

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

2009 H1N1 Influenza Improvement Plan

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Statement by Secretary Sebelius

In the approximately three years since the start of the 2009 H1N1 influenza pandemic, the U.S. Department of Health and Human Services (HHS) has continued our efforts to improve the nation's readiness for a future influenza pandemic. It is essential that these efforts continue since influenza viruses with pandemic potential continue to spread widely in animals and sporadically infect humans, and the place and time of the next pandemic cannot be anticipated. Prior pandemic preparedness efforts and investments provided the groundwork for the 2009 H1N1 response; now those preparedness strategies and plans need to be adjusted to incorporate real world experiences and recent technological advances.

Since the 2009 H1N1 influenza pandemic, we have collaborated with state, local, and community partners to implement innovative approaches for increasing seasonal influenza vaccination rates and addressing health disparities for minorities and at-risk individuals, such as those with disabilities. We have also invested in the advanced development of new, additional antiviral medications to add to the nation's existing pandemic influenza medical countermeasure arsenal. Furthermore, in December 2011, the first U.S. facility to use a faster and more flexible technology to make influenza vaccine was dedicated. This facility, a public-private partnership of HHS and Novartis Vaccines and Diagnostics, Inc. of Cambridge, Massachusetts, marks the first change in influenza vaccine manufacturing in the United States in fifty years and may be able to produce 25 percent of the vaccine needed in the United States during a pandemic.

Pandemic preparedness requires a multi-sector approach beyond just vaccines, antiviral medications, and other medical countermeasures. After examining our 2009 H1N1 experience, we highlighted several successes and opportunities for improvement in a variety of areas in *An HHS Retrospective on the 2009 H1N1 Influenza Pandemic to Advance All Hazards Preparedness*. In the accompanying *2009 H1N1 Influenza Improvement Plan*, we articulate HHS' key priorities for modifying and updating prior pandemic plans on many fronts, including influenza virus detection and characterization, community mitigation measures, medical surge capacity, communications, international partnerships and collaborations, and cross-cutting support areas, in addition to vaccines and other medical countermeasures. Many of these activities will have effects beyond just pandemic influenza preparedness and will advance all-hazards preparedness more broadly.

Preparedness is a process, not an end-state. By focusing on these priority actions, we will be even better prepared to handle the next influenza pandemic and other public health emergencies we will certainly face in the future.

Sincerely,

Kathleen Sebelius

EXECUTIVE SUMMARY

In 2009, the world experienced the start of the first influenza pandemic of the 21st century, caused by the novel 2009 H1N1 influenza virus. The 2009 H1N1 pandemic arose against a backdrop of five years of pandemic planning efforts—including efforts on the part of the United States (U.S.) and the international community as a whole—to develop, refine, and regularly exercise pandemic plans at national, state, and local levels, and to engage the private sector and non-profit partners. Many of these activities were initiated in response to the re-emergence of highly pathogenic avian influenza (HPAI) H5N1, or “bird flu,” in wild birds and poultry in Southeast Asia in late 2003, and its subsequent infection in humans. Those who become infected through contact with infected birds face a mortality rate of approximately 60 percent. Because humans do not have immunity to this novel influenza virus, it could cause a pandemic if it becomes readily transmissible among humans, rather than solely from contact with infected birds. While the prior planning efforts acknowledged that characteristics of a future pandemic are impossible to predict, most planning focused on an H5N1-like severe pandemic scenario, with the assumption that this would adequately prepare the U.S. to respond to any potential pandemic.

These prior pandemic planning efforts provided a solid foundation for the response to the 2009 H1N1 pandemic. However, the characteristics of the pandemic resulting from the 2009 H1N1 influenza virus and the disease it produced differed in many ways from the severe pandemic circumstances anticipated with an H5N1 influenza virus pandemic. It was not anticipated that a new strain of influenza virus with pandemic potential would emerge within North America, that it would arise from a non-avian species origin, and that its severity would be significantly less than with H5N1. Yet influenza viruses with pandemic potential, including H5N1, continue to spread widely in poultry and other animals and sporadically infect humans, demonstrating the continued need for pandemic preparedness planning. The real-world test of the 2009 H1N1 response provided valuable insight into the scope of previous planning and emphasized the need for continued planning and implementation efforts that focus on a broad range of scenarios, including differing severity levels.

Prior to the 2009 H1N1 pandemic, planning for an influenza pandemic and other hazards, especially those pertaining to manmade threats, had proceeded in many ways on separate but related tracks. Yet the experience with 2009 H1N1 confirmed the value of all-hazards, national-level preparedness planning, and those aspects of prior plans and strategies that need to be refined and updated.

Within the context of all-hazards preparedness, the *HHS 2009 H1N1 Influenza Improvement Plan* is a refined blueprint that outlines next priorities for those aspects of pandemic influenza preparedness that are influenza-specific and describes the ways in which those next steps need to be accomplished, informed by the 2009 H1N1 influenza pandemic experience. The intent of this plan is to communicate key priorities of the Department of Health and Human Services (HHS) for modifying and updating the prior pandemic plans, and through this document, inform pandemic influenza preparedness planning of state, local, tribal, and territorial agencies, international organizations, and emergency planners in the non-profit and private sectors. By sharing this new approach to pandemic preparedness, we hope to expand wide-ranging collaboration between HHS and our many stakeholders as we re-enter the inter-pandemic phase

and work together to enhance the public health resiliency of the nation. These key priorities are listed below for reference, as well as at the end of each relevant chapter.

SUMMARY OF KEY PRIORITIES

Chapter 2: Detection and Characterization of Influenza Viruses

- Provide a nimble and accessible way to visualize available data for professional audiences, the general public, and policymakers (HHS lead: CDC; Target Date: November 2012);
- Develop and evaluate more accurate point-of-care tests and provide timely guidance and support to clinicians in using improved diagnostic testing for management and treatment decisions in outpatient settings as well as in-patient facilities (HHS lead: CDC, ASPR/BARDA, and FDA; Target Date: December 2012);
- Develop a more systematic method for assessing and communicating the impact of an emerging pandemic influenza virus through rapid characterization of the virus' transmissibility and severity of disease in the host (HHS lead: CDC; Target Date: December 2012);
- Expand surveillance for antiviral susceptibility (HHS lead: CDC; Target Date: December 2012);
- Enhance modeling capability and collaboration in order to determine burden of disease and effect of interventions (HHS lead: CDC and NIH; Target Date: December 2012);
- Develop a process to characterize animal influenza viruses with pandemic potential to assess the risk of emergence as a human pathogen and potential severity (HHS lead: CDC and NIH; Target Date: December 2012);
- Update systems for virologic surveillance to cost-efficiently collect representative specimens for use in vaccine virus candidate selection, antiviral resistance monitoring, and seasonal influenza surveillance (HHS lead: CDC; Target Date: January 2013);
- Ensure implementation of laboratory reference diagnostics for influenza at public health laboratories and refine the methods by which specimens are tested for surveillance purposes (HHS lead: CDC; Target Date: February 2013);
- Improve the timeliness and accuracy of laboratory assays for measuring influenza immunity to enable ongoing assessment of serologic evidence of infection during a pandemic (HHS lead: CDC, NIH, and ASPR/BARDA; Target Date: March 2013); and
- Expand and automate syndromic and clinical surveillance (e.g., improving the use of electronic health records) (HHS lead: CDC and ONC; Target Date: May 2013).

Chapter 3: Community Mitigation Measures

- Build the evidence base for recommending mitigation measures through research and evaluation. Validate measures through stakeholder and community input in order to develop a strong scientific basis for recommending these measures during a future pandemic (HHS lead: CDC; Target Date for non-pharmaceutical intervention (NPI) 5-yr research agenda development: December 2012; building evidence base: ongoing);
- Develop evidence-based models to enhance understanding of the benefits and societal costs of social distancing measures, and incorporate results into future planning efforts (HHS lead: CDC; Target Date for development of an evidence-based model to explore 5 pre-

pandemic planning scenarios: December 2012; development of evidence-based mathematical models will continue beyond 2012);

- Refine the decision-making process for the recommendation and implementation of NPIs and meet with stakeholders to review response options for a set of basic pandemic severity scenarios (HHS lead: CDC; Target Date: December 2012);
- Develop updated recommendations and guidance for the use of NPIs during a pandemic that incorporate the latest scientific findings, including transmissibility of the virus, as well as updated severity measures, availability of pharmaceutical interventions, and the practicality of implementation by states, locals, employers, and providers (HHS lead: CDC; Target Date for internal CDC review of updated guidance document: December 2012; final version to be completed by end of 2013, depending on the interagency clearance process);
- Develop strategies to effectively communicate the severity of the pandemic and the rationale for implementing certain NPIs (HHS lead: CDC; Target Date for formative research: December 2012; development of communication materials by end of 2013); and
- Develop and implement systems for monitoring the effect of a pandemic on schools and places of employment (HHS lead: CDC; Target Date: December 2015).

Chapter 4: Medical Surge Capacity

- Promote the development of healthcare coalitions and other collaborative regional planning entities at the sub-state/regional levels, and integrated medical care surge plans within these coalitions that would be appropriate in a pandemic (HHS lead: ASPR/OPEO; Target Date: July 2012);
- Develop goals and measures that assess the capability to deliver medical care in response to a public health emergency or disaster, at the level of the healthcare coalitions (HHS lead: ASPR/OPEO; Target Date: September 2012);
- Explore the acceptability and feasibility of developing nurse phone triage lines that can be used during a pandemic to provide an alternative to face-to-face provider encounters (HHS lead: CDC; Target Date: October 2012);
- Support the use of structured training, exercises, and improvement plans to maximize the healthcare coalition's preparedness efforts (HHS lead: ASPR/OPEO; Target Date: November 2012);
- Develop and implement strategies to recruit volunteer health professionals and integrate volunteers into public health emergency responses, including an influenza pandemic (HHS lead: ASPR/OPEO; Target Date: November 2012);
- Support the development of state and local-level crisis standards of care protocols, toolkits, and resources (HHS lead: ASPR/OPEO; Target Date: November 2012);
- Develop a framework and process for decision making regarding allocation of scarce federal public health and medical resources when the demand exceeds available resources (HHS lead: ASPR/OPEO; Target Date: December 2012); and
- Develop a system that can provide information about the stress on the healthcare system, and increase visibility on the availability of community healthcare resources (HHS lead: ASPR/OPEO; Target Date: March 2013).

Chapter 5: Medical Countermeasures (MCMs) for Influenza other than Vaccines

Emergency Use Authorization and Regulatory Issues

- Develop a USG-wide plan to distribute MCMs for pandemic influenza (HHS lead: CDC; Target Date: June 2013);
- Develop systems to monitor safety, effectiveness, and shortages of MCMs during a pandemic (HHS lead: CDC, FDA, and ASPR/BARDA; Target Date: November 2012);
- Develop a plan to prevent/reduce the number of fraudulent products during a pandemic (HHS lead: FDA; Target Date: November 2012);
- Provide pre-EUAs for investigational products to the FDA for review prior to and during an influenza pandemic or other event (HHS lead: ASPR/BARDA and CDC; Target Date: December 2012); and
- Establish internal procedures to ensure that research data and/or expanded access protocols for candidate products under investigational applications (IND, IDE) have been submitted and reviewed by FDA prior to an event that can quickly be activated during an influenza pandemic or other event (HHS lead: ASPR/BARDA, NIH/NIAID, and CDC; Target Date: December 2012).

