U.S. Department of Health and Human Services

Pandemic Planning Update V

A Report from Secretary Michael O. Leavitt

March 17, 2008

"Once again, nature has presented us with a daunting challenge: the possibility of an influenza pandemic... Together we will confront this emerging threat and together, as Americans, we will be prepared to protect our families, our communities, this great nation, and our world."

—President George W. Bush

Message from the Secretary

"The Federal government cannot mount an effective response to the threats that we face as a nation without partners at every level of government and throughout society."

– HHS Secretary Mike Leavitt

Forty million people died when the last major influenza pandemic swept around the world in 1918. We have seen two less severe pandemics since then. We will no doubt see another sometime in the future. We don't know when, and we don't know how bad it will be. But we know it will happen sooner or later and that what we do now will save lives — maybe millions of lives — in the future.

We have come a long way since November 2005, when President Bush mobilized the nation to prepare for an influenza pandemic. HHS continues to play a prominent role in pandemic preparedness, giving highest priority to those tasks that it is best positioned or uniquely able to undertake. These include:

- stockpiling pre-pandemic vaccine and antiviral drugs;
- providing financial and technical assistance to States to help them, among other things, create complementary stockpiles of antiviral drugs and develop and test various mitigation strategies;
- creating a domestic vaccine production capacity commensurate with the expected requirements of a pandemic;
- sponsoring advanced development projects toward the next generation of vaccines, therapeutics, and diagnostics; and

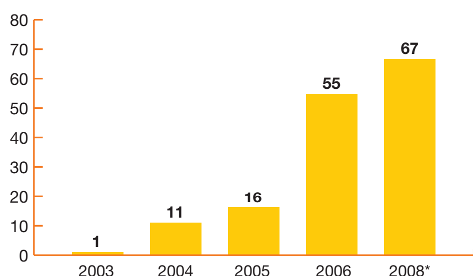
In our last Update, we mentioned many of the important milestones we have passed already. We have licensed the first H5N1 influenza vaccine for humans and stockpiled enough antiviral medicine to treat 40 million Americans. We have committed over $1 billion to diversify influenza vaccine production technology. And we have worked with the world's leading vaccine companies to accelerate the development of cell-based influenza vaccine production to increase the nation's domestic vaccine production capacity. We have also invested heavily in clinical research and surveillance programs here at home and around the world.

We have held flu summits in every State of the Union, plus our first on-line "blog summit" last June. We have organized, equipped, and trained response teams and begun to modernize the U.S. Public Health Service Commissioned Corps to enhance its response capabilities.

Since our last Update, we have entered a new phase in our preparations. The milestones are farther apart but no less significant. We are now tackling some challenging issues that can only be resolved with the collaboration of the full range of stakeholders — State and local officials, public health and medical professionals, religious leaders and ethicists, the business community, organized labor, non-governmental organizations, and individuals from all walks of life. Each is needed to find the best answers to difficult questions such as "How do we decide who receives the first vaccines from our limited supplies?" and "Who should be responsible for stockpiling medical countermeasures such as facemasks, respirators, ventilators, and antiviral medications?"

Message from the Secretary (cont.)

These issues will have a significant impact on how States, counties, cities, communities, corporations, families, and individuals prepare for and respond to pandemic disease. None can be addressed fairly and fully without the participation of the persons likely to be affected.



We have mounted an unprecedented effort on the part of the Department and the Federal government to garner thoughts and comments on these issues from as many people as possible, using new communication tools such as blogs and web casts as well as large public forums, smaller group meetings, and conference calls.

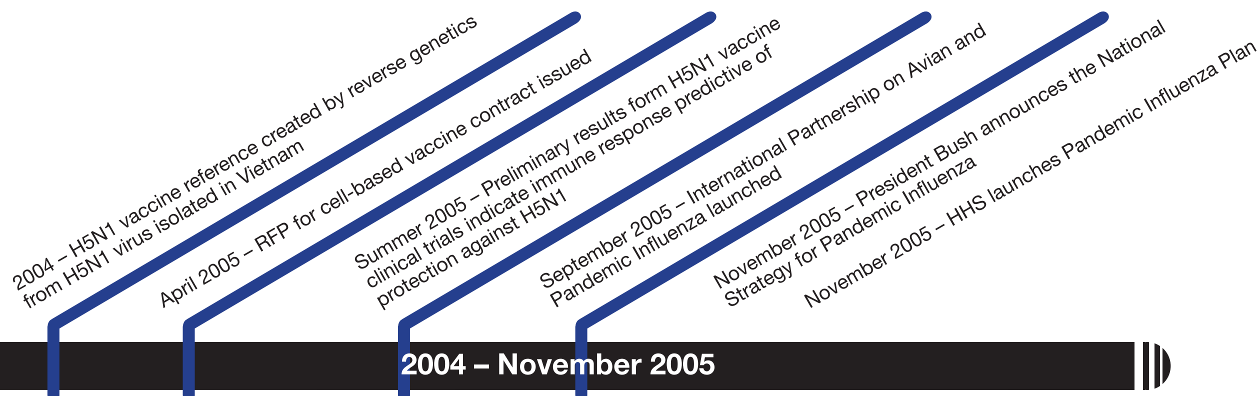
In December 2007, the Department held its first ever web dialogue to discuss the proposed vaccine allocation plan. More than 400 people from 37 States took part in the five-day on-line conversation with Federal, State, and local health officials. The web dialogue followed two public meetings on vaccine allocation, in Henderson, NC, and Milwaukee, WI. We have also met with various stakeholder representatives to discuss the feedback from the public meetings and the web dialogue.

