

## Pandemic Flu Preparedness: LESSONS FROM THE FRONTLINES



**T**he recent H1N1 (swine) flu outbreak demonstrated how rapidly a new strain of flu can emerge and spread around the world. As of June 1, 2009, the H1N1 virus was reported in 62 nations, with nearly 17,500 confirmed cases and more than 100 deaths. The sudden outbreak of this novel flu virus has tested the world's public health preparedness. H1N1 provided a real-world test that showed the strengths and vulnerabilities in the abilities of the United States and the rest of the world to respond to a major infectious disease outbreak.

This report examines early lessons learned from the response and ongoing concerns about overall U.S. preparedness for potential pandemic flu outbreak. The first section reviews 10 key lessons based on the initial response to the H1N1 outbreak; and the second section discusses 10 underlying concerns and provides recommendations for addressing serious continued vulnerabilities in the nation's preparedness in the event that H1N1 returns in the fall, either in its current form or as a

more virulent strain, or if a different strain of influenza, like the H5N1 (bird) flu, emerges.

Overall, the H1N1 outbreak has shown that the investment the country has made in preparing for a potential pandemic flu has significantly improved U.S. capabilities for a large scale infectious disease outbreak, but it has also revealed how quickly the nation's core public health capacity would be overwhelmed if the outbreak were more widespread and more severe.

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## SUMMARY OF TEN EARLY LESSONS LEARNED FROM THE 2009 H1N1 OUTBREAK

1. Investments in pandemic planning and stockpiling antiviral medications paid off;
2. Public health departments did not have enough resources to carry out plans;
3. Response plans must be adaptable and science-driven;
4. Providing clear, straightforward information to the public was essential for allaying fears and building trust;
5. School closings have major ramifications for students, parents, and employers;
6. Sick leave and policies for limiting mass gatherings were also problematic;
7. Even with a mild outbreak, the health care delivery system was overwhelmed;
8. Communication between the public health system and health providers was not well coordinated;
9. WHO pandemic alert phases caused confusion; and
10. International coordination was more complicated than expected.

## SUMMARY OF TEN RECOMMENDATIONS FOR ADDRESSING CORE VULNERABILITIES IN U.S. PANDEMIC FLU PREPAREDNESS

In addition to the lessons learned from H1N1, there are a number of systemic gaps in the nation's ability to respond to a pandemic flu outbreak. To further strengthen U.S. preparedness, the following core areas must be addressed:

### Strategic National Stockpile and Vaccine Development Recommendations:

1. **Maintaining the Strategic National Stockpile** -- making sure enough antiviral medications, vaccinations, and equipment are available to protect Americans, which includes replenishing the stockpile when medications and supplies are used;
2. **Vaccine development and production** -- enhancing the biomedical research and development abilities of the United States to rapidly develop and produce a vaccine; and
3. **Vaccinating all Americans** -- ensuring that all Americans would be able to be inoculated in a short period of time.

### Adaptable, Science-Based Planning and Coordination Recommendations:

4. **Planning and coordination** -- improving coordination among federal, state, and local governments and the private sector preparedness and planning activities on an ongoing basis, including taking into account how the nature of flu threats change over time;
5. **School closings, sick leave, and community mitigation strategies** -- improving strategies to limit the spread of disease ensuring all working Americans have sick leave benefits and that communities are prepared to limit public gatherings and close schools as necessary; and
6. **Global coordination** -- building trust, technologies, and policies internationally to encourage science-based, consistent decision making across borders during an outbreak.

### Core Public Health Infrastructure Improvement Recommendations:

7. **Resources** -- providing enough funding for the on-the-ground response, which is currently underfunded and overextended; and
8. **Workforce** -- stopping layoffs at state and local health departments and recruiting the next generation of public health professionals.

### Surge Capacity and Care Recommendations:

9. **Surge capacity** -- improving the ability for health providers to manage a massive influx of patients; and
10. **Caring for the uninsured and underinsured** -- ensuring that all Americans will receive care during an emergency, which limits the spread of the contagious disease to others, and making sure hospitals and health care providers are compensated for providing care.

# TEN EARLY LESSONS LEARNED FROM THE 2009 H1N1 OUTBREAK

# 1 SECTION

**1. Investments in pandemic planning and stockpiling antiviral medications paid off.** Federal, state, and local efforts to develop and exercise pandemic response plans over the last several years enabled public health officials to react to the outbreak effectively and keep the public informed. Investments in antiviral stockpiles and enhanced vaccine manufacturing capacity also proved to be prudent.

**2. Public health departments did not have enough resources to carry out plans.** Federal, state, and local health departments are stretched too thin to adequately respond to emergencies after decades of underfunding the public health infrastructure. Capacity to track, investigate, and contain cases of H1N1 has been hampered due to lack of resources. For instance, CDC and state laboratory testing was days to more than a week behind the on-the-ground reality. Also, the country must make a sustained commitment to pandemic preparedness by providing consistent federal funding for stockpiling medicines and medical supplies, training, and planning activities. However, there have been no state and local pandemic preparedness funds appropriated since fiscal year (FY) 2006. If the current outbreak had been more severe, state and local health departments likely would have been even more overwhelmed.

**3. Response plans must be adaptable and science-driven.** For years, pandemic flu planning focused on the potential threat of the H5N1 (bird) flu that has been circulating in Asia for the past 10 years. In addition, much of the planning anticipated that there would be a six-week lead time between the time a novel flu strain was detected before it reached the United States. H1N1 showed that a new flu strain can emerge quickly or go undetected for a period of time and rapidly spread throughout the world. As the epidemic unfolded, new knowledge required government officials to reassess guidance offered to the public and the medical community. For example, as it became clearer that H1N1 was circulating widely in communities and largely causing mild cases, the U.S. Centers for Disease Control and Prevention (CDC) officials lifted their recommendations on school closures to match the changing circumstances. Different communities faced different situations, such as the extent

of the spread of the virus into a community, which resulted in the need for different policies in different places.

**4. Providing clear, straightforward information to the public was essential for allaying fears and building trust.** Informing the public about what is known about an outbreak, acknowledging that certain information is not yet known, and updating facts as they become available is paramount to help contain the spread of disease and also give people the facts they need to be prepared, not scared. During the outbreak, the President and other leaders around the country served as clear spokespeople, conveying consistent, accurate information about good hand hygiene, cough/sneeze etiquette, and the need for people to stay home if sick. Effective leadership and communication helped dispel rumors and myths--from allaying concerns about the safety of imported Mexican foodstuffs to reversing the unfair characterization of Spanish-speaking people as carriers of the contagion. Public health officials also encountered the need to explain to members of the public that different policies are not necessarily inconsistent, but tailored to local realities.





“COMMUNICATION WAS KEY, INCLUDING THE NEED FOR US TO BE CAREFUL TO SAY WHAT WE DID NOT KNOW, FORESHADOWING POSSIBLE CHANGES IN POLICY, AND BEING CLEAR AT THE OUTSET THAT WHAT WE LEARNED ABOUT BOTH SEVERITY AND TRANSMISSIBILITY WOULD DETERMINE OUR RESPONSE.”<sup>1</sup>

