

Department of Health and Human Services

Pandemic Planning Update II

A Report from Secretary Michael O. Leavitt June 29, 2006



"While pandemics have happened several times in the past, never before have we had all of the tools of today. Never before have we possessed the wealth of knowledge on the problem and the ability to prepare. The challenge is immense, but so is our will to protect and preserve."

Message from the Secretary

Last March, I wrote that we are in a race, a race against a fast-moving, highly pathogenic avian H5N1 flu virus; a race to prepare in every possible way against a potential human flu pandemic. Three months later, the pace has not slackened.

The deadly avian H5N1 virus has now been confirmed in 53 countries, an increase of 16 nations since March. Three additional nations have reported human cases. The number of reported human cases now stands at 228, an increase of thirty

percent, and more than half of the people infected have died. (please see addendum)

Countries with H5N1 Avian Influenza and **Human Deaths (both cumulative)** 140 130 Countries with H5N1 avian influenza in animals 130 120 Human Deaths 110 100 90 80 76 70 60 53 50 40 35 30 16 20 10 2003 2004 2005 2006 (please see addendum) Through June 24

More troubling was a family cluster identified in Sumatra, Indonesia. The incident involved a fatally ill woman who apparently contracted the flu through exposure to poultry and who then infected other family members. Seven people became ill; six died. All were genetically related and had close exposure to the initial victim. A World Health Organization (WHO) team, including Centers for Disease Control and Prevention (CDC) specialist Dr. Tim Uyeki, was quickly dispatched to the village to test, monitor for further spread of the virus, and administer antivirals to people potentially exposed.

Test results released last week revealed that the virus mutated slightly in one of the victims, a 10-year old boy, and that the boy passed the virus to his father, who also died. Dr. Uyeki says this is the first evidence that a person caught the virus from a human and then passed it on to another person. Uyeki stressed that the virus died with the father and did not pass outside the family.

"It stopped. It was dead end at that point," he said, adding that viruses are always slightly changing and there was no reason to raise alarms. It has been more than a

month since the last death in this family-cluster occurred, and no related cases have been identified.

Pandemic Preparedness Five Priorities

- Monitoring disease spread to support rapid response
- Developing vaccines and vaccine production capacity
- Stockpiling antivirals and other countermeasures
- Coordinating federal, state and local preparation
- Enhancing outreach and communications planning

We continue to learn. Some scientists expected that, by now, high-pathogenic H5N1 would have arrived in North America, brought here by migratory waterfowl. That hasn't happened, at least not yet. Migratory birds continue to be reservoirs of H5N1, but the spread of H5N1 through Western Asia to Europe and Africa is now thought to have been caused at least in part by the international trade in poultry. We continue to learn how much we have to learn.

While the H5N1 avian influenza virus appears to be the greatest pandemic threat, there are other strains of concern which we must also address. Guided by our five priorities (see box), we have accelerated the pace of our planning and preparation.

Planning summits have been held in all but two states, and almost every state and every federal agency has either a draft or final pandemic plan in place. Many states are coordinating their strategic plans with neighboring states, and community planning is underway across the nation.

Message from the Secretary (cont.)

We took a major step toward building vaccine production capability when, in May, we added to previous investments and invested more than \$1 billion in the advanced development of cell-based vaccine technology. Shifting from the current egg-based

technology is critical to the ability to quickly produce vast quantities of vaccine should a pandemic develop. However, licensed cell-based vaccine production in the U.S. is at least several years away.

We continue to stockpile antiviral drugs. The Strategic National Stockpile (SNS) now contains sufficient antivirals to treat more than 7 million people. An additional 19 million courses of Tamiflu and Relenza are on order, and we expect the SNS to contain 26 million courses by the end of 2006. We also continue to stockpile N95 respirators (20.2 million on hand) and surgical masks (12.3 million on hand).