Antiviral Drugs

- Review and evaluate potential benefits and disadvantages of different antiviral use strategies and reassess the quantity and composition of antiviral medications that should be stockpiled by various levels of government and other partners, taking fiscal constraints and manufacturing capacity into account (HHS lead: ASPR/BARDA and CDC; Target Date: November 2012);
- Develop new plans for antiviral distribution and dispensing (HHS lead: CDC; Target Date: December 2012); and
- Complete at least Phase 2 development on one existing and one new class of antiviral drugs, combination therapies, or pediatric antiviral dosage form for EUA (HHS lead: NIH and ASPR/BARDA; Target Date: December 2014).

Ventilators

- Reassess the quantity and composition of ventilators that should be stockpiled by various levels of government and other partners for pandemic influenza and other threats, taking fiscal constraints into account (HHS lead: ASPR/OPP and CDC; Target Date: November 2012);
- Identify opportunities to promote ventilator standardization and interchangeable components (HHS lead: ASPR/OPP; Target Date: June 2012);
- Reassess strategies for distributing ventilators in the SNS to the states, to help ensure federal assets will be used equitably across the U.S. (HHS lead: ASPR/OPP and CDC; Target Date: July 2012); and
- Invest in the development of innovative ventilator equipment with standardized interchangeable components that are lower cost, easier to use, and flexible for a variety of populations, conditions, and settings (HHS lead: ASPR/BARDA; Target Date: December 2012).

Respiratory Protective Devices (RPDs)

- Determine whether the stockpiling of respirators in the SNS should be continued and if so, develop requirements for stockpiling, taking into account national need, including domestic manufacturing surge capabilities and sourcing of raw materials, and a system

for allocation and distribution (HHS Lead: CDC/SNS, ASPR/OPP, and ASPR/BARDA; Target Date: December 2012);

- Encourage RPD manufacturers to pursue both NIOSH certification and FDA clearance to ensure an ample supply of FDA-cleared N95 respirators are available for use in healthcare settings during a pandemic: HHS lead: CDC (including NIOSH), ASPR/BARDA, and FDA; Target Date: July 2012);
- Develop systems to monitor safety, effectiveness, and shortages of RPDs after deployment (HHS lead: CDC (including NIOSH) and FDA; Target Date: July 2012);
- Conduct research to better understand influenza transmission, to clarify when surgical masks are sufficient, and when the use of N95 respirators or other devices may be more appropriate (HHS lead: CDC (including NIOSH), ASPR/BARDA, and FDA; Target Date: December 2012);
- Innovate and strengthen RPD design, use, testing, and certification for both occupational and community settings for a wide population, including the pediatric population (HHS lead: CDC (including NIOSH); ASPR/BARDA, and FDA; Target Date: December 2012); and
- Develop and/or revise relevant RPD use/reuse guidance and policies (HHS lead: CDC (including NIOSH) and FDA; Target Date: January 2013).

Antimicrobial Agents for Treatment of Pandemic Influenza-Associated Secondary Bacterial Infections

- Support basic and translational research and advanced development of broad spectrum antimicrobial agents and bacterial vaccines to mitigate secondary bacterial infections (HHS lead: NIH and ASPR/BARDA; Target Date: July 2012);
- Encourage the use of pneumococcal vaccines in populations for whom its recommended, and take advantage of seasonal influenza vaccination as a time to administer them (HHS lead: CDC and OASH; Target Date: September 2012);
- Develop a plan to use antibiotics in the SNS against secondary bacterial infections associated with pandemic influenza (HHS lead: CDC; Target Date: September 2012); and
- Determine whether the federal stockpiling of IV antibiotics for bacterial infections secondary to influenza should be continued, and if so, develop requirements for stockpiling (HHS lead: ASPR/ OPP and CDC; Target Date: September 2012).

Chapter 6: Vaccine Manufacturing, Distribution, and Post-Distribution

- Develop a process to provide transparent and realistic vaccine output range projections, in conjunction with vaccine manufacturers, for federal officials, state and local vaccine planners, and the public (HHS lead: ASPR/BARDA and CDC; Target Date: June 2012);
- Encourage influenza vaccine manufacturers interested in developing pandemic vaccines to study pandemic vaccine candidates in children to determine safety and immunogenicity. (HHS lead: ASPR/BARDA and FDA; Target Date: Dec 2013);
- Refine policies and plans related to pre-pandemic vaccine distribution modalities (pre-pandemic vaccine allocation guidance, utilization strategies, stockpiling goals, and communications plans) (HHS lead: ASPR/BARDA, FDA and CDC; Target Date: October 2013);

- Review and refine as necessary the pandemic vaccine prioritization strategy and implementation plans, including communications plans (HHS lead: ASPR/OPP, OASH and CDC; Target Date: October 2013);
- Increase partner participation in planning for the administration of vaccine, including government health officials, community planners, providers, schools, employers, pharmacists, and distributors (HHS lead: CDC; Target Date: October 2012);
- Refine ancillary supply and distribution strategies, including exploring options for new and efficient dose delivery systems (HHS lead: ASPR/BARDA; Target Date: October 2012);
- Implement the recommendations of the President's Council of Advisors on Science and Technology influenza vaccinology report and the HHS Public Health Emergency Medical Countermeasure Enterprise Review to develop improved influenza vaccines and manufacturing technologies that shorten the timeframe for first and last dose availability (HHS lead: ASPR/BARDA, NIH, CDC, and FDA; Target Date: September 2013).¹
- Improve methods for preparing and calibrating reagents for vaccine potency testing (HHS Lead: FDA; Target Date: December 2013);
- Refine and expand the use of immunization information systems among all providers, including non-traditional providers. (HHS lead: CDC; Target Date: January 2013);
- Increase the percentage of persons receiving annual influenza vaccinations, and develop guidance to be used when limited vaccine availability requires targeted vaccination of persons with high-risk conditions (HHS lead: CDC; Target Date: March 2013);
- Evaluate approaches and develop recommendations for using adjuvanted vaccines to enhance current and future vaccination campaigns (HHS lead: ASPR/BARDA , FDA, and CDC ; Target Date: June 2013);
- Develop a state-of-the-art fast, flexible and adaptive vaccine tracking system suited for pandemic and other vaccine-preventable emergencies, capable of providing real-time information on vaccine location across the entire vaccine spectrum from dose availability at the manufacturers to administration, with near term priorities focused on allocation adjustment, dose requesting, and distribution tracking. (HHS lead: CDC, FDA, and ASPR/BARDA; Target Date: June 2015); and
- Enhance and facilitate use of post-market vaccine safety monitoring systems, conduct influenza vaccine safety studies in vulnerable/special populations (e.g., pregnant women), and explore opportunities to improve awareness of vaccine adverse events and reporting by clinicians and other vaccine providers (HHS lead: OASH, CDC, FDA, ASPR/BARDA, and NIH; Target Date: January 2014).

Chapter 7: Communications

- Develop an approach, definitions, tools, and models for a risk communications response plan (HHS lead: ASPA, ASPR, SAMHSA, and CDC; Target Date: March 2013);

¹ A detailed listing of the recommendations from these reports can be found here: President's Council of Advisors on Science and Technology. (August 2010)., Report to the President on Reengineering the Influenza Vaccine Production Enterprise to Meet the Challenges of Pandemic Influenza. August 2010. Available online at: <http://www.whitehouse.gov/sites/default/files/microsites/ostp/PCAST-Influenza-Vaccinology-Report.pdf> Last accessed. September 2010; and HHS. (August 2010). The Public Health Emergency Medical Countermeasures Enterprise Review. August 2010. Available online at: <https://www.medicalcountermeasures.gov/documents/MCMReviewFinalcover-508.pdf> Last accessed.. August 2010.

- Develop mechanisms to further integrate social media and other communication tools into preparedness activities (HHS lead: ASPA and CDC; Target Date: August 2012);
- Continue to ensure internal operation plans for pandemic influenza communication are updated, exercised, evaluated, and improved for effective communication strategies (HHS lead: CDC and ASPR; Target Date: September 2012);
- Work with international partners to share communications strategies and harmonize communication messages (HHS lead: ASPA and ASPR; Target Date: October 2012);
- Improve sharing public health emergency messages and translated and culturally appropriate materials with non-English speaking communities across the U.S. (HHS lead: ASPA, CDC, and CFBNP; Target Date: November 2012);
- Refine and implement partnership strategies to improve communications with hard-to-reach/at-risk populations, including identification of key community spokespersons prior to a pandemic (HHS lead: ASPA, SAMHSA, and CDC; Target Date: November 2012);
- Develop procedures that ensure the timely development and dissemination of culturally appropriate public education materials in plain language, which define and clarify roles and responsibilities across HHS (HHS lead: ASPA; Target Date: November 2012);
- Develop plans to ensure the availability of adequate communications staff to handle rapidly changing information during a pandemic and to provide both consistent and accurate public health information (HHS lead: CDC, ASPR and ASPA; Target Date: November 2012);
- Increase capacity for developing plain language and easily understood materials for public audiences (HHS lead: ASPA and CDC; Target Date: December 2012);
- Develop procedures to ensure that information is provided in accessible and alternative formats in future pandemics (HHS lead: ASPA and CDC; Target Date: December 2012);
- Strengthen and maintain existing relationships and communications with governmental and non-governmental agencies, as well as the media and other trusted entities (HHS lead: ASPA, CDC, and IEA; Target Date: December 2012); and
- In support of the U.S. government MOU with WHO, support capacity building for the Risk Communications Core Capacity under the International Health Regulations (HHS lead: ASPA and CDC; Target Date: December 2012).

Chapter 8: Cross-Cutting Preparedness Issues

- Identify tactics for advanced preparation that will allow all levels of government and the academic and private sectors to quickly mobilize scientific resources during any emergency (HHS lead: ASPR; Target Date: April 2013);
- Develop and implement recommendations to expedite the use and distribution of federal funds during any emergency (HHS lead: ASFR and ASPR; Target Date: August 2012);
- Develop, and refine as necessary, a mechanism and accompanying standard operating procedure for collaboration during an emergency for HHS leadership to identify and resolve policy issues and to ensure coordination, integration, and follow up of policy, budget, legislative, and external communication strategies (HHS lead: ASPR; Target Date: July 2012);
- Identify and develop a plan to address any legal barriers to effective federal public health preparedness and response (HHS lead: ASPR; Target Date: March 2013);

- Develop mechanisms to quickly surge federal, state, and local staffing levels during any emergency and provide respite opportunities to staff (HHS lead: ASPR, CDC, and FDA; Target Date: June 2013); and
- Promote budget, financial, legal, and other administrative preparedness concepts at the state and local government levels to include identifying barriers and challenges to hiring; contracting and the procurement of necessary resources; and identifying and/or putting in place statutory authorities that can be used during an emergency to implement response activities using available funding (HHS lead: ASPR and CDC; Target Date: October 2012).

