

THE SECOND FRIDAY REPORT – #3 – March 9, 2007

A monthly newsletter update on local, state, national and worldwide events and happenings concerning Pandemic Influenza brought to you by the York/Adams Metropolitan Medical Response System (YAMMRS)

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1. Avian Influenza

Countries elsewhere in the World continue to have isolated outbreaks of the highly pathogenic H5N1 influenza strain among poultry flocks, while North America and South America remain uninvolved so far. Russia, Kuwait and Vietnam have shown recent outbreak activity.

2. Human A/H5N1 Influenza

The World Health Organization (WHO) reports, as of March 8, 2007, that there have been 277 confirmed cases of human A/H5N1 influenza in 12 countries, resulting in 168 deaths (61% fatality rate). That's an increase of 5 more cases, 1 more country and 2 more deaths since last month's Report. Laos is the most recent addition to the list of involved countries with human cases. We continue in the WHO's Phase 3, which means a new influenza virus (A/H5N1) causes human cases but there is no or very limited sustained human-to-human transmission. We have been in Phase 3 since January 2004.

(www.who.int/csr/disease/avian_influenza/en/index.html)

3. Seasonal Influenza

One State Health Department epidemiologist recently characterized Pennsylvania's flu season this year as "wimpy." The report continues, "Positive tests are still increasing in the SE and NE, but the rest of the state looks like it is stalling." Now that we are in mid-March, flu season will soon be ending. In York, this winter the flu season hardly seemed to get off the ground.

4. Item of Interest on the H5N1 Vaccine Development Front

On February 27, 2007, a U.S. Food and Drug Administration (FDA) panel recommended that the agency approve the nation's first H5N1 influenza vaccine, despite new evidence that the vaccine is less protective than reported in a clinical trial last year.

The panel of health advisors, convened to weigh the risks and benefits of the "prepandemic" vaccine made by Sanofi Pasteur, called the vaccine "safe and effective." The FDA is not bound by the advisory panel's recommendations but usually follows them.

The vaccine is based on an H5N1 virus isolated from a Vietnamese patient in 2004. Two companies, Sanofi and Chiron Corp., have been producing clade 1

H5N1 vaccines for the national stockpile under U.S. Department of Health and Human Services (HHS) contracts worth more than \$200 million.

At least 3 million courses of the vaccine are already in the national stockpile. The government's most recent pandemic planning update, released in November 2006, said up to 5 million more courses could be added in 2007 if vaccine seed stock supply and production yield are adequate. The stockpile goal is 20 million courses.

Sanofi revealed that two 90-microgram (mcg) doses, administered 28 days apart, generated a protective immune response in 45% of the patients. That level is less than the 54% rate reported almost a year ago in the *New England Journal of Medicine*. The higher rate was based on interim findings.

The two-dose course used in the trial is 12 times the standard (15-mcg) dose used in the seasonal flu vaccine and lags behind its 75% to 90% protection rate. However, according to one FDA official, the vaccine is still better than nothing in the event of a pandemic.

In its final analysis presented to the FDA panel, Sanofi echoed interim findings that there were almost no serious side effects, even at the highest dosages. The company said no clinically significant adverse reactions were identified after a two-dose, 7-month controlled follow-up study in adults aged 18 to 64.

Last November, the World Health Organization (WHO) cautioned governments against rushing to stockpile prepandemic flu vaccines because too many scientific questions about them remained. The WHO said vaccines that seemed to work well against one H5N1 clade might not work well against others. Also, the agency said no one knew what level of measured immune response indicated an adequate level of protection.

However, on February 16, 2007, the WHO issued a statement saying that a number of new vaccines against various strains of H5N1 look promising.

When HHS issued its most recent pandemic preparedness update, it acknowledged that a prepandemic vaccine would provide only partial protection against new viral strains. "It is, for now, the best vaccine defense we have, and so we are stockpiling it," the HHS said in the update.

The HHS has said that it is moving forward with the development of a clade 2 H5N1 vaccine based on more recently circulating strains of H5N1. Also, HHS has supported the development of cell-based vaccine production methods that would streamline and modernize vaccine production and is exploring new adjuvants (additives that would boost response) to stretch the vaccine supply.

A final note from the Editor: Please let me know about items that you would like to share with others concerning Pandemic Influenza. Also, if you would like to hear about a particular Influenza topic, please feel free to contact me at dhawk@yorkcity.org. If others would like to be added to the mailing list, please forward email addresses either to me at the above email address or to Bernadette Lauer at bklauder@ycdes.org.