A cross-government working group was then tasked with defining a priority order for administering vaccine to counter an influenza pandemic. That group now is weighing the information received from the rounds of public consultation and is updating an earlier draft document to accommodate the most persuasive comments and critiques. The intent is to have a plan suitable for public release within the next several months.

"This isn't just about us, it's about our neighborhoods and where we live."

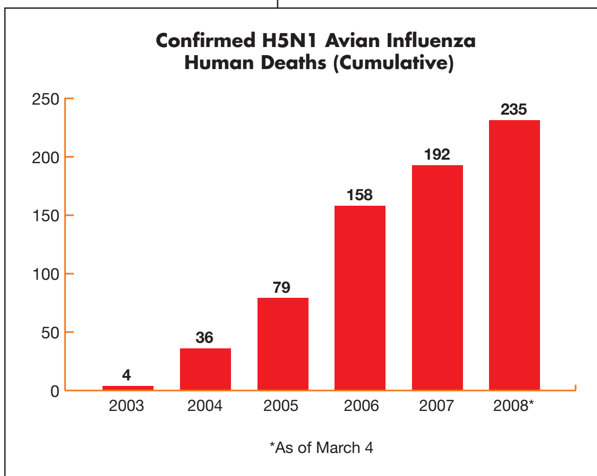
– Dr. Greg Dworkin,
founding editor,
Flu Wiki blog

Through the fall of 2007, we also held nearly twenty meetings around the country to discuss the shared responsibility concept of stockpiling medical countermeasures and the feasibility of private-sector stockpiling of antivirals. These meetings included senior leaders and subject matter specialists from throughout the Federal government, along with governors, mayors, State and local health officials, employers, health care providers, first responders, organized labor and law enforcement. Some meetings were conducted by conference call, but we also met in Atlanta, GA, Seattle, WA, Scottsdale, AZ, the Raleigh-Durham, NC, area, and Washington, DC.



Message from the Secretary (cont.)

In December, we launched a public education campaign to encourage people to prepare now for a future pandemic. The campaign, titled *Take the Lead: Working Together to Prepare Now*, is aimed at community leaders such as clergy, employers, and health care providers, and is designed to provide them with the information they need to communicate the importance of pandemic planning by families and individuals. It was developed after consultation with over a hundred leading organizations such as the American Medical Association, Catholic Health Association, Red Cross, Lions Clubs, and the U.S. Chamber of Commerce. We also held our first-ever blog featuring ten prominent leaders blogging over a five-week period on the subject of individual pandemic planning. The blog attracted more than 35,000 individual visitors, 1,600 comments, and more than 300 in-bound links from other websites, blogs and message boards.



There's still much to be done. Preparedness is a process — learning, adapting, and growing. In 2008, we will continue these unprecedented efforts to reach out to stakeholders for help in shaping some of the most difficult pandemic planning issues. We will also be finalizing policies and guidance based on the input we have received thus far.

The media buzz has died down, but the "bird flu" virus has not. Avian influenza is still highly pathogenic, inflicting a heavy toll on domestic and wild bird populations in Asia, Europe, and Africa and, from time to time, infecting humans. To date, some 370 people have contracted the disease, largely through exposure to sick or dead birds; 235 of them have died.

We don't know if the H5N1 virus will spark the next pandemic, but we know that it's just a matter of time before something does. There is simply no reason to believe that this century will be different than any past century. The difference now is that we better understand the threat, so we can increase our preparedness for a pandemic before it comes, in order to diminish its potential impact.

The Federal government cannot mount an effective response to the threats that we face as a nation without partners at every level of government and throughout society. It is every American's continued commitment that will make our country a safer and a healthier place.

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

December 2005 – First state summit in MN

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

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

January 2006 – RFI issued on advanced development of promising antivirals

January 2006 – Release of individuals and families, faith-based and community organizations, and school districts (K-12) checklists

December 2005 – January 2006

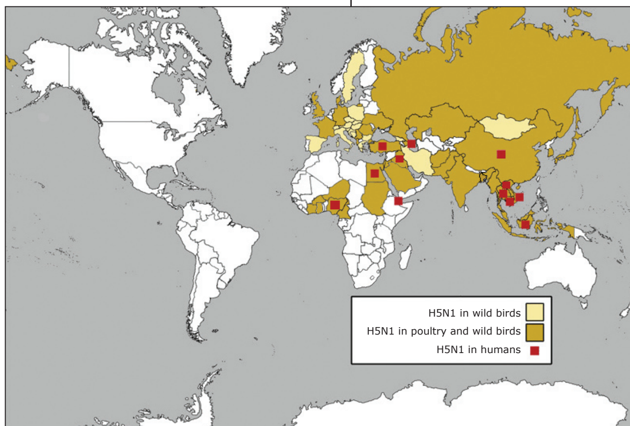
Monitoring and Surveillance

"If you empower with feasible steps, you'll make social change."

– Pandemic Flu Leadership blogger

Responding to a pandemic will demand the cooperation of the entire world community. No nation can go it alone.

