Department of Health and Human Services

Pandemic Planning Update

A Report from Secretary Michael O. Leavitt

March 13, 2006

"President Bush asked Congress for $7.1 billion to fund preparations, and in December 2005 Congress appropriated $3.8 billion to help the Nation prepare. Of that, $3.3 billion was allocated to HHS. This report outlines how that funding is being used to help achieve HHS's five primary objectives."

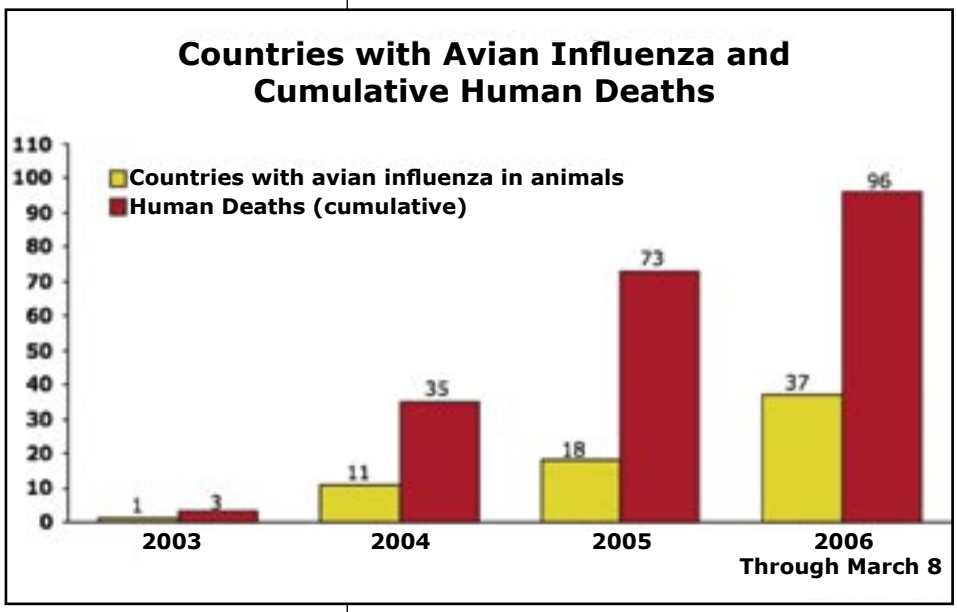
Message from the Secretary

"Let me be clear. It is only a matter of time before we discover H5N1 in America. The migration patterns of the wild fowl that carry the virus make its appearance here almost inevitable."
–Secretary Michael Leavitt, HHS

We are in a race. We are in a race against a fast moving virulent virus with the potential to cause an influenza pandemic. In November when President Bush announced the National Strategy for Pandemic Influenza, the highly pathogenic H5N1 avian flu virus was confirmed in birds in 16 countries. It was known to have infected 122 people and 62 – half of those infected – died.

Today, four months later, H5N1 has spread to 37 nations on three continents; 175 people have been infected and 96 of them have died. To date, most of those people were exposed to infected poultry. Fortunately, there has been no sustained human-to-human transmission of the disease, but the rapid spread of H5N1 is reason for concern.

We are in a race, a race against a quick changing virus, for H5N1 has not only spread, it has evolved. There are now two main variants, or clades, of H5N1 and it is this second, newer clade that is spreading across western Asia into Europe, the Middle East and Africa. This second clade has killed over 60 percent of those it is known to have infected.



Let me be very clear. It is only a matter of time before we discover H5N1 in birds in America. The migration patterns of the wild fowl that carry the virus make its appearance here almost inevitable.

The arrival of the first H5N1 bird in America should not be cause for alarm or panic. It does not mean that a pandemic is at our doorstep. It should, however, motivate us to pick up the pace, to renew pandemic preparations on every front at every level.