Chapter 9: International Partnerships and Capacity-Building Activities

- Develop strategies to guide the provision and/or receipt of international assistance in order to limit or reduce the negative public health and social impact of an influenza pandemic (HHS lead: ASPR and OGA; Target Date: September 2013);
- Work with international partners to identify and address logistical, regulatory, and legal barriers to the international sharing of medical countermeasures (HHS lead: ASPR; Target Date: September 2013);
- Develop strategy/plan and begin implementation to strengthen strategic partnerships focused around the implementation of all eight core public health capacities highlighted in the International Health Regulations (2005) (HHS lead: OGA, ASPR, and CDC; Target Date: October 2013);
- Develop strategy/plan and begin implementation to support partner country systems to identify and share seasonal influenza virus types, subtypes, and information with the global health community (HHS lead: CDC; Target Date: November 2013);
- Develop strategy/plan and begin implementation to assist partner countries to develop new or enhance existing response capabilities to monitor safety, effectiveness and shortages of MCMs and routinely exercise a multi-sectoral response (HHS lead: ASPR, CDC, OGA, FDA, and NIH; Target Date: November 2013);
- Determine approaches to better support the WHO and WHO Regional Offices in their efforts to prepare for and respond to an influenza pandemic (HHS lead: ASPR, CDC, OGA, FDA, and NIH; Target Date: December 2013);
- Develop strategy/plan and begin implementation to work with international partners to foster development of public health surge capacity in support of pandemic response (HHS lead: CDC; Target Date: December 2013);
- Work with partner countries to enhance their human resource capacity and work toward the establishment of comprehensive national workforce plans (HHS lead: CDC; Target Date: December 2013);
- Develop strategy/plan and begin implementation to collaborate with partner countries in developing or enhancing nationally-supported surveillance systems capable of identifying and responding to an outbreak of influenza caused by a novel virus with pandemic potential (HHS lead: OGA and CDC; Target Date: December 2013);
- Develop sustainable approaches to ensure international access to pandemic influenza vaccine, including collaboration with WHO and other international partners on development of the new Global Action Plan for Influenza Vaccines (GAP II) (HHS lead: OGA, FDA, and ASPR; Target Date: January 2014).

CHAPTER 1: INTRODUCTION

Influenza (flu) viruses cause respiratory illness and are contagious. They spread relatively easily from person-to-person and can cause mild to severe illness, which in some cases may lead to death. In temperate climates, most influenza infections occur during colder months—from approximately October to May in the United States. Flu seasons are unpredictable both in duration and severity. Often, many flu virus subtypes circulate at once and the subtypes dominating circulation in a given season often change. Over a period of 30 years—between 1976 and 2006—estimates of annual flu-associated deaths in the U.S. ranged from a low of 3,000 to a high of 49,000 people.² Influenza viruses are notable for their rapid rate of mutation, allowing them to evade existing immunity. This is a key driver of the need for seasonal vaccination.

A pandemic is a worldwide epidemic of disease. Influenza pandemics occur when an influenza virus mutates or when multiple virus strains combine, or reassort, in such a way that people have little or no immunity to it. The virus becomes easily transmitted between people, causing large disease outbreaks worldwide. Four influenza pandemics occurred in the past hundred years (1918, 1957, 1968, and 2009). Influenza viruses, especially highly pathogenic influenza strains like H5N1, remain a very urgent global infectious disease threat. Between 2003 and November 2011, the World Health Organization (WHO) confirmed 570 human cases of H5N1 infection, and almost 60 percent of those infections have been fatal.³

A severe influenza pandemic can affect society well beyond just the health and medical sectors. Potentially high rates of illness (25 - 30 percent of the U.S. population) and death could affect critical infrastructure, private-sector activities, educational institutions, and the movement of goods and services across the nation and the globe—resulting in significant economic and security consequences. Workplace absences due to high rates of illness and death among not only those who are sick, but also among caretakers of the ill, could have a significant impact on employers and the economy. The Congressional Budget Office has estimated that the immediate disruptions from a severe pandemic could cause a 4.25 percent reduction in the nation's Gross Domestic Product (GDP). Likewise, a mild pandemic could also slow economic growth and impact approximately one percent of GDP.⁴

In response to this emerging threat, the White House published the 2005 *National Strategy for Pandemic Influenza* (NSPI),⁵ which was immediately followed by the release of the *HHS*

² Thompson MG, Shay DK, Zhou H, Bridges CB, Cheng PY, Burns E, Bresee JS, Cox NJ. (2010). et al. Updated Estimates of Mortality Associated with Seasonal Influenza through the 2006-2007 Influenza Season. *MMWR*, 2010; 59(33): 1057-1062.

³ World Health Organization. (November 15, 2011).³ Cumulative Number of Confirmed Human Cases of Avian Influenza A/ (H5N1) Reported to WHO, 2003-: 15 November 2011. Available online at: http://www.who.int/influenza/human_animal_interface/EN_GIP_20111115CumulativeNumberH5N1cases.pdf Last accessed. November 25, 2011.

⁴ Congressional Budget Office. (December 8, 2005; Revised July 27, 2006).⁴ A Potential Influenza Pandemic: Possible Macroeconomic Effects and Policy Issues. The Congress of the United States: Congressional Budget Office. December 8, 2005; Revised July 27, 2006. Available online at: <http://www.cbo.gov/ftpdocs/69xx/doc6946/12-08-BirdFlu.pdf> . <http://www.cbo.gov/sites/default/files/cbofiles/ftpdocs/69xx/doc6946/12-08-birdflu.pdf> Accessed August 31 Last accessed August 31, 2011.

⁵ White House Homeland Security Council. (November 2005). National Strategy for Pandemic Influenza. Available online at: <http://www.flu.gov/professional/federal/pandemic-influenza.pdf> Last accessed. December 9, 2011.

Pandemic Influenza Plan.⁶ In 2006, the *National Strategy for Pandemic Influenza: Implementation Plan*⁷ further guided efforts focused on planning for a severe pandemic at federal, state, local, private, non-profit, community, and individual/family levels. Activities undertaken in support of these national pandemic plans focused around on the following three goals: (1) stopping, slowing or otherwise limiting the spread of disease; (2) limiting the domestic spread of a pandemic, and mitigating disease, suffering, and death; and (3) sustaining infrastructure and mitigating impact to the economy and the functioning of society.

In April 2009, a novel influenza A virus—a reassortant of avian, swine, and human influenza viruses—was detected during a clinical trial evaluating an HHS-supported influenza diagnostic test in the U.S. This novel 2009 H1N1 influenza virus was subsequently found to be the same one causing an expanding outbreak of late-season respiratory illness in Mexico. Although this virus was likely new to humans, it is now suspected to have been circulating in swine for some time.

On April 25, 2009, based on all available information and on the advice of an international panel of experts, the Director-General of the WHO declared the 2009 H1N1 influenza outbreak to be the first public health emergency of international concern under the International Health Regulations (2005) (IHR). With the continued geographic spread of the virus in susceptible populations around the world, WHO declared a global pandemic on June 11, 2009, making 2009 H1N1 the first influenza pandemic in over 40 years. Unlike seasonal influenza viruses, the 2009 H1N1 influenza virus continued to circulate throughout the summer months in the Northern Hemisphere, and caused a second larger wave of disease the following fall. In the end, the epidemic within the U.S. lasted for over a year.

While most 2009 H1N1 infections were mild, an increased incidence of severe cases resulting in death were observed particularly in individuals under the age of 65, including in pregnant women, young children, and among those with certain predisposing conditions, including but not limited to asthma, obesity, and diabetes.⁸ During the peak of the second wave of disease in the fall of 2009, there was widespread influenza activity in 48 states⁹—very unusual so early in the season for the Northern Hemisphere. Visits to healthcare providers for influenza-like illness as well as influenza-related hospitalizations and deaths among children and young adults were also significantly higher than typically seen with seasonal influenza virus infections.

Due to previous pandemic planning efforts, the United States was more prepared to detect and respond to the 2009 H1N1 pandemic than it otherwise might have been. This pandemic occurred

⁶⁶ HHS Pandemic Influenza Plan. U.S. Department of Health and Human Services. (November 2005). HHS Pandemic Influenza Plan.. Available online at: <http://www.hhs.gov/pandemicflu/plan/> Last accessed: <http://www.hhs.gov/pandemicflu/plan/>. Accessed December 16, 2011.

⁷ White House Homeland Security Council. (May 2006).⁷ National Strategy for Pandemic Influenza: Implementation Plan: White House Homeland Security Council. May 2006. Available online at: <http://www.flu.gov/professional/federal/pandemic-influenza-implementation.pdf> Last accessed. December 9, 2011.

⁸ This was different from seasonal influenza, in which ninety percent of flu-related deaths, and more than half of flu-related complications occur in people age 65 and older. Flu.gov. Seniors. Available online at: (<http://www.flu.gov/individualfamily/seniors/index.html> Last accessed. December 2011).

⁹ The Oct 31, 2009 weekly influenza report showed widespread activity in 48 states, and regional activity in MS and HI. Note that this report reflects geographic spread of flu within each state and does not reflect severity. CDC. FluView: 2009-2010 Influenza Season Week 43 ending October 31, 2009. Available online at: <http://www.cdc.gov/flu/weekly/weeklyarchives2009-2010/weekly43.htm> Last accessed. August 31, 2011.

against a backdrop of ongoing pandemic planning, including efforts on the part of the United States and the international community as a whole to develop, refine, and regularly exercise pandemic plans at international, national, state, and local levels, along with private and non-profit sector partners. While the imminent threat of the 2009 H1N1 influenza pandemic has subsided, the risk of another pandemic from the H5N1 or another strain of influenza virus has not diminished. The H5N1 virus is still endemic in wild birds in many parts of the world and continues to infect people sporadically, often with deadly results. Since pandemics arise infrequently, and the date, location, and strain of the next pandemic cannot be anticipated, it is critical to avoid complacency. Pandemic influenza preparedness activities must continue given that no one can prevent the next pandemic from emerging.

Prior to 2009 H1N1, pandemic influenza planning and planning for other hazards progressed on separate, though related, parallel tracks. However, the 2009 H1N1 experience confirmed the value of all-hazards, national-level preparedness planning. Several recent reports also highlighted this need, including:

- HHS' *National Health Security Strategy of The United States of America* (NHSS), published in December 2009;¹⁰
- HHS' Office of the Assistant Secretary for Preparedness and Response's (ASPR's) *The Public Health Emergency Medical Countermeasure Enterprise Review: Transforming the Enterprise to Meet Long-Range National Needs* released in August 2010;¹¹
- President's Council of Advisors on Science and Technology's *Report to the President on Reengineering the Influenza Vaccine Production Enterprise to Meet the Challenges of Pandemic Influenza*, published in August 2010,¹²
- *Presidential Policy Directive/PPD-8: National Preparedness*, released in March 2011;¹³ and
- *An HHS Retrospective on the 2009 H1N1 Influenza Pandemic to Advance All Hazards Preparedness* (2009 H1N1 Retrospective), published in March 2012.

Furthermore, the 2009 H1N1 experience also confirmed that certain aspects of prior plans and strategies need to be refined and updated. Taking that into account, the intent of this document is to communicate HHS' priorities for modifying and updating the prior 2005 *HHS Pandemic Influenza Plan*, informed by lessons learned from the 2009 H1N1 experience, which are highlighted in the 2009 H1N1 Retrospective.