An example of how closely we are connected to the rest of the world came late in 2007. For the first time in Pakistan, local officials identified a cluster of suspect human cases of H5N1. But delayed notification led to the international travel of an individual who had been exposed to H5N1 while in Pakistan. That person then requested medical attention after arriving in New York State and the exposure to H5N1 was discovered. Though the individual was quickly found to be negative to H5N1 and presented no risk to the community, the case underscored the need for close cooperation with our international partners to detect and contain the virus.



During 2007, Laos, Myanmar, and Nigeria, along with Pakistan, also reported first-time human cases of avian flu in humans. As in similar past events, the Centers for Disease Control and Prevention (CDC) dispatched specialists to work with the World Health Organization (WHO) and local public health officials to determine the extent of the problem. Their reports, along with international networks of cooperation, have helped HHS keep close track of developments around the globe. Continued progress in virus and disease detection, enhancement of surveillance systems, and other aspects of pandemic preparedness are critical to our national security.

International Cooperation

In October 2007, senior representatives of eight allied nations plus the European Commission and WHO gathered in Washington for the seventh annual meeting of the Global Health Security Initiative (GHSI). The GHSI works to identify health-security needs and decides on courses of action that can be jointly taken to fill those needs. HHS has worked closely with other member countries to reach the common goals of informing other member of health emergencies as they arise and working together to coordinate national and international responses to disease threats, including pandemics.

February 2006 – State summits in CT, IA, MA, FL, OH, NV, DE, AL, MO, NE, MD

February 2006 – Laboratory assay for diagnostic testing of avian influenza A/H5 approved

March 2006 – Releases of medical offices and clinics, home health care, child care and preschool, and colleges and universities checklists

March 2006 – Pandemic flu supplemental guidance sent to States

March 2006 – 19 state summits in SC, SD, ND, WY, WI, PA, IL, NC, VA, IN, PR, CO, UT, ID, TX, NM, OR, CA, and the Virgin Islands

March 2006 – RFP issued for advanced development of antigen-sparing technologies

February 2006 – March 2006

Monitoring and Surveillance (cont.)

"Pandemics are earthshaking events. They reshape societies, they reshape economies, and they reshape geopolitics."

– HHS Secretary Mike Leavitt

HHS also continues to engage actively with other countries around the world to help prepare for the possibility of a pandemic influenza outbreak and to help minimize and contain the impact of an outbreak, should one occur. Working with the U.S. Department of Agriculture (USDA) and the U.S. Agency for International Development (USAID), HHS has provided training, direct assistance, supplies, reagents, and technical support to the WHO, national ministries of health and non-governmental organizations. Further, HHS works actively with the Department of Defense, through its U.S. Naval Medical Research Units (NAMRUs), located in Egypt and Indonesia.

A new Southeast Asia Research Network is a multi-lateral, collaborative partnership of hospitals and institutions; it has helped Indonesia, Thailand, and Vietnam expand their advanced research sites through a collaborative partnership with the United Kingdom and the United States. These local clinical laboratories carry out research on therapeutics, diagnostics, and vaccines, including contributing to protocols to evaluate the effective use of antiviral drugs in countering severe seasonal or avian flu.

Virus Sample Sharing

The science agencies of HHS and other Federal government departments are strongly committed to unrestricted sharing of virus isolates and related biological materials. The U.S. is an active partner with the WHO and other member nations in promoting this concept and in seeking remedies for those countries who do not believe their interests are served by this practice.

HHS continues to encourage nations around the world to share samples of influenza viruses. For the past 50 years, WHO's Global Influenza Surveillance Network has provided the world with early warning of evolving flu viruses. All nations have a responsibility to share data and virus samples.

March 2006 – FDA approves Relenza for the prevention of Influenza A and B in adults and children

March 2006 – States receive initial grant funding for pandemic preparedness

March 2006 – Order of 16.2 million courses of Tamiflu and 3.9 million courses of Relenza

April 2006 – State summits in TN, AK, WA, HI, LA, MI and the District of Columbia

April 2006 – FDA issues guidance for industry on diagnostic devices to detect influenza A viruses

May 2006 – Homeland Security Council releases National Strategy for Pandemic Influenza: Implementation Plan

March 2006 – May 2006

Medical Countermeasures

Since the HHS Pandemic Influenza Plan went into effect in November 2005, the Department has advanced the nation's pandemic preparedness in a broad range of activities. HHS has worked to expand and diversify domestic vaccine production and surge capacity, enlarge H5N1 pre-pandemic vaccine and antiviral drug stockpiles, support advanced development of cell culture and antigen-sparing influenza vaccines and new antiviral drugs, support advanced development of point-of-care clinical diagnostics, and stockpile medical supplies, ventilators, and personal protective equipment such as facemasks and respirators. HHS is also building a robust and comprehensive portfolio leading to a broad array of medical countermeasures — vaccines, antivirals, and diagnostic tools.

Many of the advanced development contracts to carry out these activities have made commitments pending successful completion of milestones. One example is the advanced development of cell-based seasonal and pandemic influenza vaccines, in which contractors must demonstrate that they have met milestone biosecurity measures in their domestic manufacturing facilities. Another example is the advanced development of an antigen-sparing pandemic influenza vaccine, in which successful completion of phase I trials of the candidate vaccine must be obtained for confirmatory testing. This is a major step forward in the development of pandemic influenza detection and response in priority countries.