Message from the Secretary *(continued)*

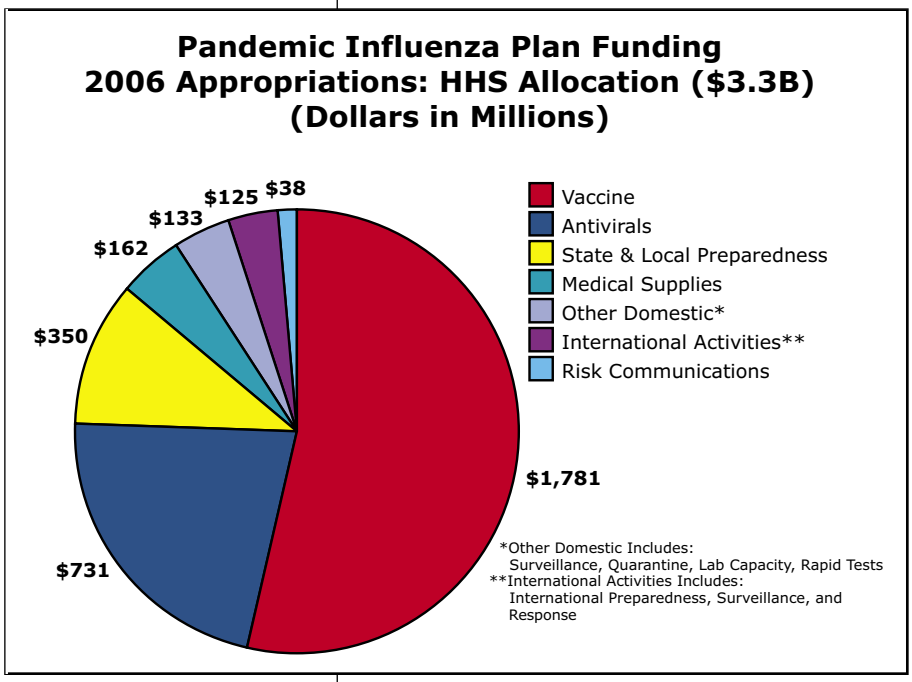
"We are better prepared today than we were yesterday. And we must be better prepared tomorrow than we are today."

Our Five Priorities

President Bush asked Congress for $7.1 billion to fund preparations, and in December 2005 Congress appropriated $3.8 billion to help the Nation prepare. Of that, $3.3 billion was allocated to HHS. This report outlines how that funding is being used to help achieve HHS's five primary objectives.

- 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

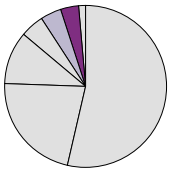
We are in a race, a race against time and complacency. There is a role for everyone and we must count on everyone to fulfill their role.



By definition a pandemic is defined as a global event. In reality, a pandemic is a local crisis worldwide. It can happen in every state and every city and every town at almost the same time.

A pandemic is not like a hurricane or an earthquake, where resources and help can be shifted from one area to another. Should it occur, every community will need to rely on its own planning and its own resources as it fights the outbreak.

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.



Monitoring and Surveillance

"For a couple of weeks, it was raining dead swans all over Europe."
–Jan Slingenberg, UNFAO