DAVID FLEMING, MD, DIRECTOR OF PUBLIC HEALTH, SEATTLE & KING COUNTY WASHINGTON

- 5. School closings have major ramifications for students, parents, and employers.** In areas where schools were closed due to H1N1, parents had to scramble to find alternative child care arrangements, which were complicated by the guidance that children home from school should stay separated. Many parents had to face taking sick leave from work to stay home to care for their children even if they were not ill, or taking days off without pay if they did not have sick leave. Many families also rely on the school meal programs and before and after school care, which were also not available when schools were closed. In the event that another outbreak occurs or the H1N1 returns in the fall and schools may have to close in more places and for longer durations, these complications would become an even bigger concern. This is especially problematic for jurisdictions that require a minimum number of days attended to graduate.
- 6. Sick leave and policies for limiting mass gatherings were also problematic.** There were numerous media reports of people with influenza-like illness continuing to go to work because they had no sick leave and feared losing their jobs, and some parents sent sick children to school because they could not stay home to care for them. In addition, while they were not instituted during the outbreak, it became clear to officials how difficult it would be to carry out plans to limit mass gatherings or cancel major events if that became necessary. In areas of Mexico, there were serious economic ramifications when officials recommended people avoid shopping and public events.
- 7. Even with a mild outbreak, the health care delivery system was overwhelmed.** Even this relatively mild outbreak proved to be a low-level “stress test” on the health system. It revealed significant problems and lack of preparedness particularly for out-patient settings where there was inadequate personal protective equipment and a limited understanding of infection control measures. At many hospitals, the “worried well” overwhelmed emergency departments.<sup>2</sup> Also, concerns about health care costs were a deterrent for many in seeking early medical attention, especially among the uninsured and underinsured. A further deterrent to seeking prompt medical care was fear among undocumented immigrants that making contact with health authorities could result in deportation.
- 8. Communication between the public health system and health providers was not well coordinated.** During the outbreak, many private medical practitioners reported that they did not receive CDC guidance documents in a timely fashion. Other practitioners noted that CDC guidance lacked clinically relevant information and was difficult to translate into practical instructions.
- 9. WHO pandemic alert phases caused confusion.** The WHO pandemic alert phase system was not well matched with the realities of the H1N1 outbreak, since most of the planning was built around concerns of a much more severe pandemic outbreak and focused on the geographic spread and transmission patterns, but not the severity of the disease. WHO is currently considering how to revise its pandemic alert phases to address both the geographic spread as well as the severity of the virus.
- 10. International coordination was more complicated than expected.** Despite advice from the WHO, some countries chose to close their borders to Mexican citizens or banned pork products from the United States and Mexico. These measures were not based on either science or reasonable public health practices and caused unnecessary economic losses. Once a flu virus is circulating throughout the population, containment strategies, like travel restrictions, generally will not work, given that it is possible to infect others before a person develops flu-like symptoms. Also, the effectiveness of some mitigation strategies implemented (face masks in Mexico) were overstated.

# TEN RECOMMENDATIONS FOR ADDRESSING CORE VULNERABILITIES IN U.S. PANDEMIC FLU PREPAREDNESS

## SECTION 2

The investment in pandemic flu preparedness helped the country respond to the first round of the H1N1 outbreak much more effectively than could have been achieved a few years ago. However, the limits of the response underscored ongoing gaps in the nation's core capabilities and the need to build up and modernize the public health infrastructure, which has been underfunded and under resourced for decades. Unless these gaps are addressed, our ability to respond to emergencies will remain inadequate.

### A. STRATEGIC NATIONAL STOCKPILE AND VACCINE DEVELOPMENT RECOMMENDATIONS

The fact that the country had stockpiled a supply of antiviral medications made it possible to rapidly deploy medicine to treat flu patients around the country, though ultimately large supplies were not needed. The outbreak showed the limits of the current stockpile, which is currently based on a system that relies on states to purchase a portion of the medications, and does not have mechanisms in place for constantly replenishing and updating the supplies.

In addition, the importance of the investment the country has made in biomedical research, and in particular vaccine development and production, is underscored as scientists race against

the clock to develop an H1N1 vaccine for the fall of 2009 while continuing to develop vaccines for other flu viruses.

The possible need to find ways to swiftly vaccinate the entire U.S. population, however, also shows that the country does not yet have an adequate system in place to rapidly vaccinate all Americans. Nor is there a registry in place to track the two vaccinations per person.

The following recommendations relate to ensuring systems and supplies to mass treat and vaccinate the public during a flu outbreak:

#### I. MAINTAINING THE STRATEGIC NATIONAL STOCKPILE: Purchasing antiviral medications, vaccines, and equipment for the stockpile must be updated and restocked on an ongoing basis.

■ **Purchasing antiviral medications, vaccines, and equipment for the stockpile should be a federal responsibility.**

Combined, the federal and state antiviral purchases are intended to treat 25 percent of the U.S. population, or 75 million people. Prior to the H1N1 outbreak, the U.S. Department of Health and Human Services (HHS) had completed the purchase of 50 million treatment courses of antiviral drugs for the federal portion of the antiviral stockpile goal. The federal government should replenish its share of the antiviral stockpile deployed to states and localities intended for treatment during the current H1N1 outbreak and purchase additional courses for prophylaxis.

■ **HHS needs to develop a workable plan for both the use and stockpiling of antivirals.** Currently, states are expected to purchase a portion of the antiviral medications that would be needed to protect citizens in their states through a program that included 25 percent subsidy from the federal government. HHS must develop a plan for use and distribution of stockpiled antivirals during a pandemic. This plan should consider existing federal and state stockpiles, as well as how to address current shortfalls. HHS must recognize that while some states, have already expended resources to develop their own stockpiles, others have not, either as a result of limited resources or operational constraints.

**See Appendix B for a list of state purchases of antiviral medications as of October 2008.**

In addition to antivirals and vaccines, even before the H1N1 outbreak, the stockpile had existing shortfalls in the number of masks, respirators, and medications needed to respond to this and other possible pandemics, which must be completed to be prepared for the possibility of other strains of flu. As of 2008, HHS had purchased 105.8 million N95 respirators; 51.7 million surgical masks; 20 million syringes for pre-pandemic vaccine; and 4,000 ventilators.<sup>3,4</sup> It is important to continue to evaluate medical supply needs for the stockpile and replenish supplies as they are used.

## **2. VACCINE DEVELOPMENT AND PRODUCTION: A vaccine is the most effective way to protect the public from an infectious disease outbreak, but current vaccine development and production capacity is severely lacking.**

■ **U.S. vaccine development and production capabilities must be enhanced.** The *National Strategy for Pandemic Influenza* sets out two goals related to vaccine stockpiling: To stockpile enough H5N1 (bird flu) pre-pandemic vaccine to inoculate 20 million people at the onset of a pandemic influenza, and to be able to vaccinate the entire U.S. population of some 300 million within six months from the onset of a pandemic influenza. In light of the H1N1 (swine flu) outbreak, the federal government is embarking on a similar course of action with respect to the first goal. HHS has issued contracts to manufacture and test pre-pandemic vaccines against the newly-emerging 2009-H1N1 virus for the Strategic National Stockpile. The goal is to build a stockpile of at least 40 million doses of 2009-H1N1 vaccine to inoculate 20 million people (this assumes two doses of vaccine will be necessary). Laboratories are already working on generating the seed viruses needed for vaccine production. Once the manufacturers have completed their seasonal influenza vaccine production, they will start production of the 2009-H1N1 vaccine.<sup>7</sup>

However, with respect to the goal of vaccinating the entire U.S. population within six months of an influenza pandemic, challenges remain due to still-limited U.S. vaccine production capabilities. U.S. production capacity is “completely inadequate,” according to a report from the Congressional Budget Office (CBO).<sup>8</sup> Former HHS Secretary Leavitt urged his successor to ensure completion of manufacturing facilities, so that in the event of a worldwide pandemic, U.S. citizens are not dependent on foreign governments to provide a vaccine.<sup>9</sup>

During the H1N1 outbreak, HHS released a total of 11 million treatment courses to help states, in addition to moving 400,000 treatment courses to Mexico to help stop the spread of the virus. In order to replenish the Strategic National Stockpile, HHS announced at the end of April 2009 that it would purchase an additional 13 million antiviral treatment courses.<sup>5</sup> States have purchased 23 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).<sup>6</sup>

HHS is supporting a multi-pronged approach for boosting U.S. domestic production capacity by subsidizing the construction of new manufacturing plants and the renovation of existing ones; funding research and development of cell-based manufacturing technology, while securing an egg supply for egg-based production; and advancing the research and development of adjuvants, substances that can be added to a vaccine to boost its ability to produce an immune system response. However, a September 2008 report by the Congressional Budget Office (CBO) has raised serious concerns about the ability of HHS to meet these goals.<sup>10</sup>

Other factors that might impede the nation’s ability to inoculate the entire population include cost and the public’s reaction to the vaccine. According to a CDC estimate, it may cost up to \$8 billion to procure 600 million doses of the 2009 A-H1N1 vaccine for 300 million people (two doses per person). This figure does not include needles, syringes, distribution, and the like.