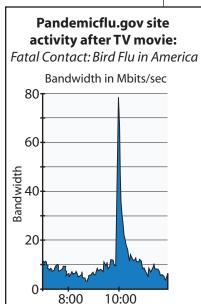
Information is our friend. When ABC aired its TV drama, *Fatal Contact: Bird Flu in America*, we saw an opportunity to educate people. We prepared a viewer's guide and ABC cooperated by promoting www.pandemicflu.gov at the conclusion of the movie. Web site activity immediately following the movie set a new record as people sought answers to questions raised by the TV drama.

The role of the media will be critical should a pandemic develop. Agriculture Secretary Mike Johanns and I have been meeting with media executives, editors, producers, correspondents, radio talk show hosts and bloggers so they know what we know, and so we know what they will need should a pandemic threat become imminent. We discussed our mutual roles, asking

for accurate, responsible reporting and promising to "flood the zone" with the best information we have in every form possible. Ultimately, messaging from the federal government, in the event of a pandemic, will be coordinated and harmonized with all appropriate stakeholders.

These and other developments are detailed below. While we have accomplished much in a short period of time, the race we are in is not a sprint, but a marathon. In June, Congress passed the President's FY 2007 emergency funding request of \$2.3 billion to help achieve our pandemic preparedness goals. These funds, the second installment of the President's request, will allow us to continue the essential work outlined here.

As I wrote in my first report, "Preparation is a continuum. Each day we prepare brings us closer to being ready. We are better prepared today than we were yesterday. And we must be better prepared tomorrow than we are today."



Time

"Our epidemiological investigation did not include any other plausible source of infection except for limited human-to-human transmission to explain infection in all seven of these cases."

–Dr. Tim Uyeki, CDC Referring to the Indonesia situation.



Monitoring and Surveillance

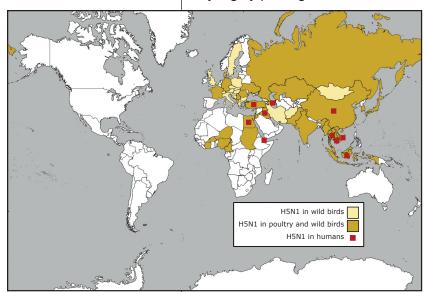
"They were able to do all this [research] working with people on a remote island in Indonesia. What it does is affirm that our distant warning system has been vastly improved."

Dr. William Schaffner,
 Vanderbilt University
 Medical Center

Early detection is vital to effective preparation for a potential pandemic influenza. Should avian H5N1 mutate into a virus easily transmitted from human to human, any hope of containing or slowing a pandemic requires almost immediate notification and action. Constant international surveillance is also critical to determine if the virus mutates again into a new form, which affects the development of pre-pandemic vaccines. The goal is to be able to detect and respond to an outbreak anywhere in the world within two weeks.

International Cooperation

The United States has pledged to contribute \$334 million to the international effort to assist nations most severely affected by bird flu. Funds will be used in the detection, containment, and mobilization of resources in areas affected by highly pathogenic avian influenza.



In May, the United States shipped an amount of the antiviral drug Tamiflu to a secure location in an Asian country. The Tamiflu could be used as part of the international community's efforts to contain a pandemic. However, if containment was not possible, the Tamiflu would be sent back to the U.S. stockpile of antiviral influenza medications.

We are working with the WHO, the United Nations Food and Agriculture Organization (FAO), the World Organisation for Animal Health (OIE), the Institute Pasteur and concerned national governments to closely monitor and quickly respond to outbreaks of humans

infected with avian influenza.

The CDC is continuing to monitor the situation in Indonesia where, on average, one person died of H5N1 every 2½ days in the month of May. Working with WHO and local health officials, surveillance and control efforts focused on the family-cluster incident (story above) in Sumatra. Daily house-

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Monitoring and Surveillance (cont.)

to-house monitoring for influenza-like illness was conducted throughout the village and in health care facilities where patients were treated and no further

related cases were detected.

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Map of Indonesia showing location of extended family cluster of H5N1.

