



OCTOBER 2006: VOLUME 1, NUMBER 1

ANTIVIRALS FOR INFLUENZA

Welcome...

The Johns Hopkins University School of Medicine and The Institute for Johns Hopkins Nursing are pleased to welcome you to this premier issue of *eInfluenza Review*. Over the course of this series, we will be exploring and reporting on key aspects of preventing and treating influenza.

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If you find the information presented in this series valuable, please recommend *eInfluenza Review* to your colleagues. The easiest way to do so is by [viewing this page](#) or via the links above.

In this issue...

The mortality and morbidity numbers surrounding influenza are striking. According to the CDC, with some substantial seasonal variations, the average number of deaths per year in the United States attributed to the disease is 36,000. About 90% of those deaths are in persons over 65 years, with most occurring in the “elderly elderly” (over 85 years). Further, the number of influenza-related excess hospitalizations is about 226,000 per year. While vaccination is the preferred method of prevention, antiviral agents can be used for both prophylaxis and treatment; it is therefore critical for all practitioners to understand their correct use.

In this issue, we review the current knowledge-base regarding pharmacology, efficacy, resistance, patient types and recommended dosages, side effects, and expected outcomes for the use of antiviral therapies during this influenza season.

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GUEST EDITORS OF THE MONTH



Commentary & Reviews:
John G. Bartlett, MD
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Guest Faculty Disclosure

John G. Bartlett, MD, has disclosed that he has served on the HIV Advisory Board for Glaxo Smith Kline, Abbott and Bristol-Myers Squibb.

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The authors have indicated that there will be no reference to unlabeled/unapproved uses of drugs or products in this presentation.

LEARNING OBJECTIVES

The Johns Hopkins University School of Medicine and The Institute for Johns Hopkins Nursing take responsibility for the content, quality, and the scientific integrity of this CE activity.

At the conclusion of this activity, participants should be able to:

- Identify the correct use of antiviral agents for the prophylaxis and treatment of influenza;
- Recognize the patient types who should be treated with antiviral agents and when they should be treated;
- Describe the expected results of treatment with antiviral agents in these patients

COMMENTARY

There are four drugs in two classes for the treatment and prevention of influenza. The adamantanes (amantadine and rimantadine) now have resistance rates of over 90% for clinical isolates in the US for the 2005-06 season, and, as reported by Smith et al, the CDC warns against their use. The neuraminidase inhibitors – zanamivir and oseltamivir – appear to be equally effective for prophylaxis and treatment, but, as discussed in Moscona's 2005 NEJM article, are completely different in terms of method of delivery, pharmacology and side effects. Oseltamivir is a capsule, distributed systemically and may cause GI side effects. Zanamivir is inhaled, nearly all is in the respiratory tract, and it can cause pulmonary side effects including bronchospasm.

For treatment, both drugs must be given within 48 hours of the onset of symptoms to show benefit; this correlates with the time of maximum influenza virus replication. Perhaps the most important observation, as reported by Kawai et al in their Japanese multi-center study, is the fact that within this 48 hour window of opportunity, the benefit is substantially greater when the drug is given early. This means there should be no time delay in the decision to treat.

In terms of **treatment benefits**, there is a modest reduction in duration of fever (the endpoint of the trials). In addition, as Smith reports, there are also benefits in terms of earlier return to work or school, prevention of hospitalization, etc. The greatest medical benefit is in persons at greatest risk for complications of influenza. This is a well-described group who are also the highest priority for influenza vaccine – primarily the elderly, and those with chronic diseases, especially lung, cardiovascular, and neurologic syndromes.

Diagnosis: Early treatment of influenza presumes an ability to make a rapid

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diagnosis. For clinicians, the standard practice of making this “clinical diagnosis” is usually based on fever, malaise and cough in the midst of an influenza epidemic. As the Smith review points out, this would result in an over-treatment and undertreatment rate of about 30%. The point-of-care diagnostics (POC) may help here since results are available within 30 minutes. As Poehling et al report, POC diagnostics will still miss about 20-30% of cases, but if positive, the patient nearly always has influenza by culture.

For **prophylaxis**, both zanamivir and oseltamivir are 80-90% effective in prevention. However, it needs to be emphasized that influenza vaccine is the preferred method to prevent influenza. The highest priority for antiviral therapy would be for those who are prioritized for the vaccine, but did not receive it for some reason; it might also be used when there is a mismatch between the vaccine and the epidemic strain. The antivirals may also be used to reduce viral shedding in unvaccinated hospitalized patients with influenza as a method of infection control, or given to healthcare workers in the midst of an epidemic to protect both them and their patients. The duration of prophylaxis is usually ten days at half the treatment dose, which should provide time for the influenza vaccine to “kick in”. For persons who have continuing exposure and cannot take the vaccine or benefit from it, antiviral prophylaxis should continue for the duration of risk.

THE FUNDAMENTALS OF INFLUENZA PREVENTION AND CONTROL

Smith NM, Bresee JS, Shay DK et al. **Prevention and Control of Influenza**. *MMWR* 2006;55 (R10):1-42.