New cooperative efforts are leveraging resources from throughout HHS, along with other Federal departments, States and industry. Since 2005, HHS has awarded 27 contracts totaling $3.5 billion to develop plans and begin projects within the medical countermeasures program.

No one can say with certainty when new technologies such as recombinant DNA vaccines will take center stage for influenza vaccine manufacturing. But HHS is committed to accelerating the maturation of DNA vaccines and other emerging technologies, funding important research on DNA vaccines against influenza viruses and soliciting contract proposals for advanced development of a DNA vaccine. This latter initiative is a critical milestone on the path from the laboratory bench to the manufacturing floor.

May 2006 – HHS awards contracts totaling more than $1 billion to develop cell-based influenza vaccine

May 2006 – Department of State establishes Avian Influenza Action Group to coordinate U.S. international effort

May 2006 – Release of long-term care and other residential checklist

May 2006 – 7 State summits in MS, OK, NJ, KS, NH, MT and tribal leaders

June 2006 – CDC issues updated interim guidance for laboratory testing of persons with suspected infection with avian influenza A (H5N1) virus in the United States

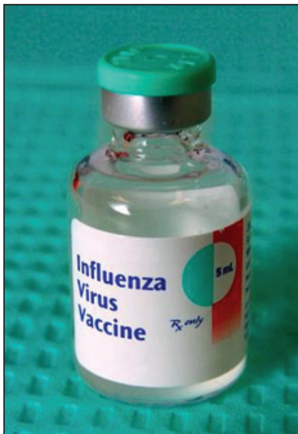
June 2006 – Congress passes $2.3 billion funding for pandemic preparedness

May 2006 – June 2006

Medical Countermeasures (cont.)

"Many people want good information and good advice, and now there is an answer to the question, 'What can I do?'"

– Dr. Greg Dworkin, founding editor, Flu Wiki blog



Vaccines and Vaccine Production Capacity

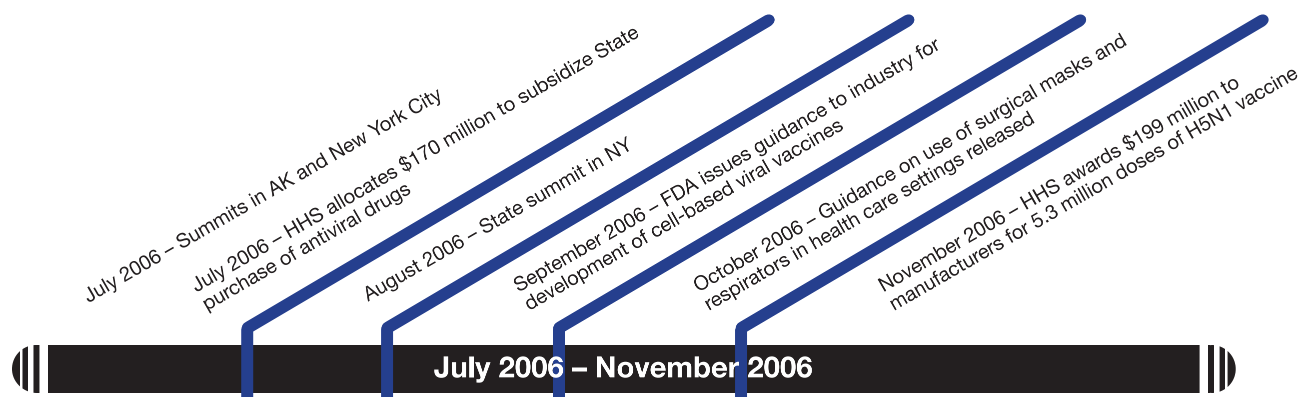
A flu pandemic poses unique public health challenges. A novel influenza virus means that everyone in the world is susceptible, and the entire population should be vaccinated for optimal protection. Our investments in science and vaccine research will help bring about a new generation of influenza vaccines that could take the threat of a pandemic off the table. But our current approach requires that production of a pandemic vaccine can only start once that virus appears — after the flu pandemic begins — and we will be challenged to allocate a limited supply of vaccine early in a pandemic. We are taking steps now to address these challenges.

Vaccine Production

One of HHS' highest priorities, in concert with an array of leading pharmaceutical companies, is to enhance and expand U.S.-based production capacity to the point that it can generate 600 million doses of a pandemic influenza vaccine (two doses for every American) within six months of the time that a reference strain of the actual pandemic virus is developed. When this initiative began just over two years ago, the U.S. had only a small fraction of this target capacity. Only two domestic manufacturers of approved influenza vaccine existed, and only one of those had a product that was licensed for use in all appropriate age groups.

Today, with HHS funding, six companies are in various stages of implementing commercial-scale production cell culture methods and/or expanding their capacity for conventional manufacturing using chicken eggs. The target date for achieving the 600 million dose target is 2011. The work is on schedule.

The driving motivation to build this target production capacity within the U.S. is to ensure that we can provide pandemic influenza vaccine for every American without having to purchase and import it from foreign-based manufacturing facilities. A condition of HHS' funding for the participating companies is that their manufacturing facilities be located within the United States.



Medical Countermeasures (cont.)