Effective and efficient pandemic planning can be accomplished by both building on seasonal influenza activities each year (e.g., surveillance, vaccination, medical, healthcare, response, and communications) and integrating pandemic influenza planning into all-hazards planning efforts. Comprehensive pandemic planning also contributes to broader disease detection and response activities for other public health threats. As such, the *HHS 2009 H1N1 Influenza Improvement Plan* is a refined blueprint that outlines strategic priorities for pandemic influenza preparedness and describes the ways in which those next steps need to be accomplished.

¹⁰ Available online at: <http://www.phe.gov/Preparedness/planning/authority/nhss/strategy/Documents/nhss-final.pdf> Last accessed. December 16, 2011.

¹¹ Available online at: <https://www.medicalcountermeasures.gov/media/1138/mcmreviewfinalcover-508.pdf> Last accessed. December 16, 2011.

¹² Available online at: <http://www.whitehouse.gov/sites/default/files/microsites/ostp/PCAST-Influenza-Vaccinology-Report.pdf> Last accessed. December 16, 2011.

¹³ Available online at: http://www.dhs.gov/xabout/laws/gc_1215444247124.shtm Last accessed. December 16, 2011.

It should also serve to inform ongoing planning efforts of state, local, tribal, and territorial agencies, international partners, as well as non-profit, private sector, and other emergency planners. Another important partner is the American public, since an informed and responsive public is essential to minimizing the health effects of a pandemic and its potential consequences to society. This plan articulates the most relevant strategic priorities necessary to help ensure a successful, coordinated response to the next, possibly more severe, influenza pandemic or other event, especially one caused by another highly transmissible infectious disease.

Each of the following chapters is organized into three main sections: (1) Introduction; (2) Lessons Learned and Future Actions; and (3) Summary of Key Priorities. Most chapters follow this basic format to provide an introduction of prior planning efforts and a discussion of gaps identified during the 2009 H1N1 response, but may have additional sub-headers. Each key priority lists the lead HHS agency-or co-leads, however, much of this work will be conducted collaboratively across the department. Each priority also has a target date by which HHS aims to have completed each task or satisfy a major component of a task. These dates do not negate the long-term, iterative process of preparedness planning, and progress on these tasks is contingent upon the availability of funding and other resources.

The chapters that follow are:

- Detection and Characterization of a Future Influenza Pandemic
- Community Mitigation Measures
- Medical Surge Capacity
- Medical Countermeasures (MCMs) for Influenza other than Vaccines
- Vaccine Manufacturing, Distribution, and Post-Distribution
- Communications
- Cross-Cutting Preparedness Issues
- International Partnerships and Capacity-Building Activities

CHAPTER 2: DETECTION AND CHARACTERIZATION OF A FUTURE INFLUENZA PANDEMIC

Introduction

Every year, the U.S. conducts influenza surveillance using a variety of systems that provide data on novel virus case reports, virus characteristics, outpatient illnesses, emergency department visits, hospitalizations, and deaths. Preparedness investments and innovations in diagnostic test development, laboratory testing, and influenza surveillance over the past several years greatly facilitated early detection and ongoing surveillance during the 2009 H1N1 pandemic. The systems and tools that were in place provided local and national situational awareness about the spread of the 2009 H1N1 virus, and that information guided decision making related to the pandemic response.

Lessons Learned and Future Actions

Although the surveillance and laboratory components of the response were largely successful, the 2009 H1N1 Retrospective highlighted several opportunities for improvement in the nation's ongoing preparedness efforts, including:

- Using available surveillance systems and data to develop a national-level picture that assesses the severity of the pandemic and the transmission of the virus to inform response actions;
- Developing efficient communication and distribution mechanisms for available surveillance data;
- Improving point-of-care influenza diagnostic tests for clinical decision making;
- Ensuring more rapid access to reference diagnostic tools for influenza in public health laboratories; and
- Enhancing modeling efforts to address emerging policy questions.

These issues and several other improvements related to surveillance and laboratory capabilities are discussed below, and serve as the foundation for the key priorities related to the detection and monitoring of an influenza virus during a pandemic.

In order to maintain our surveillance and laboratory capabilities for seasonal and pandemic influenza, the U.S. must continue to both sustain and enhance tools that are now in place for detecting and characterizing influenza viruses. Virologic surveillance had improved substantially across state public health laboratories prior to the start of the 2009 H1N1 pandemic through the use of new molecular assays including real-time reverse-transcription polymerase chain reaction tests (RT-PCR). These new technologies allowed for the specific virus characterization of clinical specimens. Although there are robust systems currently in place to detect influenza, many of them require ongoing personnel support and continuing technical development to take advantage of the latest technologies and efficiencies which will provide decision makers with optimal situational awareness. To facilitate the availability and use of these laboratory diagnostic tools during a response, our preparedness activities must also consider the associated regulatory and export issues related to the use and distribution of those tools.

At the beginning of an emerging pandemic, the most vital information about the virus comes from the laboratory analysis of clinical specimens. Clinicians must recognize the importance of testing for influenza and they must have more rapid access to accurate tests for influenza A and B to inform treatment decisions. At the same time, influenza reference diagnostic tools must be readily available at public health laboratories to analyze unsubtypeable samples, and those diagnostics must be linked to a standard method for deciding which specimens are tested for surveillance purposes. Federal, state, and local public health laboratories also need to be able to assist hospitals and commercial laboratories to confirm diagnostic tests and ensure accurate and rapid identification of cases. Subsequently, at CDC and similar high complexity laboratories evaluating the emerging influenza virus, the comparative analyses of laboratory data need to be performed more rapidly and effectively by using expert systems and higher performance computers that are available for enhancing bioinformatics. Improving the accuracy of point-of-care diagnostics and facilitating rapid access to reference diagnostic tools for emerging influenza A subtypes will ultimately help to shorten the time needed to recognize novel influenza cases.

The less certain HHS and state and local public health agencies are about the shape of an evolving pandemic, the less precise we may be in our management of the pandemic overall. To assist decision makers with the implementation of appropriate interventions during a pandemic, it is important to maintain several capabilities. We were able to gain some insight into transmission characteristics and assess the clinical severity of the pandemic through multiple approaches, including animal studies, field investigations, surveillance, and forecast modeling, although room for improvement remains. In addition, we must have the laboratory capacity to detect changes in the virus that affect transmissibility and severity and measure the overall immunity to influenza subtypes. Also, to ensure that treatment with antiviral drugs is appropriate, we must also have the capability to detect antiviral resistance among circulating viruses.

Although communication of surveillance information across federal government agencies and the public was very comprehensive during the 2009 H1N1 pandemic, there were challenges with timeliness and wide distribution due to the sheer volume of information. In light of reductions within state and local health departments, it is especially important to simplify, streamline, and standardize the collection and sharing of data. More automated provision of information and messaging standards could help harmonize the reporting process. As the nation moves towards fuller implementation of electronic medical records, close examination of electronic health record systems may yield opportunities to improve surveillance and add robustness to local and national level data. However, while these innovations could become very important ways to monitor syndromic respiratory disease, it is also important to recognize that new information technologies cannot act as a substitute for the traditional work conducted by epidemiologists and laboratorians in public health departments throughout the U.S.

During the 2009 H1N1 pandemic, HHS developed a model to provide an estimated range of the total and age-related number of cases, hospitalizations, and deaths in the U.S. after April 2009.¹⁴ These estimates were updated to become more accurate as new information became available throughout the pandemic and allowed public health leaders to adjust operational and policy

¹⁴ CDC. (May 14, 2010).¹⁴ Updated CDC Estimates of 2009 H1N1 Influenza Cases, Hospitalizations, and Deaths in the United States, April 9, 2009 – April 10, 2010. Available online at: http://www.cdc.gov/h1n1flu/estimates_2009_h1n1.htm Last accessed. August 2011: http://www.cdc.gov/h1n1flu/estimates_2009_h1n1.htm.

decisions accordingly during the response. Future modeling efforts need to be enhanced and better integrated with surveillance and response efforts to more thoroughly support response actions when actual data are limited or unavailable. Furthermore, there needs to be closer collaboration among modelers, decision makers, and data collectors in order to produce models better informed by real data. In turn, this would allow specific policy questions to be addressed more directly. The analysis of disease burden from influenza on those populations most severely affected—the vulnerable and medically at-risk—also needs to improve in order to optimize communications and intervention strategies that can be targeted to those populations. In addition, a better understanding of racial/ethnic disparities may improve vaccination coverage and improve health outcomes in these populations.

The key priorities below are intended to provide better situational awareness through systems that are used to inform decision making during a pandemic.

Summary of Key Priorities

- Provide a nimble and accessible way to visualize available data for professional audiences, the general public, and policymakers (HHS lead: CDC; Target Date: November 2012);
- Develop and evaluate more accurate point-of-care tests and provide timely guidance and support to clinicians in using improved diagnostic testing for management and treatment decisions in outpatient settings as well as in-patient facilities (HHS lead: CDC, ASPR/BARDA, and FDA; Target Date: December 2012);
- Develop a more systematic method for assessing and communicating the impact of an emerging pandemic influenza virus through rapid characterization of the virus' transmissibility and severity of disease in the host (HHS lead: CDC; Target Date: December 2012);
- Expand surveillance for antiviral susceptibility (HHS lead: CDC; Target Date: December 2012);
- Enhance modeling capability and collaboration in order to determine burden of disease and effect of interventions (HHS lead: CDC and NIH; Target Date: December 2012);
- Develop a process to characterize animal influenza viruses with pandemic potential to assess the risk of emergence as a human pathogen and potential severity (HHS lead: CDC, NIH; Target Date: December 2012);
- Update systems for virologic surveillance to cost-efficiently collect representative specimens for use in vaccine virus candidate selection, antiviral resistance monitoring, and seasonal influenza surveillance (HHS lead: CDC; Target Date: January 2013);
- Ensure implementation of laboratory reference diagnostics for influenza at public health laboratories and refine the methods by which specimens are tested for surveillance purposes (HHS lead: CDC; Target Date: February 2013);
- Improve the timeliness and accuracy of laboratory assays for measuring influenza immunity to enable ongoing assessment of serologic evidence of infection during a pandemic (HHS lead: CDC, NIH, and ASPR/BARDA; Target Date: March 2013); and
- Expand and automate syndromic and clinical surveillance (e.g., improving the use of electronic health records) (HHS lead: CDC and ONC; Target Date: May 2013).

CHAPTER 3: COMMUNITY MITIGATION MEASURES

Introduction

Community mitigation measures and other non-pharmaceutical interventions (NPIs) are designed to limit the spread of influenza in the community or within certain high-risk populations and settings. These interventions are especially important before a safe and effective vaccine is available, or if the virus is not susceptible to available antiviral drugs. The early use of NPIs that are strategically targeted, layered, and implemented in a coordinated manner across neighboring jurisdictions and tailored to pandemic severity is a critical component of a comprehensive strategy to reduce community disease transmission and mitigate illness and death during a pandemic. Because mitigation strategies call for specific actions by individuals, families, businesses and other employers and organizations, the planning and preparedness for NPI implementation is complex and requires participation by all levels of government and all segments of society.

Certain interventions, including basic recommendations on hygiene, behavioral health, and community mask use, may also be chosen that will help lessen the burden on the healthcare system by decreasing demand for those services—freeing resources to reduce the severe outcomes from disease in high-risk populations. In addition, other NPI options include (1) school and child care facility closures; (2) certain workplace measures; (3) cancelling or postponing mass gatherings; (4) household isolation and quarantine; and (5) travel screening. Pre-pandemic planning guidance for these measures was published in February 2007.¹⁵ Future planning efforts should incorporate evidence-based models to enhance understanding of the benefits and societal costs of social distancing and other NPI measures.

