

Pandemic Influenza: Priorities for the New Administration and Congress

Background:

Since 2003, scientists have become increasingly concerned that a strain of influenza could become more contagious among humans and mutate into a strain against which humans have little or no immunity. The threat of pandemic flu within the United States has not passed. Globalization means that a pandemic could reach American shores quickly, with worldwide economic and health consequences.^{1,2} It is estimated that a moderate to severe pandemic could cause between 900,000 and almost 10 million hospitalizations, and an estimated 200,000 to two million deaths in the U.S. Experts predict that during a pandemic, 30 percent of the world's population will become ill, one half of whom will seek outpatient medical care. The pandemic will last six to eight weeks in an infected community, and re-infection would occur in at least two waves.

The H1N1 Outbreak:

The recent outbreak of H1N1 (swine flu), which is suspected in the infection of thousands of people and in the deaths of over 150, is the first example in several decades of a novel virus that is easily transmittable between humans. The outbreak should be a wake-up call that, despite tremendous progress, worldwide preparations are far from complete. As of May 6th:

- The Acting Secretary of HHS has declared a Public Health Emergency, which frees up federal assets to affected areas, allows emergency use authorization (EUA) of pharmaceutical interventions and laboratory tests, and implements certain liability or regulatory waivers, if necessary;³
- The World Health Organization (WHO) raised the pandemic alert level to level five, which is “a strong signal that a pandemic is imminent and that the time to finalize the organization, communication, and implementation of the planned mitigation measures is short.”^{4,5}
- Centers for Disease Control and Prevention (CDC) has deployed its staff domestically and internationally to provide guidance and technical assistance and has activated its Emergency Operations Center to coordinate the response;⁶
- The U.S. government issued a non-essential travel warning for Mexico;⁷
- HHS and the Department of Homeland Security (DHS) announced the release of a quarter of its 50 million courses of antivirals (Tamiflu® and Relenza®) and additional

¹ *Germs Go Global: Why Emerging Infectious Diseases are a Threat to America*, Trust for America's Health, October 2008. p. 9.

² *Pandemic Flu and the Potential for Economic Recession*, Trust for America's Health, March 2007.

³ <http://www.hhs.gov/news/press/2009pres/04/20090426a.html> (April 26 2009).

⁴ http://www.who.int/csr/disease/avian_influenza/phase/en/index.html (April 29 2009)

⁵ http://www.who.int/mediacentre/news/statements/2009/h1n1_20090427/en/index.html

⁶ <http://www.cdc.gov/swineflu/index.htm>

⁷ <http://wwwn.cdc.gov/travel/contentSwineFluMexico.aspx>

personal protective equipment from the Strategic National Stockpile (SNS) to states, and the Department of Defense is prepositioning an additional 7 million treatment courses of antivirals.⁸ HHS purchased an additional 13 million treatment courses to help fight influenza, including the 2009 H1N1 flu virus;

- The Food and Drug Administration (FDA) has issued emergency use authorizations for antivirals and a rapid diagnostic test and has formed an incident management approach with seven response teams that work with CDC and other partners: Vaccine Team, Antiviral Team, In Vitro Diagnostics Team, Personal Protection Team, Blood Team, Shortage Team, and the Consumer Protection Team.⁹

Policies to Date:

In November 2005, President Bush announced a National Strategy for Pandemic Influenza, followed by an Implementation Plan released in 2006. The Strategy is a government-wide plan for preventing and preparing for a pandemic led by the Department of Health and Human Services (HHS). There have been two updates published by the White House Homeland Security Council since 2006, marking progress on the action items in the Implementation Plan.