"In public health, we believe that the community-level direction is the best in dealing with public health and medical issues…who knows the behavior, the culture, the desire, the priorities of the community better than the people who actually live in that community?"

– Rear Admiral Craig Vanderwagen, Assistant Secretary for Preparedness and Response

At the same time, HHS expects that these manufacturers, once they have met the needs of the U.S. market, will have opportunities to sell their life-saving products to others around the world. Our current collaborations with WHO and other international partners are an important step toward creating the mechanisms that will be needed to combat pandemic influenza in a coordinated manner around the globe.

Vaccine Adjuvants

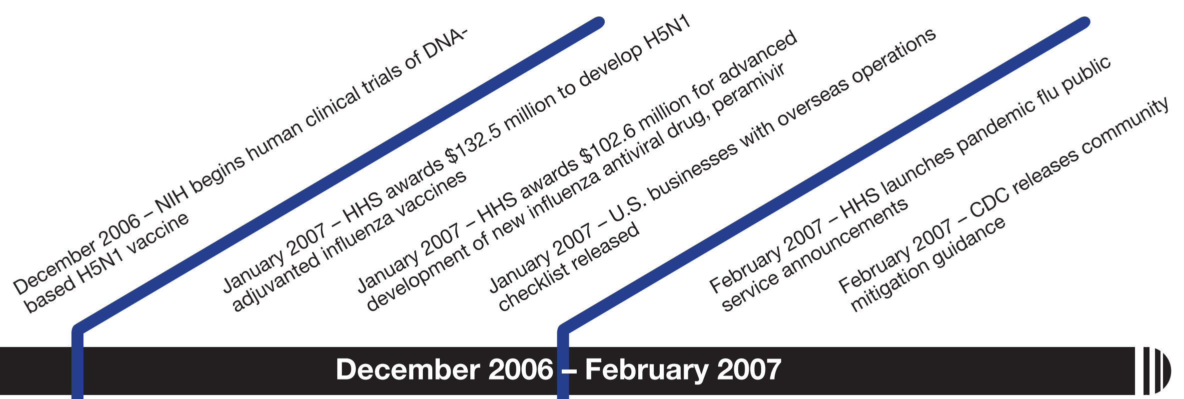
HHS has a strong interest in vaccine adjuvants. These are chemical or biological substances that are added to vaccines to increase the magnitude and, sometimes, the scope of the immune response. The addition of an adjuvant can have a dose-sparing effect — meaning that protective immunity is achieved with smaller quantities of vaccine than if the adjuvant were absent.

Further, addition of an adjuvant may increase cross-protection — the adjuvanted vaccine elicits an immune response against more strains of influenza virus than if the vaccine were used alone. HHS is funding a variety of advanced development projects involving adjuvanted influenza vaccines, and several manufacturers are pursuing independent efforts.

To date, HHS has invested more than $130 million working with vaccine manufacturers and the biotechnology community to study adjuvants.

Pre-Pandemic Vaccine

To meet the first wave of a pandemic, work has been ongoing for the past two years to build a "pre-pandemic" vaccine, one that would use likely viruses already in circulation to provide early protection against the pandemic virus for those with the most critical needs within a community. By the end of 2007, HHS had purchased and stockpiled 13 million courses of pre-pandemic vaccine.

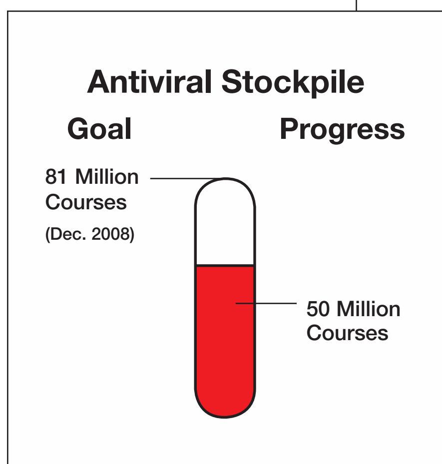


Medical Countermeasures (cont.)

Antiviral Drugs

Experience with seasonal flu has shown that antiviral drugs are a proven tool in the arsenal of weapons that could be used to help contain a flu pandemic. They can play a critical role in the earliest pandemic stages, by helping contain an early outbreak wherever it occurs, slowing the spread of the disease, and treating those who are ill during later community outbreaks.

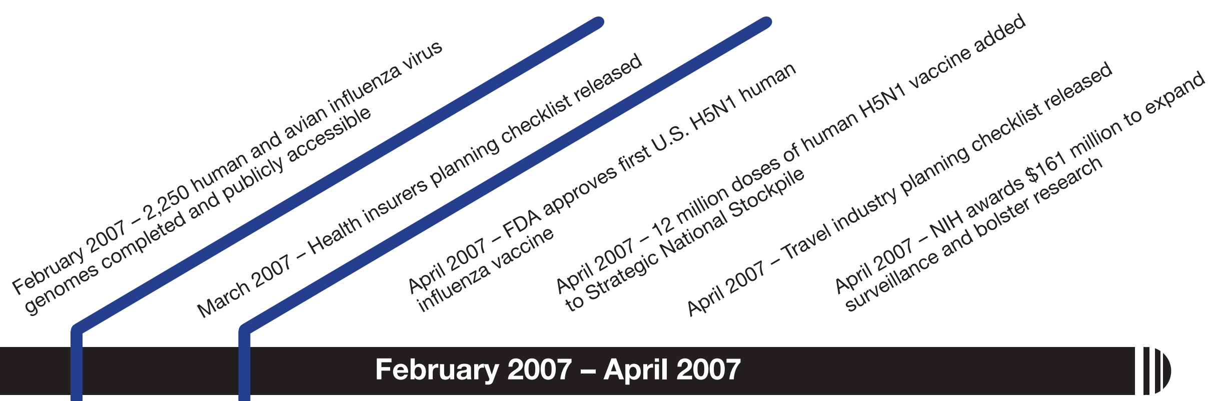
In November 2005, the Federal government determined that pre-pandemic stockpiling of antiviral drugs was essential and proposed a national target of 81 million treatment courses — assuming that, during an influenza pandemic, about 25 percent of the U.S. population would seek treatment. The 81 million antiviral treatment courses include 6 million treatment courses set aside for the early stages of an emerging pandemic.