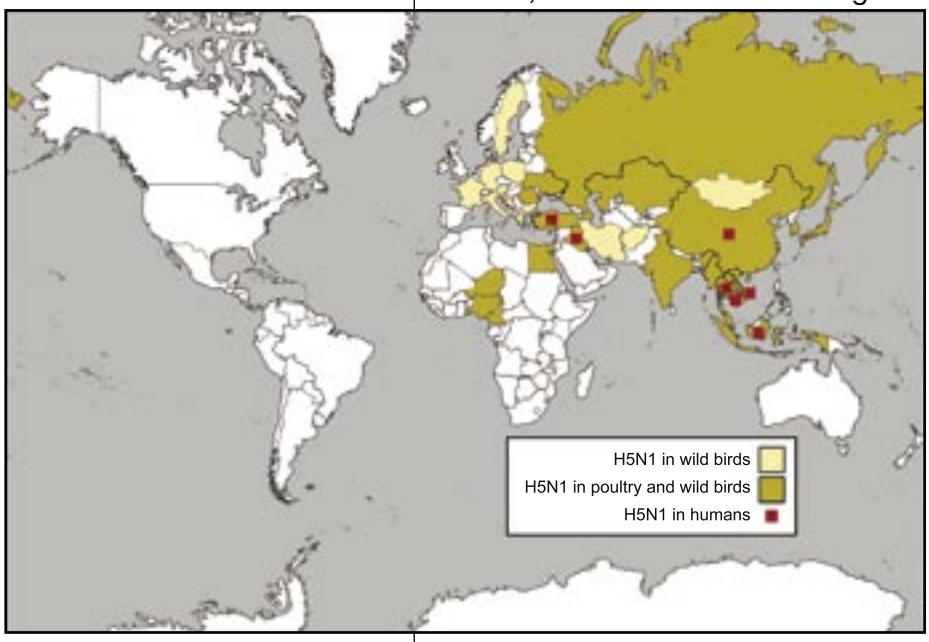
Our first line of defense is early detection. It is critical that we know immediately if the H5N1 influenza virus becomes capable of sustained human-to-human transmission. Early detection will give us the opportunity to respond, to attempt containment and to quickly gain the virus samples necessary for the development of a true pandemic vaccine.

Early detection is a race against time. Containing or slowing an influenza pandemic demands that a nascent outbreak anywhere in the world be recognized and confirmed within 1 to 2 weeks.

International Collaboration and Monitoring

This is a big job. For HHS, it means putting experts on the ground in numerous nations spread across a vast landscape. It means working shoulder to shoulder with our federal colleagues.

Early detection requires international collaboration. It means working closely with the World Health Organization (WHO), the United Nations Food and Agriculture Organization, the World Organisation for Animal Health, the Institute Pasteur, and numerous national governments. Together, we are tracking the spread of the disease, conducting epidemiological studies of human infection, training local specialists and providing them with the tools for early and accurate detection.



CDC and USAID will soon enter into an agreement with the Wildlife Conservation Society to provide additional monitoring.

Detection at Home

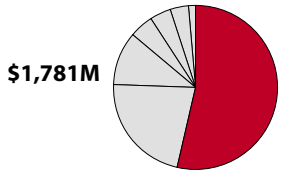
In February, the FDA approved a new laboratory test capable of diagnosing H5N1 influenza strains within four hours of receiving a sample. The new test cuts days from the time needed to confirm human infection. FDA is also providing scientific and regulatory assistance to diagnostic manufacturers to speed the development and deployment of new detection products.

Monitoring and Surveillance *(continued)*

At the International Pledging Conference on Avian and Human Influenza in Beijing in January 2006, the US committed $334 million in US grants and technical assistance to aid global effort.

As the avian infection moves closer to America, the Departments of Agriculture, Interior and Health and Human Services are stepping up the monitoring and testing of migratory birds. This surveillance is essential to provide early warning so the disease does not spread to people, poultry and pets and to insure the safety of the nation's food supply.

To monitor possible human infection, CDC is strengthening local laboratory capacity and capability, improving reporting systems and accelerating implementation of the national BioSense program, which collects real-time data from hospitals and other clinical-data sources.



Vaccines

The best defense against influenza is vaccination. It is also the most difficult defense to achieve. A fully effective vaccine cannot be developed until the virus strain it must protect against has evolved and been identified. And once developed, there must be the production capacity to manufacture enough vaccine to protect the population.

HHS, through its National Institute of Allergy and Infectious Diseases (NIAID), is addressing the problem in a number of ways. These include the development of pre-pandemic vaccines based on current lethal strains of H5N1 and collaboration with industry to increase the Nation's vaccine production capacity, as well as seeking ways to expand or extend the existing supply. We are also doing research in the development of new types of influenza vaccines.