Whether or not the public would be willing to line up for three flu shots -- one to combat seasonal flu and two to prevent the novel H1N1 flu virus -- remains to be seen. Seasonal influenza vaccine uptake, even among health care workers, has yet to meet public health goals. In the fall of 2008, more than half of Americans in a national survey said that they did not intend to be vaccinated against flu that season. Among the reasons cited were the thought that the vaccine was unnecessary, worry that the vaccine causes illness, and disbelief in the vaccine itself.<sup>11</sup>

■ **Adequate and sustained funding is needed for biomedical research and development to keep pace with new technologies.**

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.

### BIOMEDICAL ADVANCED RESEARCH AND DEVELOPMENT AUTHORITY (BARDA)

The Biomedical Advanced Research and Development Authority (BARDA) was established to encourage and facilitate research and development (R&D) of new biomedical countermeasures, diagnostics, and related technologies; however, the intentions of the Congress and the administration in creating BARDA are far from being realized. The small amount of funding provided to BARDA to date only has allowed HHS to establish an infrastructure to support a yet-to-be-seen robust advanced R&D portfolio for many innovative biomedical products. To achieve the goals identified in HHS' Public Health Emergency Medical Countermeasures Enterprise Implementation Plan, BARDA would need \$3.39 billion in FY 2009 to have a 90 percent chance of developing successful medical countermeasures for each biodefense requirement set forth in the plan.

Congress should increase the level of BARDA funding to at least \$850 million as advised by 14 senators who signed a letter to the Appropriations Committee on this issue on May 7, 2009 and as requested in last year's Presidential FY 2009 Amended Budget request.<sup>12</sup>

### FLU VACCINE CAPACITY WORLDWIDE IS LIMITED

Worldwide, the five egg-based flu vaccine manufacturers include the following:

- CSL Limited (Australia) which makes Afluria;
- GlaxoSmithKline Biologicals (Belgium) which makes Fluarix;
- ID Biomedical (Canada), which makes FluLaval;
- Novartis Vaccine (UK), which makes Fluvirin; and
- Sanofi Pasteur (Pennsylvania, USA), which makes Fluzone.

In addition, MedImmune makes FluMist, which is a live attenuated nasal spray vaccine.

On May 6, 2009, the U.S. Food and Drug Administration (FDA) approved a new egg-based influenza vaccine facility in Swiftwater, Pennsylvania, which will produce 100 million doses of Fluzone when operating at full capacity. This brings the total domestic production from Sanofi Pasteur's two-approved facilities to 150 million doses. GSK is building a manufacturing facility in the United States, but it is not yet operational or approved by the FDA. The lack of U.S. manufacturing capacity means the country will be dependent on imported vaccines, which will become more difficult to obtain in the event of a pandemic.

### 3. VACCINATING ALL AMERICANS -- the country has not developed or adequately tested a system that will ensure that all Americans would be able to be inoculated in a short period of time.

■ A robust public system is needed to be able to vaccinate all Americans for H1N1 over a short period of time. Currently, only a fraction of Americans are vaccinated each year for the seasonal flu and they typically receive shots through their doctors or private clinics. If the country is going to be successful in creating a program that can vaccinate all Americans for H1N1 rapidly in the fall of 2009, a publicly-di-

rected program will be necessary to oversee vaccinations and coordinate delivery through a combination of public and private settings. This will require an infusion of major resources to state and local health departments responsible for creating this system. Estimates by state and local health officials suggest that between \$15 and \$20 per person may be needed for administration and follow up.



## THE CASE FOR A PUBLIC SECTOR APPROACH TO DISTRIBUTION OF A PANDEMIC VACCINE

The HHS Pandemic Influenza Plan states that after a pandemic vaccine becomes available, state and local health departments will be expected to:

- Work with health care partners and other stakeholders to distribute, deliver, and administer pandemic vaccines to priority groups;
- Monitor vaccine supplies, distribution, and use;
- Monitor and investigate adverse events;
- Phase-in vaccination of the rest of the population after priority groups have been vaccinated;
- Provide updated information to the public via the news media; and
- Work with federal partners to evaluate vaccine-related response activities when the pandemic is over.<sup>13</sup>

While actual delivery of vaccines may occur in both public and private settings, it is vital for the public sector to be in charge of the overall system of delivery to assure that key public health challenges unique to a pandemic vaccine are addressed. These challenges include:

- **A pandemic vaccine must be delivered to individuals as rapidly as possible.** Americans receive their seasonal influenza vaccine over a period of many months and only a fraction of the U.S. population receives a flu vaccine annually. Health departments will need to organize (often in concert with the private sector) mass immunization clinics that can speed delivery -- possibly as many as 100-150 million doses in a month's time.
- **A pandemic vaccine will be rationed at the beginning of the production cycle,** targeted at critical infrastructure workers and high-risk individuals. Unlike seasonal influenza vaccines, which are manufactured over a long period of time but essentially distributed at one time, a pandemic vaccine will be distributed as it comes off the production line. This will require targeting of initial doses to those key personnel (such as health care workers) who will be central to a pandemic response, followed by those at highest risk for influenza complications. This kind of rationing requires careful oversight. During the 2007 seasonal flu vaccine shortage it became clear that the private distribution and delivery system was not able to systematically follow recommendations for priority populations, and health departments were forced to intervene.
- **A pandemic vaccine may require two doses.** Assuring that all individuals who receive a first dose return for a second dose will require a centrally organized system of monitoring and reminders. It may well be that private sector entities (e.g., pharmacies) have systems in place to administer such call-backs, but they must all be organized and structured in a similar manner, which can only be coordinated by a public health agency to ensure consistency with federal guidelines.
- **A pandemic vaccine will require careful monitoring and reporting of adverse reactions.** Because the pandemic vaccine will be one with which there is far less experience than a seasonal vaccine, it will be critical to assure that all adverse events are investigated. This is a public health responsibility and the system of vaccine distribution and delivery must be designed to assure rapid communication of this information to health departments and then to the FDA.
- **A pandemic vaccine must be distributed equitably, and should not be available based on ability to pay.** With nearly 50 million Americans uninsured, and with broad-scale vaccination critical to protecting not just individuals but the entire population from a pandemic, it is essential that the vaccine delivery and distribution system not depend on private insurance and reimbursement systems. It would be tragic if vaccines were more likely to be available based on insurance status or ability to pay.
- **A pandemic vaccine distribution program will require communication and outreach to the public.** This is traditionally a public health function; public health agencies have unique levels of trust with the public, especially vulnerable populations. That trust will be needed to ensure compliance with a complicated system of vaccine distribution.



## B. ADAPTABLE, SCIENCE-DRIVEN PLANNING RECOMMENDATIONS

During the H1N1 outbreak, it was clear that top government officials were following the guidance of public health experts and science was driving policies. Government officials provided clear and consistent guidance to individuals about the best ways to protect themselves. In addition, the response continued to appropriately adapt to changing circumstances as more information became known about the virus and how it was evolving, such as the timely decisions about when to close schools or limit gatherings.

The outbreak underscored the need for ongoing planning and coordination among all levels of government and between the government and private sector. It also reinforced the difficulties of international coordination and planning. Without clear lines of communication and careful planning, it is difficult to maintain an effective response strategy.

H1N1 also showed the challenges that communities face around decisions to close schools or work places or limit public gatherings. There are numerous ramifications for all of these actions that affect families and the economy. It is essential to consider the impact of these types of community mitigation strategies, and plan for ways to make them easier to implement, for instance, by ensuring sick leave benefits to workers, so they do not face the tough decision of foregoing a paycheck against staying home to care for their children during an outbreak.