Viewing such stockpiling as appropriate for shared responsibility, the Federal government proposed to acquire and stockpile about 60 percent of the national requirement directly and to look to the States to acquire and stockpile the other 40 percent. HHS then assisted States both administratively and financially to meet that stockpiling goal. Most States have availed themselves of this opportunity, with many of them purchasing the full subsidized amount or more. HHS is hopeful that States will make additional purchases through this mechanism this year.

Each State is responsible for allocating its respective share of the HHS stockpile and its own stockpile, if any. As part of their preparedness planning, States need to identify the hospital entities and other healthcare-associated places where the drugs are to be pre-positioned when an influenza pandemic is judged to be imminent.

States are not responsible for allocation of antiviral drugs that are held outside the national and State stockpiles — e.g., drugs acquired by businesses or not-for-profit entities for their employees and, possibly, the employees' families. In these instances, allocation is the responsibility of the purchaser. HHS will continue to encourage States, local governments, and private sector entities to share the responsibility for stockpiling antiviral drugs.



Medical Countermeasures (cont.)

Diagnostics

Early warning about a possible pandemic can come through quick and accurate diagnostic tools. By shortening the time between a suspected diagnosis and one that is confirmed, targeted treatment can begin earlier and fewer people run the risk of being exposed to the pandemic virus.

HHS began the search for such rapid diagnostic tests by funding the development and evaluation of new point-of-care tests and laboratory-based tests, reagents, and devices that can be used for screening and surveillance. These diagnostic tests and devices will help distinguish between seasonal flu strains and novel flu strains, such as H5N1.

In December 2007, the first of two prototype point-of-care influenza rapid test devices underwent independent evaluation; the second such test device is expected in March 2008. Both new devices will allow doctors and other health professionals to diagnose avian influenza rapidly and easily in a clinic office or other outpatient setting.

May 2007 – HHS issues interim guidance on community (nonwork) use of facemasks

May 2007 – FDA clears first respirators for public health emergencies

May 2007 – New online training course released for State and local public health responders

June 2007 – Two contracts awarded to expand domestic vaccine manufacturing capacity

June 2007 – Pandemic Flu Leadership Forum

July 2007 – HHS announces $896.7 million in funding to states for public health preparedness and emergency response

May 2007 – July 2007

State and Local Preparedness

HHS has stressed repeatedly in State pandemic influenza summits with governors and in numerous other meetings that preparedness for pandemic influenza must be a shared responsibility among governments at all levels, the private sector, and individuals. To the extent that potential partners refuse to apply their talents and assets unless the Federal government foots the bill, they are abdicating their responsibility and thereby placing their communities at higher risk than need be.

Since 1999, HHS has provided funding to State and local public health departments to enhance their preparedness for naturally occurring, accidental, or terrorist-induced emergencies. This has included strengthening relationships with public safety and emergency management agencies. Since 2002, HHS has provided all States and territories as well as four major urban areas with some $2 billion to enhance surge capacity in hospitals and other healthcare entities.

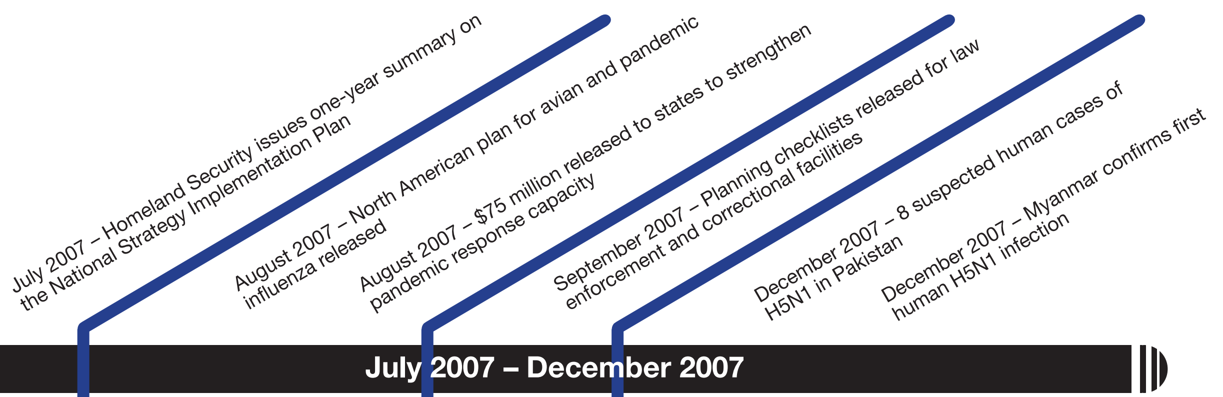
HHS is also leading an effort involving eight cabinet departments of the Federal government to help States refine their plans for countering pandemic influenza. The primary focus of the planning guidance, technical assistance, and readiness assessments is to help all agencies of State governments — not just health departments — understand what they can do to help mitigate and otherwise counter an influenza pandemic.