"As far as we know [the mutations] don't correlate with any particular functional changes about the virus. It doesn't confer any greater transmissibility or any great pathogenicity." -Dr. Keiji Fukuda, WHO

Results from the investigation of the cluster revealed that the virus mutated slightly in one of the victims, a 10-year old boy, and that the boy passed the virus to his father, who also died. This is the first documented case where a person caught the virus from one human and then passed it on to another. Officials stressed that the virus is constantly mutating, and that this particular virus died with the father and did not pass outside the family cluster.

Encouraging News

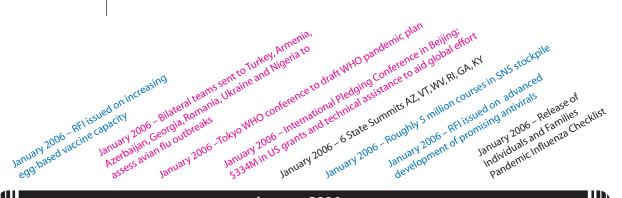
Many lessons have been learned from the world's swift response and containment of infected poultry in Vietnam. In 2005, Vietnam experienced 61 cases of H5N1. The Vietnamese government worked with the WHO, the United States and other countries to contain the problem by culling 45 million birds and substantially quelling the

outbreak. So far, Vietnam has reported no human cases of H5N1 in 2006. Similarly, Thailand experienced seven human cases of H5N1 influenza in 2005 and, through swift containment and bird culling practices, no new cases have arisen in 2006. Up to now, the disease appears to be successfully contained through culling in Vietnam and Thailand. (please see addendum)

Domestic Monitoring

Scientists are currently debating the potential role migratory birds have in the spread of high-pathogenic avian influenza around the globe. Thus far, migratory birds seem to be playing a limited role in the spread of the disease. Evidence suggests that migratory birds have not yet spread H5N1 to North America as originally predicted. Nonetheless, wild birds are considered to be natural reservoirs for all subtypes of avian influenza and prudent monitoring of wild birds is crucial to tracking the spread of the disease and disease vectors.

The Department of Health and Human Services (HHS) is currently working with Departments of Agriculture (USDA), Interior (DOI), Homeland Security



Monitoring and Surveillance (cont.)

(DHS), the International Association of Fish and Wildlife Agencies (IAFWA) and the State of Alaska in an expanded national framework for early detection of highly pathogenic avian influenza.

The expanded early detection network is working closely with local, state and federal governments to investigate and monitor live wild birds, mortality events of wild birds, birds killed by hunters, backyard poultry flocks and



environmental samples of water and bird feces. Because Alaska is a crossroads of migratory bird flyways in North America and Asia, it is a priority area for sampling of live birds and birds taken in subsistence and sport harvests. Sampling in Alaska is currently focused on species that migrate to and from wintering areas in the Russian Far East and Southeast Asia and are thought to have the highest probability of contracting the virus and bringing it to North America.

Other Developments

CDC has developed FluSurge and FluAid (pandemic modeling software) for use by communities and hospitals so that they can better understand and plan for a potential

outbreak of a pandemic virus in humans. CDC is continuing to strengthen local laboratory capability and its national influenza surveillance system.

In collaboration with the CDC, the Food and Drug Administration (FDA) cleared a new laboratory diagnostic test capable of detecting within hours the influenza A/H5 virus that causes influenza A/H5 human infection. In April, the FDA provided guidance for industries on diagnostic devices to detect influenza A viruses. The guidance provides the in vitro diagnostic industry with recommendations for evaluating performance as well as writing product labeling that assures safe and effective use of these tests.

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Vaccines and Vaccine Production Capacity

Vaccination remains a critical defense against pandemic flu. Major efforts are underway to increase our ability to produce a vaccine against a pandemic virus strain when needed, and work on "pre-pandemic" vaccines continues.

Cell-based Production

Total reliance on egg-based production methods for mass-production of a pandemic flu vaccine is a recognized vulnerability, and on May 4, HHS

invested more than \$1 billion in the advanced development of cell-based vaccine technologies. Cell-based production of influenza vaccine offers a number of significant benefits.

