

INFORMATION PAPER

Military Vaccine Agency

25 May 2007

SUBJECT: Pandemic Influenza Infection and Pandemic Influenza Vaccine

1. Purpose. To describe pandemic influenza and potential vaccines to be used for prevention.

2. Facts.

a. Microbiology. Influenza is a contagious respiratory disease caused by influenza types A or B viruses and ranges in severity from mild to life-threatening. Influenza is NOT the “common cold.” For decades, influenza A (H1N1) viruses, influenza A (H3N2) viruses, and influenza B viruses have been in worldwide circulation. “H” and “N” represent antigens (proteins) on the surface of the virus. Influenza viruses change these surface proteins over time (they mutate), so seasonal influenza vaccines require reformulation each year. Influenza pandemics occur when a new influenza virus (potentially including avian influenza virus type A/H5N1) infects humans at higher than usual rates.

b. Epidemiology. Seasonal influenza viruses are easily spread by airborne respiratory droplets from person to person (often by sneezing or coughing). Pandemic influenza outbreaks involve higher illness and death rates in healthy people, higher than the 36,000 deaths due to influenza in an average year in the United States. By the World Health Organization (WHO) classification system, the current pandemic phase is “pandemic alert period, phase 3.” WHO defines this phase as: human infections with a new subtype, but no human-to-human spread, or at most rare instances of spread to a close contact.

c. Antivirals. If taken early after influenza infection (within one or two days of symptom onset) the neuraminidase inhibitor antiviral medications zanamivir and oseltamivir can shorten the duration of symptoms by one day. The adamantanes (amantadine and rimantadine) are also possible treatments for pandemic influenza.

d. Vaccine. In April 2007, the FDA announced the first approval in the United States of a vaccine for humans against the H5N1 influenza virus, commonly known as avian or bird flu. This vaccine could be used in the event the current H5N1 avian influenza virus was to develop the ability to efficiently spread from human to human, resulting in the rapid spread of the disease across the globe. In a clinical study, 103 healthy adults received a two 90 microgram dose regimen of this vaccine. The study showed that 45% of the people receiving the 90- microgram, two-dose regimen developed antibodies at a level that is shown to reduce the risk of getting seasonal influenza. Although the level of antibodies seen in the remaining individuals did not reach that level, current scientific

information suggests that less than optimal antibody levels may still reduce disease severity and influenza-related hospitalizations and deaths.

e. Immunization: H5N1 vaccination would be given to people 18 through 64 years of age who are at increased risk of exposure to the H5N1 influenza subtype. Vaccination is given as two 1ml doses 28 days apart. Vaccination is administered as an intramuscular injection preferably in the deltoid muscle of the upper arm.

f. Cautions. Vaccination is contraindicated in people with severe allergic reactions to eggs and in those who experienced an allergic or neurologic reaction (Guillain-Barre´ Syndrome) after a previous dose of this vaccine or life-threatening reactions to previous influenza vaccination. Vaccine should be postponed for people who have moderate to severe acute illness (fever or respiratory illness).

g. Adverse Events. The most common adverse reactions are pain at the injection site, headache, malaise and myalgia (muscle aches). Anaphylaxis (a rare, severe allergic reaction) may occur after any vaccination.

h. DoD Policy. Administer vaccines against novel influenza viruses in accordance with DoD guidance found on the DoD PI Watchboard at www.dod.mil/pandemicflu.

3. References.

a. Pandemic influenza vaccine product insert.
<http://www.fda.gov/cber/label/h5n1san041707LB.pdf>

d. Multiple resources (e.g., product insert, Vaccine Information Statements) assembled by Military Vaccine Agency: <http://www.vaccines.mil/pandemic>

Approved by: COL Anderson