INFORMATION PAPER

DASG-HCA
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SUBJECT: Influenza and Oseltamivir (Tamiflu®)

1. PURPOSE. To provide information about the antiviral medication oseltamivir (Tamiflu®, Roche Pharmaceuticals) in treating or preventing influenza.

2. FACTS.

a. An influenza pandemic (a widely dispersed epidemic) is one of the greatest public health threats. Influenza types A and B cause yearly outbreaks of influenza illness in people. Usually, influenza viruses that infect birds or other animals do not cause serious illness in people. But influenza viruses can change over time (mutate). If an influenza virus in birds changes significantly, it may be able to cause serious infection in humans.

b. An avian influenza virus ("bird flu") is currently circulating in southeast Asia and elsewhere, causing over 200 human infections since December 2003. This virus is influenza type A, subtype H5N1. Sustained human-to-human transmission (needed for a pandemic) has not yet occurred anywhere in the world.

c. Immunization remains the primary strategy to prevent influenza illness. However, at the start of a pandemic, a vaccine specifically effective against the pandemic-causing influenza viral strain may not be available. Until a vaccine is available in adequate supply, oseltamivir (Tamiflu®, manufactured by Roche Pharmaceuticals) may be used as an antiviral medication (the viral version of an antibiotic). Tamiflu is approved by the Food & Drug Administration (FDA) to treat people who become infected with influenza. Tamiflu is also FDA-approved to prevent influenza disease.

d. Tamiflu as Treatment. For treatment of seasonal influenza type A (e.g., subtypes H1N1, H3N2), if started within 48 hours after symptoms begin, oseltamivir can reduce the severity and shorten the duration of influenza illness. In the most vulnerable people (the elderly and children), studies show that oseltamivir reduced the average duration of illness by about 1 to 1.5 days.

e. Tamiflu for Prevention. In healthy adults, oseltamivir is 70% to 90% effective in preventing influenza illness, when used either before or after exposure to influenza type A or B viruses. In chronically ill people living in long-term care centers, the combination of oseltamivir and influenza vaccination for seasonal prevention reduced laboratory-confirmed influenza by 92%. In children, oseltamivir is 80% effective at preventing illness after exposure to someone sick with influenza. Oseltamivir used as prevention (without immunization) is effective only if taken during the entire expected exposure period. Vulnerability to infection returns within 1 or 2 days after oseltamivir is stopped. Oseltamivir has been studied for long-term prevention for as long as 6 weeks.

f. The usual treatment dose of oseltamivir for adults and children 13 years and older is 75 mg twice a day (about 12 hours between doses) for five days. For children, the dose is based on the child's weight: < 33 lbs (15 kg)--30 mg twice daily; 33 to 51 lbs (15 to 23 kg)--45 mg twice daily; 51 to 88 lbs (23 to 40 kg) —60 mg twice daily; > 88 lbs (40 kg)--75 mg twice daily.

g. The most common side effects of oseltamivir are stomach upset and vomiting. These symptoms occur in about ten of every 100 people taking this medication. Side effects occur most often during the first two days of treatment and are less severe if oseltamivir is taken after eating a snack or meal. Other symptoms occur at rates no higher than those seen in people receiving a placebo (a sugar pill).

h. Oseltamivir is not routinely recommended during pregnancy, because there is insufficient evidence to evaluate any risk to the fetus or pregnant woman. Using oseltamivir during pregnancy should be limited to situations where the potential benefit of treating or preventing influenza illness justifies the potential risk to the fetus.

i. Oseltamivir is not routinely recommended in women who are nursing because there is insufficient evidence to evaluate risk to mother or child. Using oseltamivir while lactating should be limited to situations where the potential benefit to the nursing mother justifies the potential risk to the breast-fed infant.

j. Viral resistance (the ability of the virus to evade the effects of oseltamivir) is considered rare and has been reported to occur in less than 1% of people treated in the United States. Whether this low rate of resistance will continue with expanded use of Tamiflu is unknown. The greater concern is whether resistant viruses could be transferred from person-to-person. Fortunately, there is no evidence to date that oseltamivir-resistant viruses are transmitted between people.

3. SUMMARY.

a. Immunization remains the primary strategy for preventing serious influenza illness. But no FDA-licensed vaccine is currently available to prevent influenza A/H5N1 ("bird flu"). New influenza viruses may develop before vaccines can be made in large quantity. Antiviral medications may help prevent influenza until vaccine is available. A logistical rule-of-thumb is that each course of long-term prophylaxis is comparable to treatment for 12 infected patients.

b. Oseltamivir can be used to treat people already infected with influenza. Oseltamivir is useful for unimmunized people. Oseltamivir prevents infection only while being taken. Its most common side effects are upset stomach and vomiting, which can be minimized by taking the medication after a snack or meal.

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