"We need to remember that we are our brothers' and sisters' keepers, that we are responsible not just for ourselves and our families but for the common good."

– Sister Patricia Talone, Catholic Health Association

This involves State public health departments looking inward to do what is necessary to continue their respective operations. But it also involves looking outward to establish and test partnerships with other agencies of State governments, local governments and the private sector — including both for-profit and not-for-profit entities. State-based partnerships are one of the most promising ways to prepare for pandemic influenza.

In 2007, HHS made available $75 million to States, territories, and four metropolitan areas to help strengthen their capacity to respond to a pandemic influenza outbreak. This funding came in addition to the $325 million provided over the past two years.



Communications and Outreach

"This really highlights our own roles (including those of us who aren't necessarily 'community leaders') in putting the word out."

– Anonymous Pandemic Flu Leadership blogger

Strong, sustained communication about the threat of pandemic influenza and recommended countermeasures is central to preparedness. The challenge is more difficult now than two years ago because, for many laypersons, the novelty of the topic has worn off and anxiety seems to have diminished. Nevertheless, the threat remains; and the nation must not let down its guard. H5N1 avian influenza may not become the trigger for the next human influenza pandemic. All of us should hope it isn't. But, if not, history says that, sooner or later, a pandemic influenza virus will spring from some other root.

HHS is committed to continuing its strong role in public communications about seasonal and pandemic influenza. We recognize that we need multiple channels to disseminate preparedness messages and materials; and we constantly are alert to opportunities to try new approaches and strengthen existing ones.

Public Education

Pandemic planning is a shared responsibility. Even families and individuals have a role in preparing for a pandemic. To encourage individuals to take a few steps now to prepare for a pandemic, HHS reached out to well-respected organizations and leaders, including non-governmental organizations, to develop a public education campaign to provide community leaders such as faith-based and civic leaders, healthcare providers, and local employers with the information and resources they can use to help those they influence prepare now for a pandemic.

Nearly 100 organizations participated in a one-day Pandemic Flu Leadership Forum to discuss the development of this public education campaign. Participants included the American Medical Association, Catholic Health Association, Red Cross, Lions Clubs, and the U.S. Chamber of Commerce. These organizations helped shape the *Take the Lead: Working Together to Prepare Now* campaign, which was launched in December 2007.

December 2007 – 3-day web dialogue on vaccine allocation

December 2007 – first human case confirmed in Pakistan

December 2007 – HHS launches "The Great Pandemic" historical overview of 1918 pandemic

December 2007 – HHS launches "Take the Lead: Working Together to Prepare Now" campaign

February 2008 – EU FDA-counterpart gives preliminary approval to pre-pandemic vaccine

March 2008 – HHS holds first of 3 state pandemic planning webinars

December 2007 – March 2008

Communications and Outreach (cont.)

To extend the dialogue around the importance of individual planning beyond the one-day Washington, DC Leadership Forum held in June 2007, HHS held its first-ever blog on pandemic planning. Over a five-week period, ten prominent leaders contributed online to the topic of pandemic planning and the importance of individual planning. Over the course of this "Blog Summit," (http://blog.pandemicflu.gov/) there were more than 35,000 unique visitors, 1,600 comments, and more than 300 in-bound links from other websites, blogs, and message boards.

Pandemicflu.gov, the Federal government-wide website, launched a new collection of historical documents related to the 1918 pandemic, the "Great Pandemic" (http://1918.pandemicflu.gov/index.htm). Along with information about the pandemic itself, the site also gives greater detail about the Nation's health and medical care system at that time and how these were affected.

There are still many in our country whose lives do not fall within the traditional public health channels for communicating, and they are among the hardest groups to reach. These include the homeless and non-English speakers, among other groups. To help remedy this situation, HHS has begun a series of activities to ensure that these groups are included in the pandemic planning process. A project will get underway this year that will first help clarify this audience's knowledge, attitudes, beliefs, capabilities and communication message needs, especially as they relate to community mitigation recommendations. In a second stage, appropriate messages will be crafted, tested, and then distributed through non-traditional means.

"The point of preparing for pandemic is it's much more than the health sector, it's much more than emergency room, it's all society."

– Dr. Bruce Gellin,
Director, HHS National
Vaccine Program Office

Stakeholder Outreach

Over the last six months, the Department has made a significant effort to obtain input from a range of stakeholders, including State and local officials, public health and medical professionals, the business community, organized labor, and individuals from all walks of life. They have contributed their knowledge and viewpoints to inform the development of several complex and critical pandemic flu planning policies.

Ultimately, these policies will have a significant impact on how States, communities, families, and individuals prepare for and respond to a pandemic. This is an unprecedented effort on the part of HHS and the Federal government. It builds upon the work conducted in 2006 and early 2007.