Lessons Learned and Future Actions

Early in the 2009 H1N1 pandemic, neither an accurate assessment of its severity nor reliable data on appropriate triggers were available for implementing community mitigation measures, which created challenges for local communities. The 2009 H1N1 Retrospective highlighted the following opportunities for improvement; these experiences must be considered in revising this planning guidance for NPIs.

- The Pandemic Severity Index (PSI), developed prior to the 2009 H1N1 pandemic, proved to be inadequate to provide meaningful public health triggers for initiation of non-pharmaceutical interventions during the initial stage of response. As a follow-up to this, HHS' Centers for Disease Control and Prevention (CDC) is developing a new Pandemic Severity Impact Assessment Framework. However, because pandemics are often considered during their initial stages to be more severe than they actually are, a severity framework needs to remain flexible enough so that appropriate mitigation measures may be taken at times of uncertain severity.
- Although information on school closures was available, systems to track workplace or school absenteeism due to 2009 H1N1 influenza did not exist. To determine the full impact

¹⁵ Community Strategy for Pandemic Influenza Mitigation. (February 2007). Available online at: <http://www.flu.gov/professional/community/commmitigation.html> Last accessed. September 16, 2011.

of a more severe pandemic, a system to monitor its effect on schools and the workforce is needed.

- Evidence to inform policy decisions related to community mitigation measures is limited, and a stronger evidence base is needed.

Furthermore, school closure guidance caused confusion and was often at odds with local levels of disease. Although guidance was revised based on the limited data available during the pandemic, the experience from 2009 also emphasized the importance of promptly updating recommendations during a response as needed (e.g., if there is a revision of the initial assessment of pandemic severity, or a change in the availability or effectiveness of pharmaceutical interventions). The new severity framework will allow for more appropriate decisions based on of the clinical and population severity that is observed during a pandemic.

As set forth above, one of the goals of the 2005 NSPI is “stopping, slowing or otherwise limiting the spread of disease.” Planning efforts in the six years since the release of that document, combined with the experience from 2009 H1N1, indicate that it is very unlikely that we can stop an emerging pandemic, making effective NPIs even more important.

Based on the 2009 H1N1 experience, it is clear that broad recommendations for certain mitigation measures can be problematic to implement at the community level. In the early stages of future pandemics when disease transmission is not widespread, local communities will likely continue to have different perceptions of pandemic severity. In order to set expectations about the timing and desired impact of the NPI strategies, a consensus on a comprehensive response strategy comprised of non-pharmaceutical (including behavioral health) and pharmaceutical interventions and how and when they should be implemented should be sought among stakeholders prior to the next pandemic for a set of basic pandemic severity scenarios.

Issuance of recommendations need not only take disease severity and transmissibility into account, but also the expected effectiveness of an intervention strategy, the levels of susceptibility in the population, the socio-cultural, behavioral health and resiliency of the community, the overall capacity of the healthcare system, and specific risk groups for severe outcomes. At the time that each intervention is considered, it is also important to consider these strategies in the context of the availability and effectiveness of pharmaceutical interventions such as vaccines, antiviral medications, and other countermeasures. Decision makers must also consider factors related to the feasibility and impact of implementing certain interventions within a given community, including:

- Consequences of inaction in the face of a pandemic;
- Benefits of intervention compared to risks associated with secondary effects and costs of implementation;
- Time needed for implementation;
- Sustainability of interventions over an extended period of time, including coping strategies for families and communities to address secondary effects; and
- Acceptability of intervention to public health officials, political leaders, other stakeholders and the general public.
- Psychological and behavioral considerations

Willingness and ability to abide by some recommendations is likely to vary among individuals. For example, some individuals may not be able or willing to voluntarily exclude themselves from work or school for prolonged periods of time. Many employers' sick and administrative leave policies may not be flexible enough to allow certain workers to remain home when they are sick or when their children's schools have been closed due to an outbreak.

Prior to the next pandemic, there is a need to build both an appropriate decision-making process for developing and adjusting recommendations during a pandemic and effective communication strategies that (1) identify the issues to consider (e.g., legal, ethical, socioeconomic); (2) recommend who should be involved in the discussions; (3) provide strong rationale for implementing NPIs when the circumstances merit their implementation; and (4) recommend use of NPIs as appropriate. Once recommendations are made, communication messages must explain why certain measures may or may not be appropriate in a given situation.

At all levels of government, public health agencies and educational institutions must work closely to avoid sending confusing or conflicting messages. Key stakeholders at all levels of government must be consulted during the process of updating guidance for NPIs. In addition, decision making is highly influenced by psychological and behavioral considerations at individual and community levels. The inclusion of behavioral health and social sciences experts in implementation strategy and risk communication development can promote approaches that encourage people to follow health directives and take recommended protective actions.

Ultimately, future NPI decision making must be nimble, be guided by data-driven situational awareness, include real-world input from state and local stakeholders, be based on the best available scientific expertise, and be informed by behavioral considerations that influence how people make decisions. Because the negative consequences of certain strategies are not yet fully understood, more research and evaluation of mitigation measures are needed so decision makers can adequately assess and plan for the full impact of recommending any of these actions during a pandemic or other infectious disease outbreaks.

Summary of Key Priorities

- Build the evidence base for recommending mitigation measures through research and evaluation. Validate measures through stakeholder and community input in order to develop a strong scientific basis for recommending these measures during a future pandemic (HHS lead: CDC; Target Date: December 2012);
- Develop evidence-based models to enhance understanding of the benefits and societal costs of social distancing measures, and incorporate results into future planning efforts (HHS lead: CDC; Target Date: December 2012);
- Refine the decision-making process for the recommendation and implementation of NPIs and meet with stakeholders to review response options for a set of basic pandemic severity scenarios (HHS lead: CDC; Target Date: December 2012);
- Develop updated recommendations and guidance for the use of NPIs during a pandemic that incorporate the latest scientific findings, including transmissibility of the virus, as well as updated severity measures, availability of pharmaceutical interventions, and the practicality of implementation by states, locals, employers, and providers (HHS lead: CDC; Target Date: December 2012);

- Develop strategies to effectively communicate the severity of the pandemic and the rationale for implementing certain NPIs (HHS lead: CDC; Target Date: December 2012); and
- Develop and implement systems for monitoring the effect of a pandemic on schools and places of employment (HHS lead: CDC; Target Date: December 2015).

CHAPTER 4: MEDICAL SURGE CAPACITY

Introduction

During an influenza pandemic and other public health emergencies, the demand for healthcare and public health resources—facilities, personnel, clinical expertise, equipment, clinical, and non-clinical interventions—can quickly exceed any individual healthcare facility’s ability to surge. Medical surge provides appropriate evaluation and care during events exceeding the limits of ordinary medical infrastructure of an affected community. The concept of medical surge capacity incorporates not only the ability of any one healthcare facility to significantly increase service capacity but also the ability to increase response capacity in an entire community. Individually and collectively, the healthcare system’s ability to effectively and efficiently surge in a scalable fashion is dependent on (1) integration and collaboration of coalitions among healthcare (including behavioral health), public health and emergency management communities, and (2) development of mechanisms to monitor the use and availability of clinical care services and resources, as noted in the 2009 H1N1 Retrospective.

For a number of years, all-hazards medical surge planning efforts have focused on activities such as building interoperable communication systems, improving and exercising preparedness plans, tracking and sharing bed availability, volunteer personnel management, fatality management, medical evacuation plans, and coordinated regional planning. Investments in healthcare system preparedness through the HHS Hospital Preparedness Program (HPP) proved valuable during the H1N1 pandemic and HHS will maintain this momentum into the upcoming grant cycle.

Although the 2009 H1N1 pandemic did not severely stress the entire U.S. healthcare system, some facilities and communities were challenged to meet increased demand providing an opportunity to identify needed improvements to medical surge planning. Many of the improvement opportunities include:

- Expanded coalition building through a community-wide approach and the integration of non-traditional providers into the response framework;
- Establishment of plans to distribute demand for healthcare services throughout the system;
- Guidance for states on crisis standards of care;
- Increased visibility on public health and medical resources available at the community level throughout each system;
- Increased integration of volunteer health professionals; and
- Timely communication of clinical care guidance and appropriate use of diagnostics for healthcare providers.

These improvement opportunities related to medical surge capacity during a pandemic that can also be applied to an all-hazards framework are discussed below.

Lessons Learned and Future Actions

Strengthening Healthcare Coalitions

Efforts are underway to strengthen and promote healthcare coalition development across the nation. The upcoming Hospital Preparedness Program (HPP) grant cycle will expand the concept of healthcare preparedness from the facility level to the community level, through greater emphasis on operational and regional healthcare coalitions across the country. Healthcare organizations and coalitions offer a number of ways to modify service delivery and share resources. Integrating preparedness of all community health (public health, behavioral health, and medical) assets is the best method to address community healthcare preparedness. The healthcare coalition is the building block of community-level infrastructure, given the need for self-sustainment in a pandemic's broad scope and duration. Managed by ASPR, and aligned with the CDC Public Health Emergency Preparedness Program (PHEP), HPP provides leadership and funding through grants and cooperative agreements to states, territories, and eligible municipalities to improve surge capacity and enhance community and hospital preparedness for public health emergencies.

A healthcare coalition is defined as a group of healthcare organizations located in a specific geographical area or community that agree to work together to enhance the efficiency and effectiveness of all of its member organizations' collective preparedness, response, and recovery. Successful implementation of these practices requires integrated and coordinated planning and response that covers the continuum of healthcare, including inpatient facilities (e.g., trauma, long-term care), outpatient facilities (e.g., physician offices, urgent care), and other entities (e.g., emergency medical services, community health centers, nursing facilities, homecare providers, mental health and substance abuse providers, pharmacies, clinical laboratories, and medical and supply equipment vendors). To reduce the burden on emergency departments, non-hospital providers and other non-traditional partners must be better integrated into preparedness efforts.

The healthcare coalition will function as an integrated and coordinated entity across all phases of emergency response. Effective coordination results when all members of the coalition have clearly defined roles and capabilities that can be demonstrated, measured, and continuously improved through exercises and actual events. The HPP and PHEP programs are currently developing a joint FY 2012 Funding Opportunity Announcement which will provide guidance and resources for building and maintaining coalitions. This funding will support effective coalition development through requiring written agreements, as well as promoting training and exercising, and will also better link healthcare and public health. Performance measures are also being developed for healthcare coalitions.

Strategies to Support Surge

Alternate Care Sites

To provide a framework by which responders can manage demand, surge plans may also include use of an alternate care system that allows for the delivery of healthcare services along a spectrum which includes home healthcare, community-based care, and the use of alternate care sites (ACS). To respond effectively when healthcare resources are overwhelmed during a pandemic, state and local public health authorities and community planners must have plans in place for how ACS will operate. During the 2009 H1N1 pandemic, many facilities used alternate care sites for triage and to decompress overwhelmed hospital emergency departments. HHS funds awardees developing and improving their ACS plans and concepts of operation for providing supplemental surge capacity to healthcare entities. ACS plans should include planning

to provide care and allocate equipment, supplies, and personnel at such sites (e.g., in schools, hotels, airport hangars, gymnasiums, stadiums, convention centers). Plans must take into account, command and control, staffing, supply and resupply, safety and security, housekeeping, scope of care to be provided, criteria for admission, and related ethical considerations. One possible approach that needs further exploration is the use of nurse phone triage lines during a pandemic to provide an alternative to face-to-face provider encounters.