- In order to produce 300 million doses of vaccine, egg-based production would require an estimated 900 million eggs. In the case of an avian flu pandemic, egg-producing flocks could decline, jeopardizing vaccine production capabilities.
- While eggs are perishable and must be ordered months ahead of time, cell lines can be safely kept frozen indefinitely, increasing the capability to rapidly produce vaccines if an influenza pandemic were to occur.
- Vaccine manufacturers are able to bypass some of the steps needed to adapt the virus strains to grow in eggs.
- Certain people allergic to eggs cannot receive vaccines produced from chicken eggs, but can be immunized with a cell-based vaccine.

A total of five contracts were awarded for cell-based vaccine technology development:

- Solvay Pharmaceuticals, \$299 million;
- GlaxoSmithKline (GSK), \$275 million;
- Novartis Vaccines & Diagnostics, \$221 million;
- MedImmune, \$170 million; and
- DynPort Vaccine, \$41 million.

Previously, HHS awarded Sanofi Pasteur a \$97 million contract for development of a cell-based vaccine in April 2005. This company was the first



"We will continue our essential work to increase our domestic capacity to produce pandemic influenza vaccine and antiviral medications."

—Secretary Mike Leavitt



Vaccines and Vaccine Production Capacity (cont.)

to be awarded a federal contract for commercial scale production of newer influenza vaccine methodology.

HHS recognizes the need to also expand the nation's capacity to produce vaccines utilizing traditional egg-based technology. This summer, the Department will issue Requests for Proposals (RFPs) for the construction of new facilities and/or the expansion or retrofitting of existing facilities. HHS has also issued RFPs for antigen-sparing technologies, seeking ways to stimulate protection using a smaller amount of vaccine. Contracts for antigen-sparing technologies are expected to be awarded this fall.

Vaccine Availability

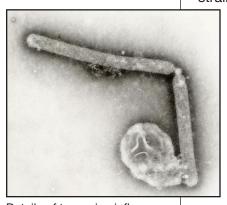
HHS has stockpiled roughly 8 million doses of vaccine against an H5N1 virus strain isolated from Vietnam in early 2004, referred to as the clade 1 virus.

Given a two-dose vaccination schedule, this would allow vaccination of 4 million people. Progress has also been made toward development of a vaccine against an H5N1 strain isolated from Indonesia in 2005 (clade 2 virus) that has circulated in Europe, Africa, and parts of Asia.

While the efficacy of these pre-pandemic vaccines cannot be predicted, there is reason to believe they may provide some level of protection for priority personnel and those at greatest risk. It is probable that H5N1 will continue to evolve, making it necessary to continuously evaluate the development of pre-pandemic vaccines.



The Implementation Plan for the National Strategy for Pandemic Influenza, released by the Homeland Security Council (HSC) in May, directs HHS to coordinate federal efforts to prioritize vaccine allocation during pre-pandemic and pandemic periods. HHS has also been directed to coordinate federal efforts to list personnel and high-risk groups who should be considered for priority access to medical countermeasures. We are currently working closely with federal departments and agencies, states and other experts to define priority groups for access to pandemic influenza vaccine.



Details of two avian influenza A (H5N1) virons, a type of bird flu virus, which is a subtype of avian influenza A.

March 2006 - States receive initial grant funding courses of Tamiflu

March 2006 - States receive initial grant funding courses of Tamiflu

March 2006 - States receive initial grant funding courses of Relenza Aviruses

April 2006 - T State Summits TN, AK, WA, HI, LA, MI.

April 2006 - States receive initial grant funding courses of Relenza Aviruses and Pacific Territorites and Pacific Territor

Antiviral Drugs

Progress continues to be made in developing a national stockpile of antiviral drugs that could lessen the impacts of influenza. As of June 1, 2006, the Strategic National Stockpile (SNS) contains:

- approximately 6.2 million regimens of Tamiflu capsules (oseltamivir) with an additional 15.4 million on order and expected to arrive through December 2006.
- approximately 8,600 regimens of Tamiflu oral suspension (oseltamivir).
- approximately 84,000 regimens of Relenza (zanamivir) with an additional 3.9 million regimens on order and expected to arrive through December 2006.