The following are recommendations for ensuring that planning and coordination are ongoing activities and that community mitigation strategies are updated and realistic:

### 4. PLANNING AND COORDINATION: Federal, state, local, and private planning and coordination must be consistent and ongoing -- reflecting the constantly changing nature of the influenza threat.

■ **Federal, state, local and private sector pandemic influenza plans should be systematically reviewed in light of the experience with the outbreak and response to H1N1.** It is critical to ensure that the plans build in flexibility in response, given that the H1N1 virus did not behave as many planners had anticipated -- it did not originate overseas and our global surveillance system did not give us the level of warning desired. It is also important to review various guidances, in particular the school closure guidance, in light of the real world experience over the last two months.

■ **The federal government should take the lead in increasing and better coordinating federal, state, local, and private planning and preparedness, and all jurisdictions should work together to create policies that follow best infection-control practices.** Often there is a flurry of planning activities when a potential health threat is identified and communication about preparation and response is strong. However, over time, while the threat remains dormant, private-public communication may decline. There should be ongoing and evergreen communication among public and private partners as to roles and responsibilities during a major health crisis, not

just when one becomes imminent. Furthermore, bringing together the creative ideas and collective expertise of diverse leaders and organizations will help build community resilience to a public health emergency. It is also important for local communities and health departments to coordinate based on the circumstances they face during an outbreak and issues that are specific to their communities.

■ **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 its actions and held accountable for protecting the public. 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.<sup>14,15</sup> HHS and the White House should engage partners in updating the National Strategy and Implementation Plan. 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.<sup>16</sup>

## CUYAHOGA COUNTY, OHIO: COMMUNICATION KEY TO EFFECTIVE H1N1 RESPONSE

The Cuyahoga County health department was formally alerted about the H1N1 outbreak late on Friday, April 24, 2009. The next day, the county activated its Northeast Ohio Health Alert Network to communicate with other local emergency preparedness partners. By Sunday, April 26th, the state of Ohio had its first confirmed case of H1N1 in a suburb of Cleveland. That same day the U.S. government declared a public health emergency and Cuyahoga County readied guidance and information to be disseminated to the public.

On Monday, April 27th, the local preparedness working group met and the 24/7 City of Cleveland/Cuyahoga County combined Emergency Operations Center was up and running to begin issuing clear and unified messaging on the H1N1 outbreak and to track the progress of and response to the outbreak. The county public information officers developed fact sheets and updated the county website with links to the CDC. The county health commissioner, Terry Allan, and Commissioner of the Cleveland Department of Public Health, Matt Carroll, began holding twice daily conference calls with partners from hospitals, nursing homes, safety forces, schools and universities, daycares, and businesses. They also established a

regular email briefing for local elected officials.

Although Cuyahoga County has only had two confirmed cases of H1N1, some local schools began unilaterally closing because of fears about ill students or faculty. The county health department was able to correct the false information that was circulating and work with schools so that they were following CDC school closure guidance. The public soon came to trust these local public health officials, which had the important effect of reducing panic and anxiety in the community.

Cuyahoga County Health Commissioner Allan attributes the rapid response and mobilization, the ability to continue normal daily operations, and the establishment of a link to the media and public, to the fact that “public health had formally integrated as an essential partner in our community emergency response system.”<sup>17</sup>

Mr. Allan warned Congress in a recent hearing, that cuts to state and local preparedness dollars could seriously affect the ability of local health departments to respond effectively to future public health emergencies.

### 5. SCHOOL CLOSINGS, SICK LEAVE, AND COMMUNITY MITIGATION STRATEGIES: Strategies to mitigate a major infectious disease outbreak include ensuring that all working Americans have sick leave benefits available and that communities are prepared to limit public gatherings and close schools as necessary.

Clear, consistent, culturally-competent communication with the public is essential during a disease outbreak, so that health departments and providers can let people know about latest developments, how to best protect themselves, when they should limit their public activities and avoid going to work or school, and when and where they should go for medications or vaccinations.<sup>18</sup> This includes letting people know the prioritization plans for vaccinations when limited amounts of vaccine may be available or when it is more important to vaccinate a target population in advance of the rest of a community.

■ **Continued work is needed in communities around the country to develop and test effective policies for slowing the spread of infection that also minimize the known social and economic consequences associated with these measures.** Such measures need to be based on sensible and practical policies that are in line with the science available at any given time of an outbreak rather than responding to panic or complacency. Current state and federal roles in invoking quarantine and isolation

policies should be clarified. The federal government, in coordination with the states, must establish clear legal authority and guidance for the use of such measures to effectively limit the spread of disease.<sup>19</sup>

■ **One of the most difficult challenges during an outbreak is managing sick leave concerns, since currently 48 percent of Americans have no paid sick days.** That means during an infectious disease outbreak, like a pandemic, they may be forced to choose between a paycheck and their own health. During the recent H1N1 outbreak, anecdotal stories emerged of workers threatened with termination if they stayed home, despite being sick. Forcing sick people to go to work or school during a pandemic not only threatens their own well-being, but the health of coworkers, customers, and schoolmates and undermines efforts to limit the spread of disease. The “Healthy Families Act” was introduced in Congress in response to the H1N1 outbreak to facilitate the ability of workers to stay home when they or their family members are ill, but it has not been acted upon.

## 6. GLOBAL COORDINATION – Efforts must be made to increase coordination across borders to build trust, improve surveillance technologies and treatment capabilities, and encourage science-based policies and decision making internationally.

- The United States should work closely with the World Health Organization to revise the pandemic phase system and to encourage countries around the world to base policies for detection and control on sound science.
- The United States should also take the lead on improving global disease surveillance. The President's 2009 pandemic flu emergency funding request includes \$220 million for enhanced global disease detection and Congress should provide these funds.

## C. CORE PUBLIC HEALTH INFRASTRUCTURE IMPROVEMENT RECOMMENDATIONS

The H1N1 outbreak highlighted many of the ongoing vulnerabilities in the nation's public health infrastructure. The system has been under-resourced for decades, and now with the economic recession leading to budget cuts in many states, most public health departments are laying off workers. The result is that health departments are already stretched too thin to maintain their day-to-day responsibilities. When an event like the H1N1

outbreak or other major disaster occurs, the health departments do not have the resources or personnel in place to adequately protect the health of their communities.

The following are recommendations for providing the resources and capabilities needed to maintain public health preparedness and for bolstering the public health workforce:

## 7. RESOURCES: Adequate funding must be provided for on-the-ground response. Right now, state and local health departments do not currently have enough resources to respond to a severe outbreak.

■ Congress should assure a reliable funding stream for all core public health activities as part of health reform -- both to prevent and address the on-going public health responsibilities of state and local government and to ensure back up capacity is available to respond to a major public health emergency. Sustained funding to ensure a fully operational and fully staffed public health system is critical to emergency response. During an emergency such as a flu pandemic, all public health workers will be needed to mount a the response. Frequent budget cuts to non-preparedness programs undercut the capacity of state and local health departments to gear up in response to the H1N1 outbreak.

■ The federal government should update as needed, fully fund, and promptly carry out the President's *National Strategy for Pandemic Influenza Implementation Plan*.<sup>20,21</sup> The National Strategy and Implementation Plan should be evergreen documents, updated as the science evolves and the White House assesses the effectiveness of implementation on an ongoing basis.

At present, public health departments around the country are under-funded and over-extended to manage the demands of their ongoing responsibilities. In the current economic climate, public health departments are facing severe cutbacks around the country. Accord-

ing to the Center on Budget and Policy Priorities (CBPP), at least 46 states face shortfalls to their 2009 and/or 2010 budgets. CBPP estimates that combined budget gaps for states in the remainder of 2009, 2010, and 2011 could total more than \$350 billion.<sup>22</sup>

■ To adequately support public health preparedness needs, Congress should:

▲ Complete the funding to implement the *National Strategy for Pandemic Influenza*. The President originally requested \$7.1 billion to carry out research and development for vaccinations, pharmaceuticals, and medical devices needed to respond to a pandemic. \$870 million of this has never been funded. This money is needed to continue pandemic R&D. This funding was originally included in the proposed 2009 stimulus bill, but it was removed before the bill's passage. Subsequently, in April 2009 President Obama submitted a request for \$1.5 billion in emergency funding for pandemic preparedness. Congress should approve this supplemental funding.