Crisis Standards of Care and Allocation of Scarce Resources

Although the medical surge that occurred was not large enough to require implementation of crisis standards of care, the 2009 H1N1 experience highlighted the need for communities to develop vetted plans for providing high quality, safe clinical care in a resource-constrained environment appropriate to state and local circumstances.

Crisis standards of care are defined by a substantial change in usual healthcare operations and the level of care it is possible to deliver, which is made necessary by a pervasive (e.g., pandemic influenza) or catastrophic (e.g., earthquake, hurricane) disaster. According to *The National Health Security Strategy* (NHSS), standards of care are developed based on clinical practice guidelines before an incident and implemented when needed in response to an event. Protocols, public engagement toolkits, and other resources will be developed by the Institute of Medicine (IOM) in collaboration with HHS to help guide state and local level establishment and implementation of crisis standards of care. These resources will be made widely available in 2012 to support healthcare system wide planning. Additionally, HHS envisions a framework and process for decision making regarding allocation of scarce federal public health and medical resources during catastrophic events when the demand for federal assistance exceeds the available resources—as may occur in a severe pandemic.

Increasing visibility on the healthcare system and available resources

As noted in the 2009 H1N1 Retrospective, there is a need for better national-level monitoring of healthcare system disruption and stress. Stress may be indicated by increased demand for patient care services (e.g., triage, assessment, treatment, admission, and discharge), shortage and difficulty obtaining enough medical supplies, pharmaceuticals, personal protective equipment or adequate ancillary ventilator supplies. Stress may also be indicated through the activation of facility disaster protocol/emergency operations plans and the implementation of surge strategies to meet that demand (e.g., expanding bed capacity within existing spaces, early discharges, cancelling elective surgeries, augmentation of personnel or reduction in staff-to-patient ratios, use of ACS, requesting mutual aid). HHS was able to adapt the national Hospital Available Beds for Emergencies and Disasters (HAvBED) system during the pandemic and these data provided proxy information for hospital system stress, although there were some limitations and reporting challenges with the system. A clearer picture of health system stress at the community level is needed with information being available as near real-time as possible so that resources can be quickly shifted. Efforts are underway to standardize reporting in HAvBED by sub-state or regional level to better understand impacts to bed availability and capacity within a state and territory, and facilitate more timely information and communication among states, territories, and federal entities through annual exercises.

To complement the ecological level perspective provided by HAvBED, HHS collaborated with existing academic acute care clinical investigation research networks to get patient-level and intensive care unit-level information regarding clinical resource requirements and stress. This collaboration successfully yielded one of the largest registries of adult and pediatric patients with serious influenza-associated disease and also provided a snapshot of intensive care unit-level impact in a subset of hospitals. In response to the successes and challenges gleaned from this effort, HHS is now actively working with the United States Critical Illness and Injury Trials Group (USCIITG) to establish infrastructure, processes and tools to collect near-real time patient level data during public health emergencies at participating EMS agencies, Emergency Departments, and Intensive Care Units. These efforts emphasize the use of everyday routine systems (infrastructure and processes) to ensure that information will be immediately functional and useful when needed for situational awareness during an emergency.

The development of a healthcare workforce surge capacity is an essential component of healthcare preparedness. Health professional volunteers were instrumental in mass vaccination efforts in the 2009 H1N1 response. For example, in Rhode Island, volunteers staffed 693 school-based vaccination clinics, administering 155,649 doses of 2009 H1N1 vaccine to school-aged children. Continued development and implementation of strategies for the recruitment and integration of health professional volunteers from volunteer management programs, such as the Emergency System for Advance Registration of Volunteer Health Professionals (ESAR-VHP) and Medical Reserve Corps (MRC), will improve our ability to respond. HHS is moving this effort forward by implementing strategies, tools, and resources to (1) increase the number of volunteer health professionals available to respond, and (2) define processes for integrating volunteers into public health emergency responses. In 2012, HHS will conduct recruitment and outreach campaigns with external stakeholders and partner with state ESAR-VHP programs to leverage their volunteer networks, and a Federal Protocol and Volunteer Playbook will be disseminated including guidance for hiring, deploying, and protecting civilian volunteer health professionals.

Summary of Key Priorities

- Promote the development of healthcare coalitions and other collaborative regional planning entities at the sub-state/regional levels, and integrated medical care surge plans within these coalitions that would be appropriate in a pandemic (HHS lead: ASPR/OPEO; Target Date: July 2012);
- Develop goals and measures that assess the capability to deliver medical care in response to a public health emergency or disaster, at the level of the healthcare coalitions (HHS lead: ASPR/OPEO; Target Date: September 2012);
- Explore the acceptability and feasibility of developing nurse phone triage lines that can be used during a pandemic to provide an alternative to face-to-face provider encounters (HHS lead: CDC; Target Date: October 2012);
- Support the use of structured training, exercises, and improvement plans to maximize the healthcare coalition's preparedness efforts (HHS lead: ASPR/OPEO; Target Date: November 2012);
- Develop and implement strategies to recruit volunteer health professionals and integrate volunteers into public health emergency responses, including an influenza pandemic (HHS lead: ASPR/OPEO; Target Date: November 2012);

- Support the development of state and local-level crisis standards of care protocols, toolkits, and resources (HHS lead: ASPR/OPEO; Target Date: November 2012);
- Develop a framework and process for decision making regarding allocation of scarce federal public health and medical resources when the demand exceeds available resources (HHS lead: ASPR/OPEO; Target Date: December 2012); and
- Develop a system that can provide information about the stress on the healthcare system, and increase visibility on the availability of community healthcare resources (HHS lead: ASPR/OPEO; Target Date: March 2013).

CHAPTER 5: MEDICAL COUNTERMEASURES (MCMs) FOR INFLUENZA OTHER THAN VACCINES

Introduction

Non-vaccine medical countermeasures (MCMs) for influenza are the drugs, diagnostics,¹⁶ and other medical products that may mitigate the adverse medical consequences of a pandemic. MCMs employed for influenza have applicability to other hazards or events. Specific MCMs critical for a pandemic response and discussed in this chapter include antiviral medications, personal protective equipment, such as respiratory protection devices (RPDs), ventilators to treat the severely ill, and antimicrobial drugs for the treatment of secondary bacterial infections. These items are selected because they are most likely to become scarce during a pandemic. Although that scarcity could have devastating consequences, strategies can be implemented now to reduce or mitigate the impact of any future shortages.

Effective MCM planning requires an integrated, end-to-end approach—spanning basic research through advanced development, manufacturing, procuring, stockpiling, storing, distributing, and dispensing, as well as tracking of product safety, effectiveness, and overall impact. This planning includes considerations of implementation limitations, such as legal protections, regulatory challenges, budget constraints and critical vulnerabilities affecting all aspects of the MCM spectrum. Before the 2009 H1N1 pandemic, the plans for the allocation and distribution of some MCMs for pandemic influenza (i.e., antiviral drugs) were more fully developed than the plans for other countermeasures, such as ventilators and RPDs.

Lessons Learned and Future Actions

The Emergency Use Authorization Process and Other Regulatory Issues

Approval, licensure, clearance, or authorization for investigational or emergency use by the Commissioner of the HHS Food and Drug Administration (FDA) is required for pharmaceutical and many non-pharmaceutical MCMs, including medical devices that enter into interstate commerce. Among the regulatory tools available, the FDA Commissioner can issue Emergency Use Authorizations (EUAs) during public health emergencies that permit either the use of unapproved MCMs or the non-approved use of approved MCMs if certain criteria are met. Many countermeasures, including various antiviral drugs, diagnostics, and RPDs, were used under EUA during the 2009 H1N1 response.¹⁷ Product use under EUA does not require the same informed consent documents and procedures that are required for clinical investigations.

Many HHS-supported investigational products have pre-EUA packages submitted to the FDA for review in advance of an influenza pandemic or other public health event. Having these packages already prepared, submitted, and FDA-reviewed in advance saved valuable time during 2009 H1N1. This practice could continue to save time during future public health emergencies as well. Because EUAs are intended to provide access to countermeasure products during emergencies, they are not intended to be mechanisms for the collection of pivotal data on the

¹⁶ Diagnostics are discussed in Chapter 2 (Detection and Characterization of a Future Influenza Pandemic), and briefly in Chapter 4 (Medical Surge Capacity).

¹⁷ Food and Drug Administration. See “Emergency Use Authorization – Archived Information.”: Available online at: <http://www.fda.gov/EmergencyPreparedness/Counterterrorism/ucm264224.htm> Last accessed. August 26, 2011.

safety and efficacy of those products. For example, during the 2009 H1N1 pandemic, approximately 2,100 treatment courses of peramivir, an investigational intravenous antiviral medication, were distributed. Although some data were collected on adverse events and outcomes, there was not a plan in place to gather information on the drug's effectiveness against severe 2009 H1N1 influenza. The EUA mechanism would not serve this purpose and these data would not meet the standards for an adequate and well-controlled study sufficient to support a claim that the product is effective against severe 2009 H1N1 influenza. This highlights the need for solutions to gather pivotal safety and efficacy data on investigational products without impeding drug access, and then rapidly analyzing the collected data and feeding it back to clinicians. Consideration must be given to having research protocols ready so clinical trials or other means of obtaining real-time data can be quickly collected to inform decision making during a public health emergency. Furthermore, coordinated and practical plans to distribute, dispense, and use stockpiled MCMs during a pandemic need to be developed that take the availability and efficacy of all pandemic countermeasures into account, whether they are FDA-approved, or likely to be available under FDA's Investigational Device Exemption (IDE), Investigational New Drug (IND), or EUA mechanisms.

Because FDA approval or clearance of a device or other diagnostic products prior to a pandemic can (1) ensure that it is safe and efficacious for its intended use, and (2) facilitate the issuance of an EUA for unapproved use, HHS's inter-pandemic efforts should include facilitating the FDA review and approval or clearance of devices and other diagnostic products likely to be useful in a pandemic and not yet cleared or approved by FDA. Such inter-pandemic efforts should also consider what steps could be taken to prevent or reduce the number of fraudulent products which may endanger the public, and require regulatory agencies to use resources that could have been used for other tasks.

Antiviral Medications

Approved antiviral medications have been shown to reduce the severity of influenza illness and shorten the time needed for recovery by reducing the duration of fever and symptoms in patients with seasonal influenza infection. Appropriate use of these drugs during an influenza pandemic may reduce morbidity and mortality in those infected and help address the overwhelming demands placed on the healthcare system, especially before a pandemic vaccine is available. However, the extent of antiviral drugs' effect against illness associated with a novel influenza strain may not be known early in a pandemic and plans for data collection to characterize risks and benefits will be important.