In sum, there will be an approximate stockpile of 26 million antiviral drug courses in the SNS by the end of 2006. At least 20 million of these treatment

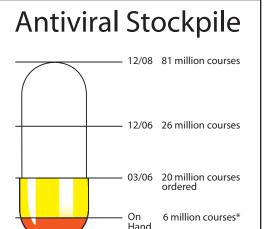
courses are to be allocated to states in proportion to population. Up to six million courses are reserved for possible opportunities to quench isolated outbreaks through community-wide preventive administration (mass prophylaxis).

HHS is also enabling states and other entities to purchase up to 31 million treatment courses of Tamiflu and Relenza at a 25% subsidy off the federal contract price. The FY06 HHS budget includes \$170 million from the supplemental appropriation to provide this subsidy. To this end, HHS is finalizing basic agreements with Roche and GlaxoSmithKline, respectively, that the states may use for subsidized purchases in accord with each state's population.

Antiviral Drug Distribution

States are responsible for the management of the antiviral drugs they receive from the SNS. States are required to develop distribution plans that cover initial storage, dividing

the allocation into distribution units, and arranging for delivery of these units to the organizations responsible for local distribution of the drugs. HHS, in collaboration with the Healthcare Distribution Management Association, is developing a model distribution plan to help states with their planning that utilizes existing private infrastructure for the distribution of antivirals and other supplies.



* a course is the number of doses needed to treat one person

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Antiviral Drugs (cont.)

First-defense Deployment

One strategy for containing or slowing the spread of a pandemic virus calls for the administration of Tamiflu to patients and their close contacts as well as to people in the area surrounding an initial outbreak. As noted above, Tamiflu was supplied to people in contact with the family cluster in Indonesia. In May, HHS sent a stockpile of Tamiflu to Asia to be pre-positioned for first defense containment efforts in the event of a pandemic flu outbreak.

Stockpiling Other Supplies

HHS will spend \$162 million to procure essential medical supplies for dealing with a pandemic. Planned purchases in 2006 include 6000 ventilators, 100 million N95 respirators, and 50 million surgical masks as well as face shields, gowns and gloves. To date, 20.2 million respirators have been stockpiled with another 87.2 million on order through September 2007 and 12.3 million surgical masks are on hand with another 39.2 million on order through September 2006.

State and Local Preparedness

"If this happens,
it's not going to be
business as usual. If it's
a pandemic, it's going
to affect the entire
world. We can't look
for outside help."

—Fire Chief Bob
Painter,
Homer, Alaska

State and local preparedness is crucial to pandemic readiness. An influenza pandemic will likely occur simultaneously or in waves across every community in our nation. All functions of society could potentially be disrupted by a pandemic. Every level of our communities must be prepared to be self-sufficient in the event of a pandemic outbreak.

Congress allocated \$350 million this year to assist with state and local preparedness. Of this, \$100 million has been allocated to states to begin their planning process by identifying gaps in preparedness. States are now submitting applications for how they will spend the remaining \$250 million. The plans are expected to cover three areas:

- Prioritize the gaps identified in an earlier funding application and propose a work plan to address them,
- Develop a distribution plan for antivirals, and

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State and Local Preparedness (cont.)

• Design a full-scale state/local pandemic influenza response exercise.

We have convened state summits in all but two states, and the remaining two summits are now scheduled. Summits have also been held in Puerto Rico and

The Minnesota Department of Health followed its summit by holding a TV call-in show, during which 12 public health and public safety experts answered more than 200 calls from citizens who wanted more information about bird flu and pandemic flu.

the Caribbean and Pacific territories, and with Tribal leaders. In each state, the governor, state, local and federal officials and members of the community have come together to strategize planning for a potential influenza pandemic. Most states have worked with HHS to complete a planning agreement detailing shared and independent responsibilities for pandemic planning.