2004 – H5N1 reference strain created by reverse genetics from H5N1 virus isolated from Vietnam

April 2005 – RFP for cell-based vaccine contract issued

Summer 2005 – Preliminary results from H5N1 vaccine clinical trials in healthy adults aged 18-64 indicate an immune response predictive of protection against the H5N1

September 2005 – International Partnership on Avian and Pandemic Influenza launched

October 2005 – Southeast Asia fact-finding mission led by HHS Secretary and State Department

November 2005 – WHO Global Meeting

November 2005 – Issuance of HHS Pandemic Influenza Plan

2004 April November 2005

Vaccines *(continued)*

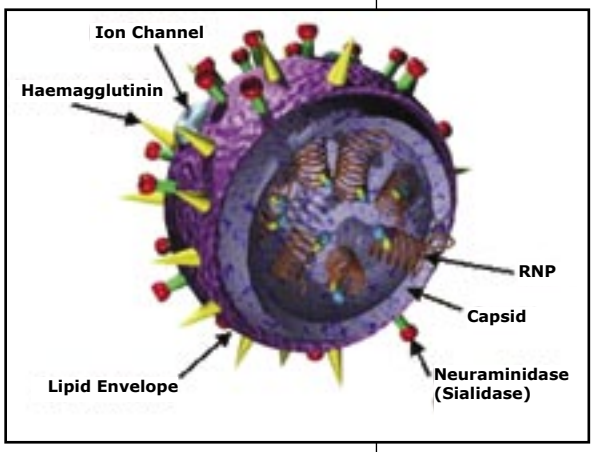
There is simply no way to predict which strain, if any, might produce a virus capable of mass human-to-human transmission – or which vaccine will be most effective against it.

In early 2004, NIAID researchers applied a technology called reverse genetics to the H5N1 virus isolated from a patient in Vietnam to create an H5N1 reference vaccine strain. Working with industry, NIAID was able to create an inactivated H5N1 virus vaccine for clinical testing. In this testing, conducted in the summer of 2005, the vaccine induced an immune response predictive of protection against the H5N1 virus. We then contracted with two companies to manufacture nearly 8 million doses of this vaccine for strategic stockpiling.

Vaccine for a Changing Virus

However, all influenza viruses evolve, or "drift" genetically over time. By 2005/2006 winter the H5N1 strain had drifted enough to result in a second distinct strain of H5N1. This strain, also lethal, is now circulating in Europe, Africa and parts of Asia. Its appearance dictates that we begin developing a second pre-pandemic vaccine.

The CDC has already taken the first step by producing the reference virus that will serve as a seed from which a second vaccine might be developed. It is probable that H5N1 will continue to evolve, making it necessary to develop a series of vaccines. There is simply no way to predict which strain, if any, might produce a virus capable of mass human-to-human transmission – or which vaccine will be most effective against it. For this reason it is prudent to maintain stockpiles against each of the main circulating H5N1 strains.



In March, FDA released draft guidance for clinical data that are needed to show safety and effectiveness for new seasonal and pandemic influenza vaccines. The FDA also outlined an approach for an accelerated approval of these vaccines.

December 2005 – Passage of the Public Readiness and Emergency Preparedness Act (PREP Act)

December 2005 – Enrollment for clinical trials with H5N1 vaccine in healthy adults (>65 years of age) was completed

December 2005 –Tabletop public affairs exercises with US Departments and representatives from Canada and the UK

December 2005 –WHO Global Pandemic Communications Meeting in Switzerland, HHS led US delegation

December 2005 – First State Summit, Minnesota

December 2005 – Release of State and Local Pandemic Influenza Checklist

December 2005 – Convening of States Summit, in Washington, DC

December 2005 – Release of Business Pandemic Influenza Checklist

Vaccines *(continued)*

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Increasing Vaccine Capacity

The current U.S. capacity for manufacturing egg-based vaccines is not sufficient to supply our entire population. HHS is working with industry to determine ways to increase that capacity, including developing new facilities and expanding production in existing facilities. A request for formal proposals will be issued in April 2006.

The threat of liability has been a major obstacle to developing a strong domestic vaccine industry. HHS worked with the Department of Justice and Congress to address the problem. As a result, Congress adopted legislation (PREP Act) providing industry with limited liability when meeting a declared public health emergency.