The 2005 *HHS Pandemic Influenza Plan* set the goal of ensuring sufficient antiviral medication to treat 25 percent of the U.S. population by establishing a national stockpile of 81 million courses of antiviral drugs. Of those courses, 50 million were to be part of HHS' Strategic National Stockpile (SNS) with the remaining portion procured by states in their stockpiles, which were enabled by federal cost-sharing assistance. Before April 2009, HHS had met its total stockpiling goal with 44 million treatment courses in the SNS, and an additional 6 million regimens set aside for containment purposes. State purchases toward their collective goal of 31 million treatment regimens totaled approximately 23 million regimens at the start of the

pandemic.¹⁸ While the federal government developed guidance on antiviral drug use, it was the responsibility of each state to develop its own plans for allocation and dispensing of stockpiled antiviral drugs to its population. All employers, public and private, were also encouraged to plan and prepare for an influenza pandemic, with some employers (including HHS) establishing their own antiviral stockpiles to protect their workers.¹⁹ As the 2009 H1N1 pandemic began in the spring of 2009, HHS initially deployed 25 percent (11 million courses) of the antiviral drug treatment regimens from the SNS on a pro rata basis to state health departments, in addition to the 820,000 doses that the U.S. donated to other countries in the Western Hemisphere.

The antiviral drugs deployed to the states from the SNS and those pre-purchased by states were not all used during the response and a significant number remain in state stockpiles. In the fall of 2009, to address shortages of Tamiflu® for Oral Suspension (liquid formulation) in commercial supply chains, over 500,000 bottles of pediatric oral suspension were distributed from the SNS to states to fill production supply gaps and meet the increasing demand to treat pediatric populations. This was the only type of antiviral drug for which the U.S. encountered a supply shortage during the 2009 pandemic. To help lessen the impact of this pediatric formulation shortage, HHS also published a guidance document for pharmacists on how to convert capsules into a dosage form that children could more easily swallow.²⁰ In addition, clinicians were given access to the investigational intravenous antiviral drug peramivir for treatment of seriously ill hospitalized H1N1 influenza patients; it was made available to hospitals in October of 2009 via EUA through an electronic request system that the CDC established.

The 2009 H1N1 pandemic exposed challenges associated with antiviral drug utilization, allocation, and dispensing. The 2009 H1N1 Retrospective highlighted several opportunities for improvement, many of which relate to topics such as (1) insufficient national supply of antiviral medication in a dosage form optimal for some pediatric populations (i.e., suspension); (2) different approaches used by states to distribute antiviral medications received from the SNS resulting in greater availability of antiviral drugs in some states compared with others; and (3) no ability to track where stockpiled and privately distributed antiviral medicines went and how they were used.

A regular reexamination of the nation's antiviral stockpiling strategy is necessary based on the experience of the 2009 H1N1 pandemic and the changing global antiviral drug market. The examination should include a determination of appropriate domestic quantities, the composition of available antiviral medications, identification of the responsible entity or entities, potential rapid international procurement/sharing mechanisms, and should take manufacturing capacity into account. Future strategies for federal and state antiviral drug stockpiles must address not only fiscal cost and maintenance concerns but also the need for procedures to modify the composition of the stockpiles based on factors such as the emergence of drug resistant influenza

¹⁸ Some states took further advantage of the low price available to them through the federal contracts; between April 2009, and the end of these contracts on September 1, 2010, an additional 3 M regimens were purchased by states.

¹⁹ Flu.gov. Guidance on Antiviral Drug Use during an Influenza Pandemic. Available (available online at: http://www.flu.gov/individualfamily/vaccination/antiviral_use.pdf Last accessed August 30, 2011. Flu.gov.) and Considerations for Antiviral Drug Stockpiling by Employers in Preparation for an Influenza Pandemic. Available (available online at: http://www.flu.gov/professional/business/antiviral_employer.pdf Last accessed. August 30, 2011.

²⁰ CDC. (December 1, 2009).²⁰ Opening and Mixing Tamiflu® Capsules with Liquids if Child Cannot Swallow Capsules. December 1, 2009. Available online at: http://www.cdc.gov/h1n1flu/antivirals/mixing_tamiflu_qa.htm Last accessed. November 23, 2011.

viruses, the approval of new products and new pediatric dosage information, and pediatric population doses. It is important to review and evaluate potential benefits and disadvantages of (1) different antiviral use strategies, including single drug treatment to enhance the role of antiviral drugs before and after vaccine becomes available, for pandemics specifically, and to improve response during other future public health emergencies; (2) new classes of influenza antiviral drugs (including new viral and host targets); (3) combination therapy (combining different classes of antiviral agents) and its impact on treatment effectiveness; and (4) post-exposure and outbreak (pre-exposure) influenza prophylaxis.

Ventilators

Mechanical ventilators serve an essential role in managing respiratory failure from severe respiratory illnesses, including influenza. Due to the complexity of most of the current equipment, their use in hospital settings is typically managed by trained respiratory therapists and nurses in intensive care units under the direction of an intensive care physician. Until easy-to-use equipment is widely available, sufficient numbers of trained personnel to oversee ventilator use are as important to pandemic influenza preparedness as the availability of sufficient quantities of ventilators themselves. Respiratory failure requiring mechanical ventilation is also characteristic of many other diseases and conditions that could manifest in a mass casualty event.²¹ As such, the HHS maintains ventilators in the SNS for a future pandemic or other public health emergency to augment state and local needs.

During the 2009 H1N1 pandemic, ventilator shortages were not reported to HHS, and ventilators were not deployed from the SNS. Results of a survey conducted in the summer of 2009 showed great geographic variation in the nation's population-adjusted ventilator supply, and revealed that the nation's supply is higher per capita than any other developed country, albeit significantly lower than the current estimated need during a severe pandemic (although the estimation of ventilator need should also be reassessed). After adjusting for population, it also revealed that there were many more pediatric-capable ventilators (for children weighing at least 5 kg) than adults only-ventilators, at that point in time.²² If a large proportion of the U.S. population were to become severely ill during a pandemic and required mechanical ventilation, the healthcare system would quickly become overwhelmed. The number of respiratory-compromised patients is likely to easily surpass the number of available ventilators and trained personnel by several-fold. Additionally, there is limited availability of ventilators and supplies to address the needs of some categories of patients. For example, there are currently no FDA-approved or cleared transport ventilators in the SNS for newborns and small premature babies (<5kg).

To ensure that HHS and the healthcare sectors' investments align with need, it is necessary to reassess the quantity and composition of ventilators the U.S. should have available, and where the responsibility to purchase and perhaps stockpile them lies. HHS must also reassess strategies for distributing ventilators in the SNS to the states, to help ensure federal assets will be used equitably across the U.S. to help fill the greatest need, wherever it may exist. In addition, due to a variety of ventilator products and accessory parts, there is currently a lack of ventilator standardization and interchangeable components, which could further complicate a shortage of

²¹ The term "mass casualty" covers all potential CBRN disasters (Chemical, Biological, Radiological or Nuclear)

²² Rubinson L, Vaughn F, Nelson S, Giordano S, Kallstrom T, Buckley T, Burney T, Hupert N, Mutter R, Handrigan M, Yeskey K, Lurie N, Branson R. (2010). et al. Mechanical Ventilators in US Acute Care Hospitals. *Disaster Med Public Health Prep.* . 2010 Oct;4(3):199-206.

ventilators during a pandemic or other public health disaster. HHS must continue to support the development of next generation, low cost, easy-to-use ventilators with interchangeable components suitable for a variety of populations (neonates to adults) in a number of emergency scenarios, consistent with other all-hazards planning efforts. The development of easy-to-use ventilators will increase the ability to treat severely ill patients in facilities with fewer highly trained personnel.

Respiratory Protection Devices (RPD)

Respiratory protection devices (RPDs), which include filtering facepiece respirators such as N95 respirators and facemasks, may help prevent the spread of viruses from one person to another.²³ However, the ability of available RPDs to prevent transmission of airborne influenza infection has not been well studied. Prior to the 2009 H1N1 pandemic, the U.S. Government (USG) published “Interim Public Health Guidance for the Use of Facemasks and Respirators in Non-Occupational Community Settings during an Influenza Pandemic.”²⁴ Due to the limited information on the effectiveness of RPDs, including facemasks and respirators in controlling the spread of pandemic influenza, this guidance aimed to provide interim recommendations for a severe influenza pandemic, based on public health judgment. The significant underlying knowledge gaps concerning influenza transmission make the development of effective guidance on the use of RPDs to protect against pandemic influenza virus transmission challenging—as was experienced before and during the 2009 H1N1 response. HHS is working to better understand influenza transmission and how various RPD products may help prevent it. Once these knowledge gaps are better understood, recommendations on RPD use and reuse (for cases of supply shortages)²⁵ should be updated as appropriate. Research to better understand RPD effectiveness continues.

There were reports of spot shortages of RPDs during the 2009 H1N1 pandemic. To alleviate these shortages, 75 percent of the SNS’s N95 respirators and 25 percent of its surgical masks (nearly 100 million total devices) were deployed for use in healthcare settings. Because the specific N95 respirator products delivered from stockpiles during the 2009 H1N1 response were not well matched to the N95 respirators that each receiving healthcare entity used under non-emergency circumstances, it required users to undergo just-in-time fit-testing with the new product, which was time consuming. Not all of the NIOSH-certified N95 respirators in the SNS

²³ A respirator is designed to protect the wearer from breathing in very small particles, which might contain microorganisms or other particulates/contaminants. The ‘N95’ designation for respirators means that the respirator blocks at least 95% of very small test particles. If properly fitted, the filtration capabilities of N95 respirators exceed those of face masks. Most respirators are intended for occupational exposure to particles and must be fit-tested for occupational use to ensure appropriate fitting. A facemask is a loose-fitting device designed to protect others from the wearer’s secretions by covering the mouth and nose and may afford some protection from splashes or droplets from other people. All respirators must be certified by CDC’s National Institute of Occupational Safety and Health (NIOSH). Under section 201(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(h)), RPDs intended for use to prevent the transmission of infections are medical devices, and FDA must clear (or approve) these devices for such use (see Food and Drug Administration. (July 2004). Guidance for Industry and FDA Staff: Surgical Masks - Premarket Notification [510(k)] Submissions; Guidance for Industry and FDA”. Available online at: <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm072549.htm> Last accessed).” July 2004. Available online:

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm072549.htm>.)

²⁴ Occupational Safety and Health Administration, U.S. Department of Labor & HHS. (2009).²⁴ Guidance on Preparing Workplaces for an Influenza Pandemic. U.S. Department of Labor / Occupational Safety and Health Administration, and HHS. 2009. Available online at: <http://www.osha.gov/Publications/OSHA3327pandemic.pdf> Last accessed: <http://www.osha.gov/Publications/OSHA3327pandemic.pdf> . Accessed 25 November 25, 2011.

²⁵ RPDs are ‘single-use only’ medical devices, and reusing RPDs may require FDA clearance.

were also FDA cleared, which required issuing EUAs to allow their occupational use by healthcare providers for the prevention of transmission of infection. RPD manufacturers should be encouraged to pursue both NIOSH certification and FDA clearance to ensure an ample supply of these RPDs is available for use in healthcare settings during a pandemic.

Finally, more efforts are also needed to provide the general adult public with RPDs that provide an appropriate level of protection but do not require fit training and testing,²⁶ and to ensure the availability of respiratory protective devices for children that provide protection against respiratory disease and fit their smaller faces.²⁷ HHS is continuing to explore new technologies to protect all users from inhalable threats.

