 2 years old); adults 65 years of age and older, pregnant women, people of any age with certain chronic medical conditions (for example,

asthma, diabetes, lung disease, people with weakened immune systems, etc.) and people younger than 19 years of age who are receiving long-term aspirin therapy. Children 2-4 years of age are at somewhat higher risk of hospitalization from 2009 H1N1 and seasonal flu compared to older children, and for seasonal flu and have high rates of outpatient and emergency department visits for influenza.

Antiviral Drugs and Flu Vaccine

Can antiviral drugs be helpful for people unable to take the flu vaccine?

Yes. CDC and ACIP recommend use of antiviral drugs for people allergic to eggs (which can cause them to have an allergic reaction to the vaccine) or for people who previously have encountered complications from Guillain-Barre syndrome (GBS) associated with influenza vaccination. In addition, taking antiviral drugs may be recommended among persons that may not have a good immune response to the flu vaccine.

Should people use antiviral drugs before or after receiving the live attenuated influenza vaccine (LAIV) called FluMist®?

LAIV is one of two types of flu vaccine. It is given as a nasal spray and contains weakened, live virus. Flu antiviral drugs taken from 48 hours before through 2 weeks after getting LAIV can lower or prevent the vaccinated person from responding to the vaccine and the person may not get immune protection from the vaccine.

Antiviral drugs can be taken with the inactivated (i.e. killed) flu vaccine.

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