▲ Provide resources for state and local health departments to adequately prepare for outbreaks. State and local officials are the front line responders to outbreaks, yet they have not received any new federal funding for pandemic flu preparedness since 2006. \$350 million is



needed annually to adequately maintain state and local pandemic preparedness activities. The President's FY 2009 pandemic flu emergency supplemental includes \$350 million for state and local pandemic preparedness, which should be enacted.

- ▲ **Maintain investments 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.**

- ▲ **The federal government should modernize and provide sustained support of disease surveillance systems, public health laboratories, communications systems, and other core public health capabilities needed for rapid detection and response to public health threats.**

## CURRENT STATUS OF STATE PREPAREDNESS

A Government Accountability Office (GAO) report published in September 2008, found that the HHS-led review of state pandemic influenza response plans found “many major gaps” in state pandemic planning in 16 out of 22 priority areas.<sup>23</sup> The GAO concluded that “while the federal government has provided some support to states in their planning efforts, states and localities have had little involvement in national planning for an influenza pandemic...even though the National Pandemic Implementation Plan relies on these stakeholders efforts.”<sup>24</sup>

A January 2009 “Assessment of States’ Operating Plans to Combat Pandemic Influenza” report from HHS to the White House Homeland Security Council found that many states scored well in areas such as protecting citizens and administering mass vaccinations, but found major gaps in such areas sustaining state operations, developing community mitigation plans, and maintaining key infrastructure.<sup>25</sup>

According to federal guidelines, state plans are required to demonstrate the state’s ability to accomplish a range of expectations, but states have not been adequately funded to meet these demands:<sup>26</sup>

- Ensure public health continuity of operations during each phase of a pandemic;
- Ensure surveillance and laboratory capability during each phase of a pandemic;
- Implement community mitigation interventions, e.g., school closings or cancelation of large public events;
- Acquire and distribute medical countermeasures, like Tamiflu® or Relenza®;
- Ensure mass vaccination capability during each phase of a pandemic; and
- Ensure communication capability during each phase of a pandemic.

## SEATTLE & KING COUNTY, WASHINGTON: RESPONSE TO SWINE FLU AMID BUDGET CUTS AND EVOLVING POLICIES

A month into the outbreak, Seattle & King County had more than 160 cases of H1N1 and several schools were closed to prevent the further spread of the novel flu virus. The local response to the H1N1 outbreak was undertaken amidst concerns about steep cuts in local public health funding. In fact, the last day of the 2009 Washington state legislative session -- in which Seattle & King County’s public health funding was cut by \$14.4 million from \$201.6 million to \$187.2 million -- was the same day as cases were first identified in the United States. According to the *Seattle Post Intelligencer*, the King County operating budget deficit for 2010 could be \$50 million and the 2009 budget may have to be further revised downward.<sup>27</sup>

A major concern is that two programs which helped in the recent response face an uncertain future without additional funding: the childcare health program, which allowed nurses to work with schools to screen for possible cases, and the communicable disease program. According to Dr. David Fleming, Director of Public Health for Seattle & King County, at the height of concern the public health nurses who were working overtime conducting education and outreach to schools and

daycares, were slated, as a result of previous budget reductions, to receive their lay-off notices two weeks later.<sup>28</sup>

The budget cuts also are likely to severely strain local and state laboratory testing capability. According to Dr. Fleming, “Limitations in testing capability in our local laboratory, at the state laboratory, and at CDC led to a national picture of the outbreak as reported in the national media that was a week to 10-days-old from the front line reality. We had widespread community illness before CDC posted a single confirmed case in Seattle.”

Dr. Fleming believes the key to Seattle & King County’s success to date in containing the H1N1 outbreak is attributable to communication, and local health officials being careful to say what they didn’t know, foreshadowing possible changes in policy, and being clear at the outset that what they learned about both severity and transmissibility would determine their response. “In that context the community work that had been done on pandemic preparedness, while key, was a barrier,” Dr. Fleming says. “Changing policies to match those indicated by a less severe strain was difficult because that’s not what people had been trained to do.”



## 8. WORKFORCE: The public health workforce is seriously strained, and budget cuts are resulting in additional layoffs.

■ **Federal, state, and local governments must take action to recruit, train, and retain the next generation of public health professionals in public health.** From first responders to scientists who detect and contain diseases, the nation's public health workforce is vital to protecting the nation's health. There is a shortage of public health workers in the United States, and as Baby Boomers retire, there is not a new generation of workers being trained to fill the void of expertly trained public health workers. The country has an estimated 50,000 fewer public health workers than it did 20 years ago, and one-third of the public health workforce in states is eligible to retire within five years, and 20 percent of the local public health workforce is eligible to retire within two years.

■ **Despite tough economic times, it is important to sustain the public health workforces to protect America's health.** In the past year, public health departments around the country are being forced to layoff experts and professionals needed to protect communities from threats like pandemic flu. A preliminary survey of local health departments by the National Association of County and City Health Officials (NACCHO) has found both budget cuts and workforce reductions to health departments. A survey of 2,422 local health departments nationally in November-December 2008 found that more than half of local health departments have either laid off employees or lost them through attrition. Because of the current budget limitations, health departments have been unable to replace the lost workers, and they anticipate more cuts in 2009 and 2010.<sup>29</sup> These cutbacks have serious consequences for responding to a health emergency.

### SACRAMENTO COUNTY: H1N1 CRISIS RESPONSE IN THE FACE OF BUDGET CUTS AND LAYOFFS

On Friday, April 24, 2009 Dr. Glennah Trochet, Sacramento County's chief public health officer assembled her staff to deliver some bad news: job cuts were a near certainty due to severe budget crisis facing California and the weak national economy.

That same day health officials were warned about a novel influenza virus that was killing otherwise healthy young adults in Mexico. When the first case was diagnosed in Sacramento County on April 26, a panicky public jammed telephone lines with questions and "worried well" descended on local health care facilities, while lab technicians labored to diagnose and differentiate H1N1 flu cases from seasonal flu.

Dr. Trochet sounded the alarm and her local public health workforce jumped into action. A squad of 50 Sacramento County health workers began putting in 12-hour shifts and logged more than 1,200 hours over the first five days of the outbreak.

That kind of dedication in the face of looming budget cuts and layoffs is emblematic of the U.S. public health workforce. Across the country, the economic recession is leading to severe cuts in public health budgets. In 2008, local health departments across the country lost \$300 million and 7,000 staffers to budget cuts and could lose an equal number of workers this year, according to NACCHO.

In Sacramento County, over the past two years the Division of Public Health has seen its budget slashed in half—dropping from \$9.8 million to \$5.1 million. The department has been forced to let go more than a quarter of its staff. According to the *Sacramento Bee*, in 2008, 57.4 full-time positions were shed; an additional 31 or more could be lost in 2009, bringing staffing below 228 full-time-equivalent positions. "I hope the public realizes how much work is going on to keep them safe and to keep them well," said Dr. Trochet. "It's only when we fail that the public notices that there is a public health disaster."<sup>30</sup>

## D. SURGE CAPACITY AND CARE RECOMMENDATIONS

While the H1N1 outbreak was relatively mild and limited in duration in the United States in early 2009, hospitals and clinicians across the country reported major surges in patients, including individuals with the flu, flu-like symptoms, or the “worried well.” As health providers prepare for a potential

return of H1N1 in the fall and/or the potential of other outbreaks, caring for a major surge of patients remains one of the most difficult challenges for the public health and health care systems.

The following are recommendations for ways to better prepare for a massive influx of patients:

### 9. SURGE CAPACITY: The ability for health providers to manage a massive influx of patients during an emergency remains a major challenge for emergency public health preparedness.