At the time of the release of the National Strategy, the Bush Administration requested \$7.1 billion over three years for emergency funding for pandemic influenza preparedness. In FY 2006, Congress appropriated \$5.6 billion in emergency funding for HHS. The funding has been used for stockpiling antiviral drugs for the treatment of more than 50 million Americans, licensing a pre-pandemic influenza vaccine, developing rapid diagnostics and completing the sequencing of the entire genetic blueprints of 2,250 human and avian influenza viruses. In FY 2007 and FY 2008, while Congress provided funding for recurring preparedness activities, it failed to provide the \$870 million requested in FY 2008 for activities such as expanding vaccine production capacity, purchasing antivirals, and accelerating research and development of rapid diagnostic tests. In addition, all of the \$600 million in funding for state and local pandemic preparedness, first appropriated in FY 2006, has now been allocated, with no indication that additional funds will be forthcoming.¹⁰

Recent HHS-led pandemic influenza accomplishments include:

- As of January 2009, HHS had 12.2 million doses of pre-pandemic vaccine on hand.¹¹
- The Federal government has invested \$1 billion to expand U.S.-based vaccine production capacity, with six companies in various stages of expansion.¹²
- HHS has completed the purchase of 50 million courses of antiviral drugs for the Federal portion of the antiviral stockpile goal. As of November, 2008, the SNS contains 39.4 million regimens of Oseltamavir capsules, with 409,000 on order; and 9.9 million

⁸ http://www.dhs.gov/ynews/releases/pr_1240773850207.shtm

⁹ Testimony of Joshua M. Sharfstein, April 30, 2009: <http://www.fda.gov/ola/2009/flu043009.html>

¹⁰ *Blueprint for a Healthier America*, Trust for America's Health, October 2008, p. 64.

¹¹ *Pandemic Planning Update VI*, 2009.

¹² *Ibid.*

regimens of Zanamivir.¹³ HHS released one-fourth of the stockpile of antivirals to deploy to states during the H1N1 outbreak, and plans to spend \$251 million to replenish and build the federal supply.

- States have purchased 22 million courses of antivirals, as of January 2009 with the help of a federal subsidy (The goal is for states to purchase 31 million courses).¹⁴
- HHS has purchased medical supplies for the Strategic National Stockpile, including:
 - 105.8 million N95 respirators;¹⁵
 - 51.7 million surgical masks;¹⁶
 - 20 million syringes for pre-pandemic vaccine;¹⁷ and
 - 4,000 ventilators.¹⁸
- HHS has awarded funds for development of a new rapid diagnostic test for avian and seasonal influenza that will be used in U.S. public health labs and at World Health Organization reference laboratories. Clinical trials and FDA evaluation are expected by the end of 2009.¹⁹
- HHS deployed teams to help investigate suspected cases of human transmission of infection of influenza A in 12 countries and supported pandemic influenza preparedness activities in 40 countries.²⁰ HHS has obligated \$350 million for these efforts since 2005.²¹
- 50 states and D.C. now have pandemic influenza plans.²²

Issues for Review:

Despite this progress, the Homeland Security Council's *National Strategy for Pandemic Influenza Implementation Plan One-Year Summary* noted that preparedness gaps and vulnerabilities exist and must be addressed, with regard to our connectivity, surveillance, surge capacity, and vaccine development and production.²³ A General Accountability Office (GAO) report on the presidential transition also highlighted pandemic influenza and other emerging infectious diseases as a priority item that highlights "the need for a coordinated response to large-scale public health emergencies."²⁴ Also, in January, 2009, HHS and the Department of Homeland Security (DHS) released an assessment of states' operating plans in the event of a

¹³ *Improving Pandemic Preparedness: FY 2009 Labor HHS Appropriations Bill Department of Health and Human Services*, Trust for America's Health, Available from:

<http://healthyamericans.org/policy/criticalcare/PandemicPreparedness.pdf> (Accessed Nov 25 2008).

¹⁴ *Pandemic Planning Update VI*, 2009.

¹⁵ *Ready or Not? 2008: Protecting the Public's Health from Diseases, Disasters, and Bioterrorism*, Trust for America's Health, Dec 2008. Available from: <http://healthyamericans.org/reports/bioterror08/> (Accessed Jan 21, 2009). p.20 .

¹⁶ *Ibid.*

¹⁷ *Improving Pandemic Preparedness*, 2008.

¹⁸ *Ibid.*

¹⁹ *Pandemic Planning Update VI*, 2009.

²⁰ *Improving Pandemic Preparedness*, 2008.

²¹ *Pandemic Planning Update VI*, 2009.

²² *Ready or Not? 2008*, p. 20.