Many states have already carried the planning process to the next level, holding regional, cross-state and community pandemic planning meetings. West Virginia organized seven regional pandemic flu summits with members of local communities. Rhode Island is hosting a cross-state pandemic planning meeting with New York, Maine, Connecticut, Massachusetts, New Hampshire, and Vermont. Many other

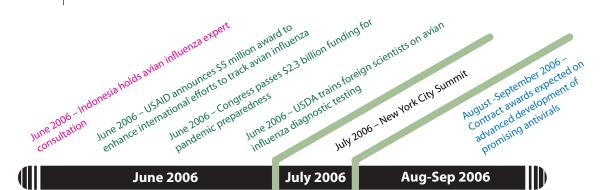
states are also coordinating their strategic plans with neighboring states.

This fall, HHS will begin holding risk communications training sessions for state and local public health professionals and community leaders in each of the ten HHS regions. Tabletop exercises will also be held, testing both planning and training by having officials interact through scripted scenarios. States are already submitting proposals detailing state pandemic planning exercises. State by state, we are moving from awareness to preparedness.

Communications

Communications is at the heart of our planning. The free and rapid flow of information both domestically and internationally is critical to everything from education to decision making.

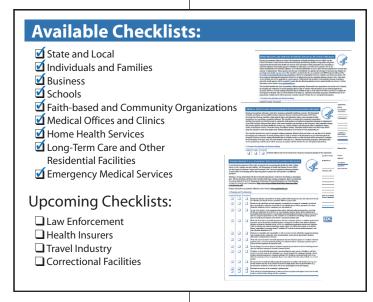
All communications materials, from fact sheets to checklists, from text to video, are made available 24/7 to a world wide audience via www.pandemicflu.gov.



Communications (cont.)

Our cross-government Web site is growing exponentially, with content increasing more than 25 percent in the past three months alone.

Highlights include the addition of a question & answer database, additional checklists, an updated *Guide for Individuals and Families* and the translation



of key documents into Spanish. With crossgovernment content ownership, a coordination council meets regularly to insure that information is current, consistent and coordinated across all related pages.

Over the last several months, we've held roundtable discussions on avian and pandemic flu with the major broadcast and cable television networks and national wire services. Reporters, producers and media executives were told of government planning efforts.

Discussion explored how the government and media would act and interact in different H5N1 scenarios. Growing out of these discussions, plans are now being drafted to conduct a tabletop exercise involving the media and health officials in a mock pandemic flu situation.

Broadcasters stressed their need for video content, and HHS plans to meet that need by building a library of video interviews and footage. Broadcast facilities in Washington and at CDC in Atlanta are being upgraded to expand emergency broadcast capabilities. Convergence technologies will allow video content to be webcast directly to the public.

We are working to communicate to all the peoples of the world the essential information they need to plan, prepare and ultimately cope with pandemic flu and its impacts. The WHO has modeled its draft communications operational plan on the HHS plan. Since March, we have supported or provided risk communications training for ministry of health communicators from twelve nations, and in April, HHS met with its Canadian and Mexican counterparts to coordinate communications in an open, timely and transparent manner.

Federal Preparedness

A response to a pandemic will require national coordination. HHS is only one of many federal departments and agencies that are taking preparatory measures to ensure that they can adequately support state and local officials in the event of an outbreak. Working with the DHS, USDA, the White House, and our other federal partners, HHS will utilize the multi-agency coordinating structures of the National Response Plan should an outbreak require a synchronized federal response.



Addendum

Since this report was published in June 2006 there are new developments detailed below:

Page 2, paragraph 2 and chart:

On August 8, 2006, the World Health Organization (WHO) confirmed that China retroactively reported a fatal H5N1 human case for 2003. This increases the number of human cases at the time of publication to 229. The chart should also reflect this increase with four human H5N1 deaths in 2003.

Page 5, paragraph 2:

On July 26, 2006, the World Health Organization reported a new case of H5N1 in humans in Thailand.