To broaden this outreach and allow as many people as possible to participate in these discussions, HHS utilized new communication technologies, including blogs and other web-based tools. Additionally, we held large public forums, smaller group meetings, and conference calls to discuss these critical issues.

Communications and Outreach (cont.)

In 2008, we will continue to reach out to stakeholders to shape some of the most difficult pandemic planning issues facing the Nation. The input we have received thus far will result in policies and guidances to be released later in 2008. Issues to be considered in this on-going dialogue include proposed vaccine allocation plans, proposed guidance for private-sector stockpiling of antivirals and respirators/facemasks, shared responsibility for medical countermeasures stockpiling, and the importance of individual preparedness.

"We need to engage individuals in such a way that they understand the reality of pandemic flu, the problems associated with it, and how to prepare their families to be successful in either reducing the risk or potentially dealing with the infection in an effective way."

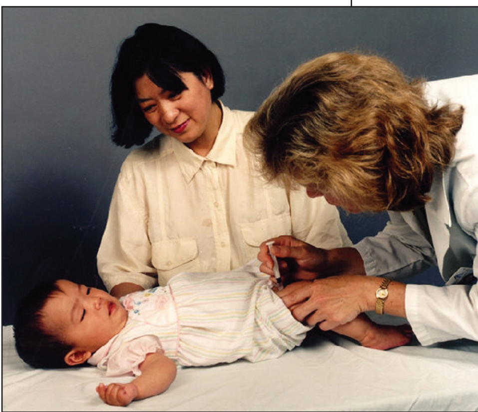
– Dr. Joseph Bocchini, American Academy of Pediatrics

Outreach on Proposed Vaccine Allocation Plan

It is very likely that a pandemic flu vaccine would only be available four to six months after the start of a pandemic. During that time, how could the available vaccines be used most wisely, including the so-called "pre-pandemic" vaccines? And who should get the first round of available vaccinations?

These difficult questions are ones that no single person or government agency can answer. Only through public discussions, multiple consultations, and joint decision-making can we be sure of offering the most broadly agreed-upon guidance for reaching our pandemic planning goals.

The first step toward an answer to the question of vaccine allocation came through consultations with people around the country. Meetings took place in 2006 with citizens in Las Cruces, NM, and Nassau County, NY. And in Washington, DC, leaders from the government, business and community sectors met on the issue. These groups of people learned first about pandemic flu and then discussed their values in relation to who should get vaccinated first. Their insights helped shape the first draft of a proposed vaccine allocation plan.



In November 2007, HHS held two public engagement meetings with citizens in Hendersonville, NC and Milwaukee, WI to obtain their feedback to the proposed vaccine allocation plan. Approximately 100 individuals attended each day-long meeting, representing a full spectrum of groups within the local communities.

In December 2007, HHS held its first-ever web dialogue to continue the dialogue on the proposed vaccine allocation plan. More than 400 people, representing 37 States, participated in the five-day on-line dialogue with Federal, State and local public health officials.

Through these discussions, experts and the public identified the most important vaccination goals as protecting those who will be the first to respond to the pandemic and care for the sick, those who keep vital community services working, those who have increased exposure due to their jobs, and pregnant women and children.

Communications and Outreach (cont.)

"Our nontraditional partners – churches, schools and PTAs, community organizations and soup kitchens – along with health departments… know the community perhaps best, understand the unique challenges each community faces and already have programs in place working with those who are most vulnerable."

– Dr. Georges Benjamin, Pandemic Flu Leadership blog

In these discussions, several senior citizens made poignant comments about vaccine allocation. On the basis of experience with seasonal influenza and the three pandemics of the 20th century, medical experts expect that infants, young children, and the elderly would be among those facing the highest mortality risk during the next pandemic. This consideration alone would justify placing elderly individuals within the highest priority strata for immunization. Yet, several senior citizens stated that they willingly would give up their place in line if that would ensure that their grandchildren were protected first. Other seniors went further to include the parents of these grandchildren, arguing that to do otherwise would be to risk having a generation of pandemic orphans.

Based on these dialogues and the thoughtful input of so many segments of society, a working group of government officials is in the process of refining the allocation plan with the goal to release the plan in the coming months.

Outreach on Countermeasure Stockpiling

In the fall of 2007, HHS senior leaders and subject matter experts held nearly twenty meetings with a range of stakeholders to discuss the shared responsibility concept of stockpiling medical countermeasures (vaccines, antivirals, rapid diagnostic tests, and masks/respirators), as well as private sector stockpiling of antivirals. These meetings took place in Seattle, WA, Raleigh-Durham, NC, Scottsdale, AZ, Atlanta, GA, Washington, DC, and by conference call. Nearly 400 people participated in these sessions, representing governors' and mayors' offices, State and local public health departments, private employers, healthcare providers (physicians, hospitals, nursing homes, assisted living facilities), law enforcement, organized labor, and first responders.

As more consultations take place, HHS will work to develop a draft guidance document that will help local decision-makers from both the public and private sectors as they work through their pandemic planning process to reach conclusions about the allocation of these critical preparedness elements.

In March of this year, the Institute of Medicine will publish a two-part study of how antivirals could be distributed to households following exposure to a pandemic flu virus. The report will add an important perspective to the on-going discussions about antiviral allocations.