During a major emergency like a pandemic outbreak, the health care system will be significantly stretched beyond normal capabilities. In the best of times, most emergency rooms already face bed shortages and staffing issues. During disasters, health providers have to adapt their regular practices to treat a large number of patients very quickly. Many of the surge capacity problems have been identified -- including having enough stuff, staff, and space to treat patients -- but solutions to these problems are often lacking.

The HHS Pandemic Influenza Plan projects that a pandemic could result in 45 million additional outpatient visits, with 865,000–9,900,000 individuals requiring hospitalization, depending on the severity of the pandemic. Such a major disaster would cross state lines and quickly overwhelm health care systems.

- **The federal government must take a lead in providing guidelines to states on surge capacity planning.** Currently, definitions of appropriate “disaster standards of care” are lacking, according to the *New England Journal of Medicine*.<sup>31</sup> Although various federal agencies have published surge guidance, there have been few incentives or unified directions to enable 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 to provide continued care for daily emergencies and chronic care when they are also responding to a major outbreak.
- **Staff:** Today’s hospitals and health care facilities operate using a “just-in-time supply chain,” which means very limited supplies are stored on-site and instead are replenished on an as needed basis, so many health providers will run

out of supplies very quickly if they have to treat a major surge of patients. In addition, hospitals are likely to run short of ventilators and decontamination units very quickly.

- **Staff:** Workforce shortages plague hospitals and health care facilities even in the best of times. According to a June 2008 report from the Center for Studying Health System Change, “the day-to-day shortages of key health personnel -- such as nurses, physicians, pharmacists, laboratory technicians, and respiratory therapists -- exacerbate the challenge of having sufficient numbers of health workers in an emergency.”<sup>32</sup> One way to increase workforce capacity is to provide incentives to medical providers, such as priority status for receiving medications or vaccinations. Another is to recruit health care providers outside of the emergency systems to serve as volunteers during disasters. Liability protection concerns for volunteers must be addressed as part of the planning process. An analysis in 2008 found that eight states have low levels of protections for health care volunteers during times of emergencies, meaning that states have only Good Samaritan or similar laws under which volunteers may be provided with an affirmative defense, but not necessarily immunity from liability. In addition, 26 states did not have statutes that extended some level of liability immunity to groups and/or organizations providing charitable, emergency, or disaster relief services.<sup>33</sup>
- **Space:** Hospitals and other facilities will have to address limited numbers of hospital beds and space to care for sick individuals. They will have to manage issues like rapid discharging of patients, canceling elective surgeries and procedures, reducing the use of tests and ancillary services, converting single rooms to accommodate more people, using cots and portable beds, and finding unused space to treat or triage patients.



## MEDICAL RESERVE CORPS: VOLUNTEER HEALTH CARE PROFESSIONALS RESPOND TO H1N1 OUTBREAK

The Medical Reserve Corps (MRC) is a national network of community-based volunteer units that support local public health and provide for an adequate supply of volunteers in the case of a public health emergency. During the H1N1 outbreak, MRC units across the nation were activated to assist in the response.

### Arizona

■ The Navajo County MRC volunteers dispatched four members to help the Navajo County Public Health Department in the receiving, inventorying, and sorting of Strategic National Stockpile (SNS) pharmaceuticals. Six MRC volunteers from this unit later assisted in the distribution of SNS supplies to local hospitals.

### Florida

■ The Sarasota County MRC sent three MRC nurses to staff a H1N1 triage phone line. Over six days they worked a total of 27 hours at two community health department sites. These volunteers were also trained in personal protective equipment (PPE) protocols to conduct physical assessments of walk in patients who possibly were ill with H1N1 flu.

### Louisiana

■ Calcasieu Parish MRC helped the Regional Office of Public Health in Lake Charles, Louisiana, with calls to hospitals, doctors' offices and other health care facilities to check on their needs and current availability of supplies. They also delivered test kits to health care facilities. Approximately 22 volunteers also were involved in community mitigation efforts, teaching proper hand washing at local schools.

### New York

■ New York City MRC physician volunteers assigned to the NYC Department of Health and Mental Hygiene helped to staff the Provider Access Line call center to answer questions related to H1N1.

### Utah

■ Davis County MRC conducted a point-of-dispensing (POD) training course in anticipation of future mass vaccinations.

### Washington

■ Whatcom County MRC volunteers were involved in respirator fit testing for the local hospital. They ran four fit test stations over one weekend. Their goal was to perform fit testing on 1,000 people over 20 days. They also staffed a telephone triage call line. Whatcom County MRC also developed a potential Alternate Care Facility for surge capacity in event of hospital overflow. Whatcom County MRC staffed a phone bank in conjunction with Peace Health St. Joseph's Hospital.

### Wisconsin

■ Southeast Wisconsin MRC volunteers staffed call centers, and clinics where they performed diagnostic testing on patients.

Source: All information provided to TFAH by the Office of the Civilian Volunteer Medical Reserve Corps.

**10. CARING FOR THE UNINSURED AND UNDERINSURED: A “State of Emergency” health benefit should be created to ensure that all Americans will be cared for during emergencies. Providing care is not only important for the individual patient, but since individuals are contagious, it also helps limit the spread of disease to others.**

With more than 15 percent of Americans lacking health insurance coverage, the financial impact on the country’s public health and health care systems could be disastrous if hospitals, community health centers, and primary care facilities treat large numbers of uninsured.<sup>34</sup> Likewise, if uninsured or underinsured patients hesitate to seek treatment because of fears of out-of-pocket costs, treating and containing the further spread of a pandemic would be nearly impossible. According to the Center for Biosecurity, U.S. hospitals could lose as much as \$3.9 billion in uncompensated care and cash flow losses in a severe pandemic.<sup>35</sup>

Health reform offers the opportunity to find ways to ensure all Americans would be covered during an infectious disease outbreak and that health providers would be compensated for providing care.

■ **However, if universal health insurance coverage is not achieved, the federal government should act now to create emergency health coverage and reimbursement.** It would have to guarantee providers some level of compensation for the services they provide during a pandemic, while encouraging individuals to come forward for diagnosis or treatment.

For the health care system, the emergency benefit would mitigate the economic impact of providing such a high level of emergency care, much of which may be uncompensated, while also foregoing revenue generating activities, such as elective surgeries, which could place hospitals and other health care providers in financial jeopardy.

The benefit would also encourage the uninsured or underinsured who fall ill to access primary care services for prompt diagnosis

and treatment and not be delayed due to concerns about their inability to pay for services. Delayed diagnosis may complicate public health officials’ abilities to control the spread of infection. Similarly, delayed diagnosis might render useless potential treatment with antivirals, since such treatment is most effective when begun early after infection.

■ **The Public Health Emergency Response Act (PHERA) is an example of legislation that would address this concern.** The act calls for bolstering public health preparedness as part of a reformed health system. It would address payment streams for hospitals and health care providers during emergencies, and it supports major equipment upgrades and maintenance of capacity for hospitals and health care facilities.<sup>36</sup>

Currently, hospital preparedness is financed through the Hospital Preparedness Program (HPP), which focuses on improving the clinical response to a large-scale health emergency. Initially run by the Health Resources and Services Administration (HRSA), HPP is now run by the Office of the Assistant Secretary for Preparedness and Response (ASPR) as mandated by the 2006 Pandemic and All-Hazards Preparedness Act. ASPR awards one-year funding grants to hospitals and other health care facilities to improve surge capacity and enhance community and hospital preparedness for all-hazards, including bioterrorism and pandemic influenza. The funding system is viewed as unpredictable and insufficient.<sup>37,38,39</sup> Hospitals only receive an average of \$82,500 a year per hospital.

**Appendix C examines options for funding an emergency health benefit.**



# PANDEMIC FLU PLANNING BACKGROUND

# A

## APPENDIX

### HOW IS PANDEMIC FLU DIFFERENT THAN SEASONAL FLU?

Most Americans are familiar with seasonal flu, a respiratory illness that strikes annually.