Current egg-based vaccine manufacturing methods are complex, difficult to expand rapidly to meet increased demand, and subject to failure if the vaccine strain does not grow efficiently in eggs. HHS is supporting research into cell-based vaccine manufacture, which holds the promise of a reliable, flexible, and easily scalable method of producing vaccine domestically. In April 2005, HHS announced a $97 million contract for the development of cell-based flu vaccine, and we expect to award additional contracts for developing cell-based vaccines this spring.

There is also research into ways to increase the effectiveness of vaccines by exploring antigen-sparing technologies such as adjuvants, substances that increase either the efficacy or potency of a vaccine. If successful, they extend a given supply of vaccine to protect more people.

If a pandemic occurs prior to licensure of a vaccine, the FDA can use its Emergency Use Authorization authority to permit the use of unapproved products (or to permit unapproved uses for previously approved products) if there's a reasonable belief the products may be effective and if the benefits would outweigh risks.

January 2006 – RFI issued on increasing egg-based vaccine capacity

January 2006 – Bilateral teams sent to Turkey, Armenia, Azerbaijan, Georgia, Romania, Ukraine and Nigeria to assess avian flu outbreaks

January 2006 –Tokyo WHO conference to draft WHO pandemic plan

January 2006 – International Pledging Conference in Beijing; $334M in US grants and technical assistance to aid global effort

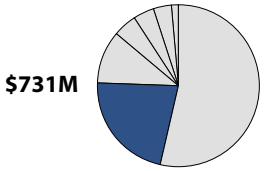
January 2006 – 6 State Summits AZ, VT, WV, RI, GA, KY

January 2006 – Roughly 5 million courses in SNS stockpile

January 2006 – RFI issued on advanced development of promising antivirals

January 2006 – Release of Individuals and Families Pandemic Influenza Checklist

January 2006 – First State Summit with signing of a Planning Agreement, Vermont



Antivirals

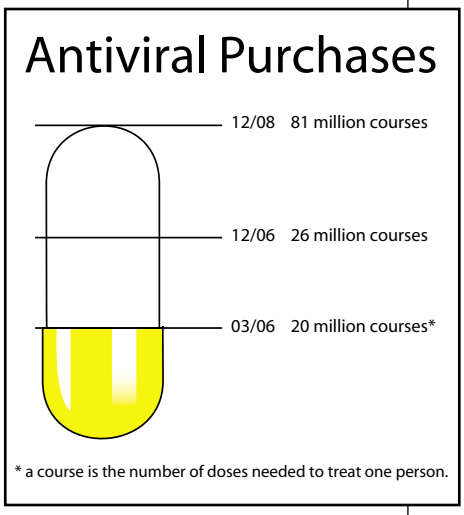
Antivirals are drugs that lessen the impacts of flu. There are currently two FDA-approved antivirals that have shown effectiveness against the H5N1 virus, Tamiflu, and Relenza. Both must be taken within 48 hours of the onset of flu symptoms. (Note that there are two other approved flu antivirals, but CDC studies show H5N1 to be resistant to them.)

The immediate goal is to stockpile enough antivirals to treat 20 million people. The longer-term goal is to be able to treat 75 million people, or 25 percent of the U.S. population.

We are building a national stockpile of these two antivirals. The immediate goal is to stockpile enough antivirals to treat 20 million people. The longer-term goal is to be able to treat 75 million people, or 25 percent of the U.S. population. Achieving this goal depends on future pandemic flu appropriations, manufacturing capacity and participation by the states.