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The authors represent the Advisory Committee on Immunization Practices for the CDC. This text draws on a large number of studies and provides a timely and authoritative review of influenza by healthcare professionals who are true experts. Although most of the document deals with immunization practices (the focus of an upcoming issue of *eInfluenza Review*), their report provides important information on the use of antivirals for prophylaxis. Key highlights of the publication include:

Susceptible Hosts: Those at high risk of severe influenza and its complications are children under two years old, pregnant women, persons >65 years, patients with concurrent conditions including chronic lung and heart disease (including asthma but not hypertension), diabetes, renal failure, hemoglobinopathies, immunodeficiency, residents of chronic care facilities, and those with conditions that compromise lung function or who are predisposed to aspiration (cognitive dysfunction, cord entries, seizure disorders etc.).

Diagnosis: Most clinicians make a diagnosis on the basis of characteristic clinical features (cough, fever and malaise) during an influenza epidemic. Multiple studies⁽¹⁻³⁾ show the sensitivity of this is 63-78% and the specificity is 55-71%. This means that of 100 cases, clinicians get it right about 70% of the time; in the context of antivirals, that means we under-use and over-use them in about 30% of cases. Rapid tests are now available for office use, can give results in 30 minutes, and have a sensitivity and specificity of 70% and 99% respectively⁽⁴⁻⁶⁾. Therefore, while these tests miss as many cases as we do, a positive is much more specific.

Antivirals for Prophylaxis: Vaccination is the preferred method for prevention, but

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oseltamivir and zanamivir are considered “critical adjuncts in preventing and controlling influenza”. The assessment for prevention is based on large clinical trials which show effectiveness in preventing laboratory-confirmed influenza illness in 84% with zanamivir and 82% with oseltamivir^(8,10). Both drugs have been shown effective in preventing influenza in household members of a diagnosed case, in institutional settings, in persons with chronic medical conditions, and in nursing homes^(11,12).

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NEURAMINIDASE INHIBITORS FOR INFLUENZA

Moscona A. [Neuraminidase inhibitors for influenza](#). N Engl J Med 2005; 353:1363.
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Moscona’s 2005 NEJM article draws on a number of studies to provide a comprehensive summary on neuraminidase inhibitors for influenza. Key highlights include:

Viral Kinetics: Viral replication peaks at 24-72 hours after onset of illness and neuraminidase inhibitors (NI) need to be given as early as possible.

Pharmacology: Zanamivir is inhaled and highly concentrated in the respiratory tract — most is in the oropharynx, 10-20% reaches the lung, and 5-15% is absorbed. Oseltamivir is a capsule with good oral bioavailability, it is widely distributed in the body, the half life is 6-10 hours, and it is eliminated primarily by renal mechanisms. Clinicians are cautioned on the need to reduce oseltamivir to half dose in patients with a creatinine clearance <30 mL/min.

Efficacy for Treatment: A large pivotal study⁽¹⁾ showed oseltamivir treatment given within 36 hours of onset of symptoms compared to placebo reduced the median duration of illness by about 30% (4.3 to 3 days) and the severity of illness by about 40%. Similar results have been achieved with zanamivir⁽²⁾.

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Treatment: Neuraminidase inhibitors given within 48 hours of onset of symptoms can reduce the duration of influenza by about one day^(2,3). Data are limited on the efficacy of these drugs in preventing the complications of influenza, but a metaanalysis of 10 trials showed a 50% reduction in rates of pneumonia and a 50% reduction in rates of hospitalization⁽⁴⁾.

Efficacy for Prophylaxis: Both drugs are 70-90% effective in preventing the disease when used for prophylaxis either before or after exposure for both influenza A and influenza B.

Side Effects: The main side effect of zanamivir has been cough, bronchospasm, and a reversible decrease in lung function in a small subset of patients. There is convincing evidence that there are no long term consequences to lung function. The current recommendation is that patients with pulmonary dysfunction given zanamivir should have a rapid-acting bronchodilator available, and discontinue the drug if this side effect occurs. The main side effect with oseltamivir has been transient nausea, vomiting and abdominal pain, noted in 5-10% of patients.

Resistance: There is minimal emergence of resistance during treatment, with a reported rate of 0-0.4% among treated adults. It is higher in children, with one report of 4%⁽⁵⁾. In general, mutations that confer resistance to neuraminidase inhibitors cause a substantial reduction in fitness of the virus, making it less pathogenic and less easily transmitted^(6,7). The clinical relevance of these observations in the mammalian model is unclear.