Seasonal flu kills approximately 36,000 people in the United States every year and hospitalizes more than 200,000, but experts generally consider it a predictable public health problem, since many people have some form of immunity to it and a yearly vaccine is available.<sup>40</sup>

A pandemic (from Greek, meaning “of all the people”) influenza is a new strain of the flu that is capable of sustained transmission among humans and, as a result, causes a global outbreak. Because there is little natural immunity, pandemic influenza will affect significantly more people than seasonal flu and like seasonal flu, is easily spread from person to person. There have been at least 10 recorded flu pandemics during the past 300 years.<sup>41</sup>

### PANDEMIC FLU IS EVERYONE’S PROBLEM

If a severe pandemic occurs, it is likely to be a prolonged and widespread outbreak that could require major changes in many sectors of society, such as schools, work, transportation, business, health care, and government. The public can greatly reduce their risk during a pandemic by being informed and prepared before the emergency. To be prepared for an outbreak, HHS encourages individuals, businesses, and communities to:

- Talk with your local public health officials and health care providers, who can supply information about the signs and symptoms of a specific disease outbreak and recommend prevention and control actions;
- Adopt business/school practices that encourage sick employees/students to stay home and anticipate how to function with a significant portion of the workforce/school population absent due to illness or caring for ill family members;
- Practice good health habits, including eating a balanced diet, exercising daily, and getting sufficient rest. In addition, take common-sense steps to stop the spread of germs including frequent hand washing, covering coughs and sneezes and staying away from others as much as possible when you are sick; and
- Stay informed about pandemic influenza and be prepared to respond.<sup>42</sup>

# B

APPENDIX

## STATE PURCHASES OF ANTIVIRAL MEDICATIONS

As of September 30, 2008, 34 states and D.C. had purchased 50 percent or more of their federally-subsidized antivirals to stockpile for use during a pandemic influenza.

34 states and D.C. have purchased 50 percent or more of their federally-subsidized antiviral drugs to stockpile for use during an influenza pandemic (1 point)			16 states have purchased LESS than 50 percent of their share of federally-subsidized antiviral drugs to stockpile for use during an influenza pandemic (0 points)		
State	All Antivirals Purchased by Entity as of 09/30/2008	Percent of Allocation Purchased*	State	All Antivirals Purchased by Entity as of 09/30/2008	Percent of Allocation Purchased**
Alabama	533,553	112.84%	Arizona	67,717	11.56%
Alaska	77,030	113.17%	Colorado	215	0.05%
Arkansas	382,398	133.52%	Connecticut	22,829	6.24%
California**	2,752,151	102.43%	Florida	66,000	3.70%
Delaware	121,164	141.05%	Idaho	8,567	5.97%
D.C.	45,000	76.86%	Maine	0	0%
Georgia	474,022	52.03%	Maryland	210,727	36.41%
Hawaii	172,487	131.56%	Massachusetts	50,662	7.52%
Illinois**	516,018	50.25%	Montana	8,174	8.48%
Indiana	650,912	100.00%	Nebraska	71,952	39.44%
Iowa	312,631	101.21%	New Mexico	77,409	39.25%
Kansas	286,084	100.00%	Oklahoma	54,015	14.67%
Kentucky	216,224	50.01%	Oregon	26,523	7.09%
Louisiana	471,804	100.00%	Rhode Island	11,900	10.53%
Michigan	1,076,950	101.74%	Texas	1,023,141	44.09%
Minnesota	340,640	64.07%	Utah	52,033	21.07%
Mississippi	338,648	111.89%			
Missouri	600,477	100.00%			
Nevada	135,514	57.56%			
New Hampshire	68,000	50.26%			
New Jersey	880,293	97.01%			
New York***	2,444,836	121.20%			
North Carolina	677,882	76.67%			
North Dakota	57,000	85.71%			
Ohio	1,388,858	115.65%			
Pennsylvania	1,298,792	100.00%			
South Carolina	459,960	105.59%			
South Dakota	80,310	100.00%			
Tennessee	613,706	100.00%			
Vermont	71,036	109.24%			
Virginia	827,661	107.03%			
Washington	417,902	64.92%			
West Virginia	227,561	119.65%			
Wisconsin	363,729	63.28%			
Wyoming	52,718	100.00%			

Notes: \*The percent reflects total state antiviral purchases and may include unsubsidized state purchases, which is why some states exceed 100% of their federally-subsidized allocation. \*\*The population count for California and Illinois does not include residents of Los Angeles County or Chicago, respectively. These two localities, along with D.C., received their own allocation of federally-subsidized antivirals based on their populations. \*\*\*New York State antiviral purchases include those made by New York City.

Source: ASPR, information updated as of September 30, 2008. <http://www.pandemicflu.gov/plan/states/antivirals.html>

## FINANCING OPTIONS FOR CREATING SURGE CAPACITY

**E**ven in a system with universal health insurance coverage, the costs of creating surge capacity in the medical care system will be above and beyond the usual system of reimbursement to providers. Therefore, an additional system to finance the creation of surge capacity will be in needed and can be addressed during the health reform debate.

### **OPTION 1: Establish a Preparedness Program under Medicare and Medicaid.**

A Preparedness Program through Medicare and Medicaid could be created to help hospitals and health providers upgrade equipment needed for emergencies, and to provide a billing mechanism for care during emergencies.

#### **Medicare**

There is precedence for using Medicare Part A (hospital insurance) to compensate hospitals for higher operating costs they incur in providing services to low-income patients, and even using Medicare Part A to preserve access to care for Medicare and low-income populations.<sup>43</sup> The Disproportionate Share Hospital (DSH) Payments are used to mitigate the financial distress that some hospitals experience in serving large numbers of low-income, uninsured or underinsured patients and Medicare and Medicaid recipients.

Medicare Part A has also been used to compensate teaching hospitals for the higher costs associated with running graduate medical education programs and training medical residents. The Direct Graduate Medical Education (DGME) provides payments to hospitals for the costs of approved graduate medical education programs.<sup>44</sup> Meanwhile, the Indirect Medical Education (IME) provides an additional payment to hospitals that have residents enrolled in GME programs, to reflect the higher cost of patient care costs of teaching hospitals relative to non-teaching hospitals.

A newly formed Preparedness Program would allow hospitals to meet and maintain enhanced preparedness accreditation standards and Medicare codes of participation. The program would link payment to a process involving the HHS Secretary defining the scope of allowable preparedness costs. Overall, this approach would be similar to the Health IT (HIT) incentive model included in the American Recovery and Reinvestment Act of 2009. The HIT program is not a traditional grant program where hospitals apply for money to do certain things and compete for dollars, etc. It is, instead, like a lot of things funded on the mandatory side, formula-based.

The HIT funding formula is based on hospitals' Medicare share and Medicare bed days. The formula calculation produces a dollar amount that an individual hospital is able to access if it can prove that it meets certain thresholds for meaningful electronic health record use. The thresholds would be defined by the HHS Secretary.

In the proposed Medicare Preparedness Program, preparedness accreditation standards and Medicare's hospital codes of participation would be reviewed and updated by the HHS Secretary to strengthen the preparedness requirements. First year funding would be available to individual hospitals on a formula-basis if they produced an action plan for their preparedness planning, the scope of which would be defined by the HHS Secretary. In subsequent years, formula-based funding would be available if individual hospitals met preparedness structure and process benchmark measures defined by the HHS Secretary. The formula would be based on hospitals' Medicare share and Medicare bed days. The HHS Secretary would be required to report to Congress annually on the use of preparedness program dollars, and in year five make recommendations for improvements in the program including addressing any need for variations in the funding formula based on geography, risk-assessment, etc.

#### **Medicaid**

In order to reach children's hospitals not reimbursed by Medicare, hospital preparedness payments would need to include a parallel funding stream in Medicaid.

Medicaid is a jointly funded, federal-state health insurance program for low-income children, the aged, blind, and/or disabled, and other people who are eligible to receive federally assisted income maintenance payments. Medicaid is a state administered program and each state sets its own guidelines regarding eligibility and services, however, the federal government sets a minimum eligibility floor ensuring a certain level of coverage to select populations.