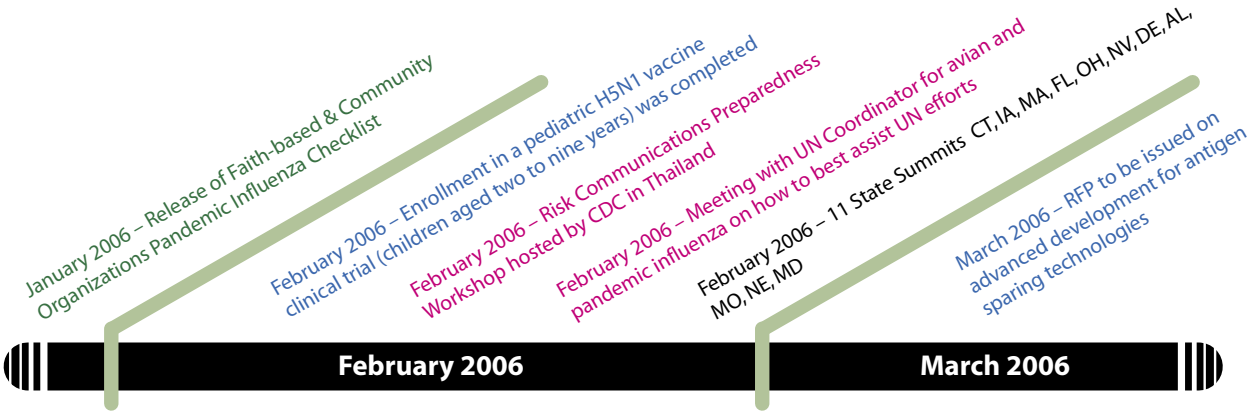
Antiviral Stockpiling

Because Tamiflu is also approved for prevention, treatment for an additional 6 million people is also being stockpiled. This will be used in an effort to help contain a first outbreak of potential-pandemic influenza. The concept is to blanket the area of the initial outbreak, giving Tamiflu to as many people as possible to prevent the flu's spread before it gets out of control.



In March, HHS purchased more than 14 million courses of Tamiflu and Relenza, which will increase the national inventory to nearly 20 million courses. The total targeted stockpile is 81 million courses by the end of 2008. HHS will purchase 50 million out right and subsidize (by 25 percent) the states' purchase of 31 million courses. (A course is the number of doses needed to treat one person – ten capsules in the case of Tamiflu.) Antivirals will be distributed among the states and territories on a per-capita basis.

FDA is monitoring Tamiflu shipments to identify potential counterfeits, and is actively investigating companies selling fraudulent, unapproved influenza products.



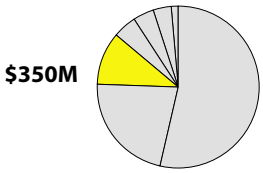
Antivirals *(continued)*

New Antivirals Needed

We are committing $200 million to the development of additional antivirals.

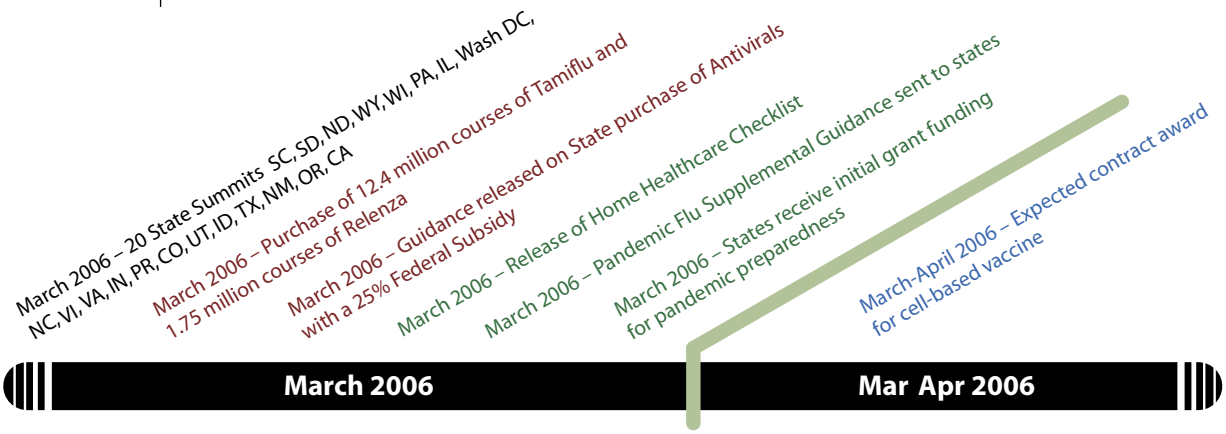
Influenza viruses can develop resistance to antivirals over time. New antivirals will be needed in the event H5N1 develops resistance to Tamiflu or Relenza. We are committing $200 million to the development of additional antivirals. HHS expects to request formal proposals later this spring and to award contracts for the advanced development of promising antivirals by September 2006.