²³ *National Strategy for Pandemic Influenza Implementation Plan One Year Summary*, White House Homeland Security Council, July 2007. Available from: <http://www.whitehouse.gov/homeland/pandemic-influenza-oneyear.html#looking> (Accessed Nov 24 2008).

²⁴ *The Upcoming Transition: GAO's Efforts to Assist the 111th Congress*, GAO, September 2008, p. 8. Available from: <http://www.gao.gov/new.items/d081174t.pdf> (Accessed Dec 4, 2008).

pandemic, as required by the Implementation Plan. The review measured states' plans for continuity of operations of state agencies and government, for protecting citizens, and for sustaining critical infrastructure and resources.²⁵ The most glaring gaps in the plans of many states included areas such as protecting government workers; sustaining transportation systems; enabling school closures; providing healthcare; managing mass fatalities; mitigating illness for workers; and integrating EMS into pandemic preparedness.²⁶

The following are issues that need to be considered by the Obama Administration and 111th Congress.

Coordination and Planning

- The federal government should update as needed, fully fund, and promptly carry out the President's National Strategy for Pandemic Influenza Implementation Plan.^{27,28} The National Strategy and Implementation Plan should be evergreen documents, updated as the science evolves and the White House assesses the effectiveness of implementation thus far.
- Congress and the Administration need to maintain invest in state and local preparedness efforts through federal grant programs such as the Public Health Emergency Preparedness cooperative agreements, which have been cut 25 percent over the last five years, state and local pandemic preparedness grants, which have expired, and the Hospital Preparedness Program.
- The federal government should take the lead in increasing and better coordinating federal-state-local government and private planning and preparedness, and all jurisdictions should work together to create policies that follow best infection-control practices. Government at all levels should work to engage the private health care system and communities in their plans and exercises. Sufficient resources must be devoted to preparing for possible disease threats and the government should be transparent about their actions and held accountable for protecting the public.²⁹
- Initial planning by HHS and other federal agencies failed to adequately involve states and localities in national preparations for a pandemic, even though the national plan relies on these efforts.^{30,31} HHS and the White House should engage partners in updating the National Strategy and Implementation Plan.

²⁵ *Assessment of States' Operating Plans to Combat Pandemic Influenza: Report to Homeland Security Council*. Homeland Security Council, January 2009. Available from: http://pandemicflu.gov/plan/states/state_assessment.html (Accessed Jan 22, 2009).

²⁶ Ibid.

²⁷ *Blueprint for a Healthier America*, p. 92.

²⁸ *Getting Beyond Getting Ready for Pandemic Influenza*, House Committee on Homeland Security, Report by the Majority Staff, Jan 2009. Available from: <http://homeland.house.gov/SiteDocuments/20090114124322-85263.pdf> (Accessed Jan 23, 2009).

²⁹ *Pandemic Influenza: Federal Agencies Should Continue to Assist States to Address Gaps in Pandemic Planning*. Washington, D.C.: U.S. Government Accountability Office, 2008.

³⁰ Ibid.

³¹ *Getting Beyond Getting Ready for Pandemic Influenza*, 2009.

- The federal government, in collaboration with the states, should share states' pandemic preparedness plans and performance grades with the public to increase transparency and build community resiliency.³²

Medical Countermeasures

- The federal government should step up its investment in vaccine and anti-viral drug development and supply to be able to more rapidly vaccinate and treat the population should a pandemic occur. The federal government should also ensure that state and local governments have the capacity to deliver these countermeasures.³³
- There is a lack of a widely-available vaccine for use during a pandemic and still-limited U.S. vaccine production capabilities. Former HHS Secretary Leavitt urged his successor to ensure completion of manufacturing facilities,³⁴ so that in the event of a worldwide pandemic, U.S. citizens are not dependent on foreign governments to provide a vaccine.
- The federal government should address currently inadequate national capabilities to distribute vaccines and medical equipment.
- The federal government should grow sufficient stockpiles of antiviral medications and other medical equipment, such as masks, respirators and gloves.
- The federal government should enhance research and development of vaccines and public health technologies. Basic technology and tools of public health must be modernized to adequately protect the American people. This includes research and development of vaccines and new technologies; and improved chemical laboratory testing capabilities.
- The federal government should replenish and augment the Strategic National Stockpile (SNS). The government should ensure the SNS contains enough vaccines, antiviral medications, and supplies to respond to public health crises, and states must be better prepared to distribute and administer needed medications to the public.
- The federal government should extend shelf-life extension to properly-stored antivirals in state stockpiles.