Practical Application: The following table summarizes relevant information for the use of zanamivir and oseltamivir for treatment and prophylaxis of influenza:

	ZANAMIVIR	OSELTAMIVIR
FORMULATION	Inhalation – 5 mg doses 10 dose dispenser	75 mg cap & syrup
PROPHYLAXIS		
Dose		
Age 1-4 yrs	-----	Dose by weight
5-12 yrs	10 mg qd	Dose by weight
13->65 yrs	10 mg qd	75 mg qd
Renal failure	Standard	Half dose (75 mg qod)
Cr Cl <30 mL/mm		
Efficacy		
Adults	81%	85-89%
Children	-----	80%
Elderly	-----	92%
Household disease	-----	84%
TREATMENT		
Dose		
Age 1-6 yrs	-----	Weight based x 5 d
7-12 yrs	10 mg bid x 5 d	Weight based x 5 d
13->65 yrs	10 mg bid x 5 d	75 mg bid x 5 d
Renal failure	Standard	Half dose (75 mg/d)
Cr Cl <30 mL/mm		
Efficacy		
Adults	1-2 days	1-2 days
Children	1.0 days	1.5 days
Given within 12 hr.	-----	3-4 days

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LEVELS OF AMANTADINE RESISTANCE

CDC: High Levels of Amantadine Resistance Among Influenza A (H3N2) Viruses and Interim Guidelines for the Use of Antiviral Agents – United States 2005-06 Influenza Season. MMWR Morb Mortal Wkly Rep. 2006 Jan 20;55(2):44-6
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This is a report from the CDC concerning results of resistance tests done on 120 strains of influenza A from clinical cases submitted during the 2005-06 influenza season as part of surveillance monitoring. As background, it was noted that the prevalence of resistance to adamantane agents (amantadine and ramantadine) were 1.9% in the 2003-04 influenza season and 11% in the 2004-05 season. However, for the 2005-06 influenza season, analysis of the 120 strains showed adamantane resistance in 109 (91%). Testing of these 120 strains for sensitivity to neuraminidase inhibitors showed uniform susceptibility. On the basis of this observation, the CDC recommended the use of neuraminidase inhibitors for treatment or prophylaxis when indicated.

EFFECTIVENESS OF OSELTAMIVIR

Kawai N., Ikematsu H, Iwaki N et al. **A comparison of the effectiveness of oseltamivir for the treatment of influenza A and influenza B: a Japanese multi-center study of the 2003-2004 and 2004-2005 influenza seasons.** Clin Infect Dis 2006;43:439-44.
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The authors compared the effectiveness of oseltamivir for the treatment of influenza A and influenza B and also examined the utility of early treatment. The method was to make a presumptive diagnosis on the basis of the rapid flu test in patients who presented with typical symptoms of influenza, and then randomly assign treatment for those stratified for influenza A or influenza B. The major outcome parameter was the duration of fever and virus eradication by cultures at 4-6 days after treatment. The analysis of fever duration was divided into four subgroups based on the time from onset of symptoms to first dose.

The results of the study showed efficacy was substantially better for influenza A antiviral activity vs influenza B on the basis of the duration of fever after treatment and the frequency of viral isolation at 4-6 days. The rate of positive cultures was 52% for those with influenza B compared to 16% for those with influenza A ($P < 0.001$). With regard to the time of treatment, the breakdown for the 3,351 participants showed a direct correlation between reductions in fever duration and earlier treatment.

These data are summarized as follows:

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Time from onset of fever	Influenza A		Influenza B	
	No. pts n=1818	Duration Fever (mean)	No. pts n=1485	Duration Fever (mean)
0-12 h	696	38 hr	518	53 hr
13-24 h	109	49 hr	577	67 hr
25-36 h	256	57 hr	200	73 hr
37-48 h	157	73 hr	190	88 hr

The investigators also performed an analysis by age category, ranging from 0-6 years to those over 64 years, and found no important differences based on age and outcome.

Among the authors' conclusions are that oseltamivir is more effective against influenza A than influenza B, better results are achieved when the drug is given soon after the onset of symptoms, and the benefit in terms of duration of fever appears similar across all age strata.

ACCURACY AND IMPACT OF A POINT-OF-CARE RAPID INFLUENZA TEST

Poehling KA, Zhu Y, Tang WY, Edwards K. **Accuracy and Impact of a point-of-care rapid influenza test in young children with respiratory illnesses.** Arch Pediatr Adolesc Med 2006;160:713-8.

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Using the QuickVue Influenza Test (Quidel), Poehling et al at Vanderbilt University designed a study to determine the impact and accuracy of point-of-care diagnostic testing for influenza in a pediatric emergency department. The analysis included a comparison of results of the rapid test with viral culture and the impact of test results on test ordering and antibiotic prescribing. The results were based on observations in 468 children, including 88 (19%) who had cultured-confirmed influenza infection — of these 205 were in the rapid test group and 51 had influenza infection.

The results showed the following:

- The rapid influenza test was 82% sensitive and 99% specific
- There was a significant decrease in diagnostic testing in the group that had a positive rapid test (39% vs. 51%, P=0.03)
- There was no decrease in antibiotic prescribing
- The use of antiviral agents was low

This study confirms the reported experience with the rapid test in terms of sensitivity. While the investigators anticipated that this information would translate into fewer diagnostic tests, fewer antibacterials, and more antivirals for influenza, their results showed limited benefits in these variables.

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The presenting faculty reported the following:

- John G. Bartlett, MD, has disclosed that he has served on the HIV Advisory Board for Glaxo Smith Kline, Abbott and Bristol-Myers Squibb.
- Jason E. Farley, PhD(c), MPH, NP has disclosed that he has no relationship with commercial supporters.

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