It is not enough to stockpile antivirals; there needs to be a plan to distribute them. HHS is discussing with the states whether the antivirals should be centrally located or warehoused locally. To receive funding, states are being required to develop distribution plans now, so that if a pandemic erupts, it will be clear where the drugs are to go and how they will get there. In addition to stockpiling antivirals, $162 million will be used to procure essential medical supplies for a pandemic. Planned purchases this year include 6000 ventilators, 50 million surgical masks, 50 million N95 respirators, and face shields, gloves and gowns.



State and Local Preparedness

State and local preparedness is the foundation of pandemic readiness. The challenges that we will face in a pandemic will be vastly different from other response situations. An influenza pandemic is likely to occur almost simultaneously across countries and communities. It will demand that every aspect of our communities be self-sufficient, able to deal with the outbreak of illness should it hit. Political leaders, employers, school leaders, healthcare leaders, faith-based and community organizations, families and the media must all be informed, engaged, and actively involved.



State and Local Preparedness *(continued)*

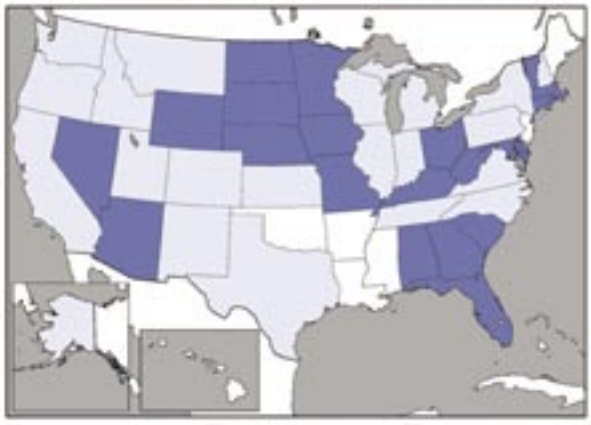
West Virginia is holding seven Regional Pandemic Flu Summits across their state to plan for the possibility of pandemic flu and specific WV preparedness needs – this is a direct outcome of HHS/ WV summit held there in January.

To that end, President Bush directed and we convened a state and local preparedness process. We are working to help states, tribes, cities, schools, businesses, churches, and families throughout our nation plan for these unique challenges. We are collaborating with governors' offices in every state to hold pandemic planning summits and exercises. To date, we have completed 23 summits and planned an additional 20: we expect to visit the remaining states and territories this spring (see map). I am hearing from governors and local officials that the summits are helpful, and the process is working.

Congress allocated $350 million this year to assist local and state preparedness. We are awarding $100 million to states right now. The remaining $250 million will be distributed later according to benchmarks we establish to measure progress.

I am asking governors to make sure that their pandemic influenza plans are an integral element of and coordinate effectively with the National Response Plan and the National Incident Management System.