In the past, Medicaid has been used to reimburse providers of medical assistance, including hospitals, for infrastructure upgrades. For example, in October 1972, Congress passed a law (P.L. 92-603) that provided for a 90 percent federal (10 percent state) financial participation for the design, development, or installation of the Medicaid Management Information System (MMIS), a mechanized claims processing and information retrieval system approved by HHS. The law also provided a 75 percent federal (25 percent state) financial participation for the operation of the MMIS.

## **OPTION 2: Use Direct and Indirect Payments to Reimburse Hospitals for Surge Costs.**

The Graduate Medical Education (GME) program currently uses both direct and indirect payments to reimburse teaching hospitals for the cost of educating medical students. Direct Graduate Medical Education (DGME) provides payments to hospitals for the costs of approved graduate medical education programs. Meanwhile, Indirect Medical Education (IME) provides an additional payment to hospitals that have residents enrolled in GME programs, to reflect the higher cost of patient care costs of teaching hospitals relative to non-teaching hospitals.<sup>45</sup>

The creation of a Direct Preparedness Payments (DPP) and Indirect Preparedness Payments (IPP) could help reimburse hospitals for the direct costs of preparedness, such as the purchase of extra supplies and beds, and provide hospitals with a modest enhancement for the ongoing costs of building

The proposed hospital preparedness program would involve a 100 percent federal match so there would be no reason for states to opt out of the program. The legislation could also include creation of a Medicaid reimbursement for the state health department's role in administering and coordinating the new program, as described later in the Eligibility for Reimbursement and Standards for Surge Capacity section.

surge capacity, including hiring and retaining personnel and recruiting a surge workforce.

Centers for Medicare and Medicaid Services (CMS) could set up a new Medicare billing code or a Diagnosis Related Group (DRG) add-on that could be used to reimburse hospitals for capital expenditures and staffing for hospital preparedness. This approach would face some challenges to implement because Medicare currently does not reimburse through DRG unrelated to direct patient care and the process would require ongoing auditing of hospitals. CMS could determine whether having preparedness training curriculum in place could be reimbursed and perhaps whether hospitals could receive an additional payment to cover the higher costs of training staff in emergency preparedness and surge capacity techniques.

### **Eligibility for Reimbursement and Standards for Surge Capacity**

CMS, in conjunction with the Assistant Secretary for Preparedness and Response (ASPR) and other appropriate partners, could develop standards and guidelines for determining both if a hospital should be eligible for (and is capable of) developing surge and what surge capacity entails. Although CMS would provide the reimbursement mechanism, ASPR, with input from Coordinating Office for Terrorism Preparedness and Emergency Response (COTPER), should oversee the program and provide oversight and technical assistance to state and hospitals to ensure efficacy. A number of issues that would need to be addressed include:

- Through the rulemaking process, a certification process would need to be developed so state health departments could determine if a hospital is eligible to participate in the program. The state would take into account the regional need for surge and the capacity of individual hospitals to participate, based on a state-wide plan.

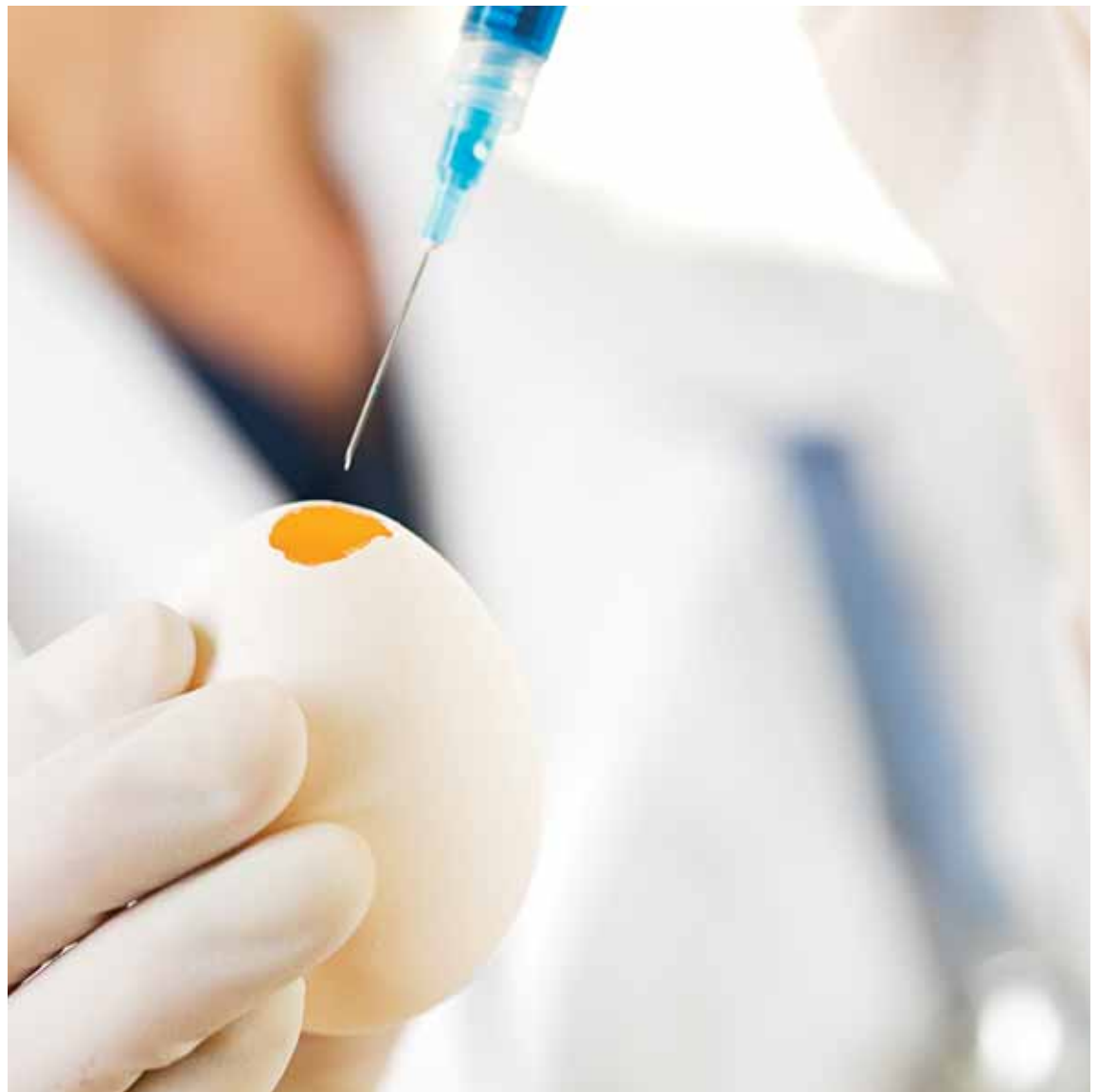
- ASPR would need to develop guidance to states for coordination of a state program, including communication between hospitals, triggering of surge protocols, deployment of assets, and other issues.
- In order to receive reimbursement, hospitals would need to meet preparedness standards as determined by the federal rulemaking process. Examples include having a hospital preparedness coordinator, a hospital-specific plan that is approved by the state, an interoperable communications system, and a continuity of operations plan.
- By agreeing to participate, hospitals would have to agree to participate in a state surge program, to be coordinated by the state health department with guidance and technical assistance from HHS.
- Prior to creating the hospital preparedness billing code, CMS would have to determine for what items it would be willing to reimburse hospitals.



# Endnotes

- 1 Personal correspondence with David Fleming, MD, Director of Seattle & King County Public Health Department, May 21, 2009.
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**Trust for America's Health** is a non-profit, non-partisan organization dedicated to saving lives by protecting the health of every community and working to make disease prevention a national priority.

**The Center for Biosecurity** is an independent, nonprofit organization of the University of Pittsburgh Medical Center. The Center works to affect policy and practice in ways that lessen the illness, death, and civil disruption that would follow large-scale epidemics, whether they occur naturally or result from the use of a biological weapon.

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