Surge Capacity

- Major gaps exist in capacity of hospitals and health care providers to manage the “surge” of patients who could become ill during a pandemic. The federal government must take a lead in providing guidelines to states on surge capacity planning. Although various federal agencies have published surge guidance, there have been little incentive or unified direction to states to implement surge planning. During mass emergencies, measures must be put in place to care for a potential surge of patients, including creating alternative care sites and recruiting additional health care personnel. Surge planning includes planning for altered standards of care and addressing legal and ethical concerns before an emergency occurs. Hospitals must also consider how continued care would be provided for ongoing health conditions during the time.
- In the context of health reform, Congress should consider incorporating preparedness planning dollars into reimbursement streams, to ensure hospitals and facilities meet surge planning benchmarks.

³² Ready or Not, 2008, p. 90.

³³ *Blueprint for a Healthier America*, p. 92.

³⁴ *Pandemic Planning Update VI*, 2009.

- Shortages remain in the number of health care providers needed to respond to a pandemic. Legal protections are a remaining barrier to healthcare professionals volunteering for public health emergencies. State and federal governments should clarify and address gaps in legal liability protections for qualified healthcare volunteers and entities that serve during an emergency.
- Congress should pass a temporary federal “State of Emergency” health benefit to cover the uninsured and underinsured during a mass health emergency. The “Public Health Emergency Response Act” is an example of such legislation.

Community Mitigation Strategies

- There needs to be clear, consistent, culturally-competent communication with the public, health departments, and providers about response plans, community mitigation strategies, and vaccine prioritization.³⁵ Risk communications strategies for how the public should be informed and apprised of pandemic developments and how they should prepare themselves and their families have been insufficient.
- Congress should enact paid sick leave provisions, such as the “Healthy Families Act,” to encourage workers to stay home when they or their family members could be infected.
- Continued work is needed on community mitigation strategies to develop the most effective and sensible policies for issues including school closures and limits on public gatherings.
- Current state and federal roles in setting quarantine and isolation policies should be clarified. The federal government, in coordination with the states, must establish clear legal authority and emergency measures to effectively contain the spread of disease.³⁶

Surveillance

- The federal government should modernize disease surveillance systems. Every health department and health agency should be part of a 21st century surveillance system that meets national standards and is interoperable between jurisdictions and agencies to ensure rapid information sharing. Plans should ensure adequate laboratory surveillance of influenza and other infectious diseases, as well as testing for pathogens such as *E. Coli*, Methicillin-resistant *Staphylococcus Aureus* (MRSA), and extensively drug resistant Tuberculosis (XDR-TB). The U.S. should take the lead on improving global disease surveillance.
- A newly developed health IT system must include public health considerations, such as disease surveillance and reporting capabilities, so public health departments can track potential pandemics.
- The federal government should review and consider the recommendations of the Institute of Medicine and GAO reports, which are due in spring/summer 2009, and the proposals of the National Biosurveillance Advisory Subcommittee. These groups are assessing the coordination and effectiveness of federal biosurveillance systems, which are scattered

³⁵ *Influenza Pandemic: Challenges in Preparedness and Planning*, U.S. Government Accountability Office, June 2008. Available from: <http://www.gao.gov/new.items/d05863t.pdf> (Accessed Jan 23, 2009).

³⁶ *Preventing and Controlling Pandemic Flu and Other Infectious Diseases*, Trust for America’s Health, March 2008. Available from: <http://healthyamericans.org/assets/files/10ThingsPanFlu.pdf> (Accessed Dec 4 2008).

across DHS, HHS, the Environmental Protection Agency, the Departments of Veterans Affairs and Defense, and the Office of the Director of National Intelligence.³⁷

³⁷ *Ready or Not? 2008*. pp. 59-63.