HHS Pandemic Planning - State Summit Overview

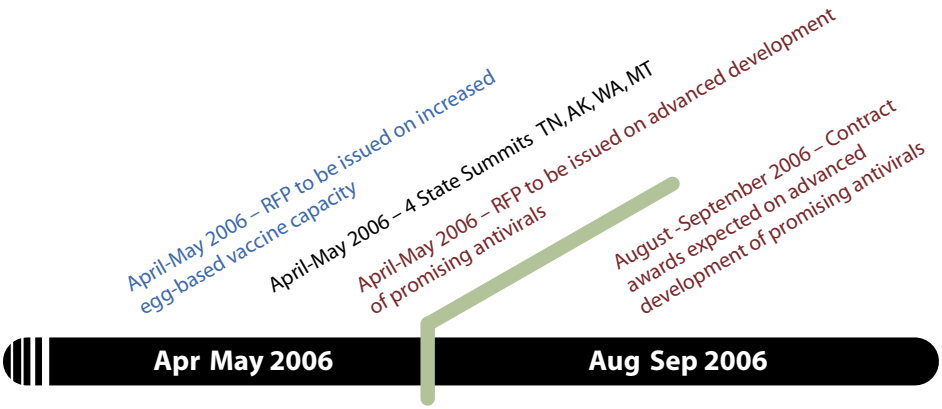


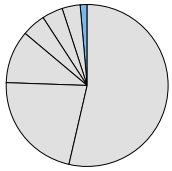
23 Completed Summits | 20 Scheduled Summits | 7 Unscheduled Summits

Including Puerto Rico and the Virgin Islands

I am asking them to establish a Pandemic Preparedness Coordinating Committee that represents all relevant stakeholders in their jurisdiction. These collaborative committees will help states to articulate strategic priorities and oversee the development and execution of operational pandemic plans.

One of the most important elements of the preparedness response is practicing. We are assisting states in the development and administration of tabletop exercises to improve our Nation's readiness to respond and recover from a pandemic. We are asking states to exercise their plans by the end of 2006, and will invite them to participate in a nationwide pandemic planning exercise within the next twelve months. These planning and response exercises will help public health and law enforcement officials establish procedures and locations for quarantine, surge capacity, diagnostics, communication and many other pandemic-related needs.





Communications

Communications and outreach are essential to preparedness. I am committed to telling people what we know when we know it; to inform the public without raising unnecessary alarm, and to collaborate with our public and private partners in a way that is fully transparent. It is my hope that every state and local partner will practice that principle as well — every person must be a communicator.

Today the media and web will be our primary pre-pandemic and pandemic communication sources.

We must all be ready to provide the best instructions and advice on what is happening, status of school, business and transportation impacts, home health care practices and basic infection control.

Congress foresaw the role and value of communications and funded our efforts to further develop comprehensive science-based risk communication strategies for pandemic influenza — communications that will touch every part of our nation with medical, social and economic implications and information on avian and pandemic influenza.

Checklists to aid in pandemic influenza preparations have been developed by CDC. These planning checklists provide specific guidance for state and local planning, businesses, health care providers, community organizations and individuals and families. Other checklists are being developed, along with toolkits that provide more specific guidance.

Available Checklists:

- ☑ State and Local
- ☑ Individuals and Families
- ☑ Business
- ☑ Schools (K-12)
- ☑ Faith-based and Community Organizations
- ☑ Medical Offices and Clinics
- ☑ Home Health Services

Upcoming Checklists:

- ❑ Emergency Medical Services
- ❑ Preschool
- ❑ Colleges and Universities
- ❑ Long Term Care
- ❑ Travel Industry
- ❑ Transportation

The global nature of pandemic preparedness and the enormity of potential impacts are fostering a spirit of collaboration across the world. Common efforts include surveillance of the disease, planning across national boundaries and economic sectors, and sharing research and technology. The U.S. and world organizations are conducting tabletop exercises and participating in international risk communications workshops and conferences at many levels.

Outreach Resources

During the 1918 influenza pandemic it was the newspapers and word of mouth that carried the news and information. Today the media and web will be our primary pre-pandemic and pandemic communication sources. Both must be used responsibly to inform and educate — to help achieve a nation prepared, but not in panic.

Communications *(continued)*

President Bush directed all federal agencies to establish a single, comprehensive web site to be the official federal source of pandemic and avian flu information. This web site, www.PandemicFlu.gov, hosts a vast array of information designed to meet diverse audience needs. It links to specialized information from federal agencies, states, international organizations and other important resources.

New broadcast capabilities will allow us to reach media outlets more quickly and ultimately provide information directly to the public via satellite. Convergence technologies will be used to integrate audio and video production on the web. Video, audio, multi-media and print materials are being developed for broad dissemination. Selected materials will be translated as appropriate.

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.