Antimicrobial Agents for Treatment of Pandemic Influenza-associated Secondary Bacterial Infections

Bacterial co-infections caused by *S. pneumoniae*, *H. influenzae*, *S. aureus* (*methicillin-sensitive and methicillin-resistant*), and group A *Streptococcus* have been important contributors to morbidity and mortality associated with both pandemic and seasonal influenza. Extensive clinical and pathological data demonstrated that during the 1918-1919 pandemic, influenza A (H1N1) virus infection in conjunction with secondary bacterial pneumonias led to many deaths, and emerging data suggest that bacterial pneumonias were also important cofactors during the 2009 H1N1 pandemic. As such, as part of the HHS Implementation Plan, in 2006, requirements for antimicrobials (including intravenous antibiotics) to be considered for stockpiling to treat secondary infections related to a pandemic influenza event were developed. Based on funding, small quantities of antimicrobials were procured and stockpiled. However, no shortages of antimicrobial agents to treat secondary bacterial infection were reported during the 2009 H1N1 response, nor did HHS need to deploy assets to support the treatment of bacterial infections or address supply chain concerns.

The prevention, diagnosis, and treatment of bacterial pneumonia remain critical priorities for pandemic influenza planning efforts. Wider use of pneumococcal vaccines in populations for whom they are recommended^{28, 29} and wide use of new bacterial vaccines as they come available are examples of such prevention efforts. The development of new antimicrobial drugs and considerations for stockpiling and distributing these products are critical for addressing medical needs during a severe influenza pandemic. Antimicrobial stockpiling requirements for secondary influenza infections should be assessed and reevaluated as part of the SNS annual review process and incorporate current standards of care and lessons learned from the treatment of patients during the 2009H1N1 response experience.

²⁶ "Guidance for Industry and FDA Staff: Class II Special Controls Guidance Document: Filtering Facepiece Respirators for Use by the General Public in Public Health Medical Emergencies" available online at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm071398.htm>.

²⁷ In September 2011, the FDA cleared a facemask for children ages 5-12 designed to be worn in hospitals and healthcare facilities to help reduce the spread of airborne respiratory tract bacteria, viruses, and other pathogens. Available online at: <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm273491.htm> Last accessed: December 2011.

²⁸ Vaccine is recommended for children under 5 years of age, adults over 65 years of age, and other individuals with certain health conditions.

²⁹ Vaccine is recommended for children under 5 years of age, adults over 65 years of age, and other individuals with certain health conditions.

Summary of Key Priorities

Emergency Use Authorization and Regulatory Issues

- Develop a USG-wide plan to distribute MCMs for pandemic influenza (HHS lead: CDC; Target Date: June 2013);
- Develop systems to monitor safety, effectiveness, and shortages of MCMs during a pandemic (HHS lead: CDC, FDA, and ASPR/BARDA; Target Date: November 2012);
- Develop a plan to prevent/reduce the number of fraudulent products during a pandemic (HHS lead: FDA; Target Date: November 2012);
- Provide pre-EUAs for investigational products to the FDA for review prior to and during an influenza pandemic or other event (HHS lead: ASPR/BARDA and CDC; Target Date: December 2012); and
- Establish internal procedures to ensure that research data and/or expanded access protocols for candidate products under investigational applications (IND, IDE) have been submitted and reviewed by FDA prior to an event that can quickly be activated during an influenza pandemic or other event (HHS lead: ASPR/BARDA, NIH/NIAID, and CDC; Target Date: December 2012).

Antiviral Drugs

- Review and evaluate potential benefits and disadvantages of different antiviral use strategies and reassess the quantity and composition of antiviral medications that should be stockpiled by various levels of government and other partners, taking fiscal constraints and manufacturing capacity into account (HHS lead: ASPR/BARDA and CDC; Target Date: November 2012);
- Develop new plans for antiviral distribution and dispensing (HHS lead: CDC; Target Date: December 2012); and
- Complete at least Phase 2 development on one existing and one new class of antiviral drugs, combination therapies, or pediatric antiviral dosage form for EUA (HHS lead: NIH and ASPR/BARDA; Target Date: December 2014).

Ventilators

- Reassess the quantity and composition of ventilators that should be stockpiled by various levels of government and other partners for pandemic influenza and other threats, taking fiscal constraints into account (HHS lead: ASPR/OPP and CDC; Target Date: November 2012);
- Identify opportunities to promote ventilator standardization and interchangeable components (HHS lead: ASPR/OPP; Target Date: June 2012);
- Reassess strategies for distributing ventilators in the SNS to the states, to help ensure federal assets will be used equitably across the U.S. (HHS lead: ASPR/OPP and CDC; Target Date: July 2012); and
- Invest in the development of innovative ventilator equipment with standardized interchangeable components that are lower cost, easier to use, and flexible for a variety of populations, conditions, and settings (HHS lead: ASPR/BARDA; Target Date: December 2012).

Respiratory Protective Devices (RPDs)

- Determine whether the stockpiling of respirators in the SNS should be continued and if so, develop requirements for stockpiling, taking into account national need, including domestic manufacturing surge capabilities and sourcing of raw materials, and a system for allocation and distribution (HHS Lead: CDC/SNS, ASPR/OPP, and ASPR/BARDA; Target Date: December 2012);
- Encourage RPD manufacturers to pursue both NIOSH certification and FDA clearance to ensure an ample supply of FDA-cleared N95 respirators are available for use in healthcare settings during a pandemic: HHS lead: CDC (including NIOSH), ASPR/BARDA, and FDA; Target Date: July 2012);
- Develop systems to monitor safety, effectiveness, and shortages of RPDs after deployment (HHS lead: CDC (including NIOSH), and FDA; Target Date: July 2012);
- Conduct research to better understand influenza transmission, to clarify when surgical masks are sufficient, and when the use of N95 respirators or other devices may be more appropriate (HHS lead: CDC (including NIOSH), ASPR/BARDA, and FDA; Target Date: December 2012);
- Innovate and strengthen RPD design, use, testing, and certification for both occupational and community settings for a wide population, including the pediatric population (HHS lead: CDC (including NIOSH), ASPR/BARDA, and FDA; Target Date: December 2012); and
- Develop and/or revise relevant RPD use/reuse guidance and policies (HHS lead: CDC (including NIOSH) and FDA; Target Date: January 2013).

Antimicrobial Agents for Treatment of Pandemic Influenza-Associated Secondary Bacterial Infections

- Support basic and translational research and advanced development of broad spectrum antimicrobial agents and bacterial vaccines to mitigate secondary bacterial infections (HHS lead: NIH and ASPR/BARDA; Target Date: July 2012);
- Encourage the use of pneumococcal vaccines in populations for whom its recommended, and take advantage of seasonal influenza vaccination as a time to administer them (HHS lead: CDC and OASH; Target Date: September 2012);
- Develop a plan to use antibiotics in the SNS against secondary bacterial infections associated with pandemic influenza (HHS lead: CDC; Target Date: September 2012); and
- Determine whether the federal stockpiling of IV antibiotics for bacterial infections secondary to influenza should be continued, and if so, develop requirements for stockpiling (HHS lead: ASPR/ OPP and CDC; Target Date: September 2012).

CHAPTER 6: VACCINE MANUFACTURING, DISTRIBUTION, AND POST-DISTRIBUTION

Introduction

A vaccine well-matched to circulating influenza virus strains is the cornerstone of seasonal influenza prevention, and in the context of a pandemic, providing population immunity to a new influenza virus is a race between the virus and the vaccine. Therefore, vaccination of a significant percentage of the U.S. population with a pandemic vaccine has been and will continue to be a critical component of mitigating the next influenza pandemic. In 2005, HHS established key pandemic planning priorities related to influenza vaccine, including (1) working with the pharmaceutical industry to develop domestic vaccine production capacity sufficient to provide vaccine for the entire U.S. population as soon as possible after the onset of a pandemic; (2) during the pre-pandemic period, stockpiling up to 20 million courses of vaccine against each circulating influenza virus with pandemic potential; (3) expanding seasonal influenza domestic vaccine production through normal commercial transactions to cover all of the U.S. population for whom vaccine is recommended; and finally; (4) at the onset of an influenza pandemic, working with the pharmaceutical industry to procure vaccine directed against the pandemic strain and to distribute vaccine to state and local public health departments for pre-determined priority groups.

Over the past several years, investments and innovations in influenza vaccine technologies and production capacity positively impacted the 2009 H1N1 pandemic vaccination campaign. Continued improvement will increase effectiveness of the next pandemic vaccination campaign in many different areas, including:

- Quicker access to more effective vaccines;
- Improved target group guidance and strategies for pre-pandemic and pandemic vaccination;
- Improved situational awareness of vaccine production, distribution, and coverage;
- Improved methods to quickly distribute, deliver, and administer vaccine;
- Refined mechanisms for vaccine safety monitoring and effectiveness studies; and
- Improved seasonal influenza vaccination coverage

Lessons Learned

Rapid availability of more effective vaccines

Future vaccination programs for the next influenza season and/or the next influenza pandemic will benefit from well-matched, more protective vaccines, which are rapidly produced in greater quantity and quickly available to the public. Recently, two reports published in August 2010, the President's Council of Advisors on Science and Technology (PCAST) *Report to the President on Reengineering the Influenza Vaccine Production Enterprise to Meet the Challenges of Pandemic Influenza* and the HHS *Public Health Emergency Medical Countermeasures Enterprise Review*, examined how vaccine development and production can be modernized to produce product more quickly and reliably. The reports recommend a number of activities related to vaccine technologies and faster production, many of which are ongoing. Examples include continued investments in new influenza technologies that hold promise for shortening the time required to

manufacture more and better vaccines, improving methods for generating candidate vaccine reassortants, continuing to encourage multiuse facilities to expand production capacity, developing an improved fill/finish manufacturing network, and developing faster and more reliable influenza vaccine potency assays and sterility testing.³⁰

Stockpiling vaccines is another method to speed up availability and use of influenza vaccine. A risk assessment process should be honed to improve how influenza vaccine strains with pandemic potential are selected for reference strain development and for the development of vaccine seed lots by manufactures. This assessment can also inform decision making for proceeding beyond seed lots into vaccine development, stockpiling, and use. Previously established goals for stockpiling pre-pandemic vaccine should also be revisited for either validation or adjustment.

Dose-sparing strategies to increase vaccine availability should continue to be explored, including the use of vaccine adjuvants which may have the added benefit of making vaccines more immunogenic, or protective. Adjuvants hold potential to (1) boost the immune response in certain population segments (e.g., the elderly); (2) provide an immune response to a broad set of influenza virus strains; (3) extend the duration of immunity and improve immunological memory for several years; and (4) increase vaccine supply when it may be otherwise limited by reducing the amount of antigen needed in the vaccine. Because of these potential benefits, HHS has been supporting the development and clinical evaluation of adjuvanted influenza vaccines.³¹ Although the U.S. 2009 H1N1 vaccine response did not include the use of adjuvanted vaccines, there is still much that can be done to advance our understanding of the public acceptability of adjuvant use, which may be necessary during the next vaccine-preventable public health emergency.

Evolve target group guidance and strategies for pre-pandemic and pandemic vaccination

When a vaccine becomes available in an influenza pandemic, early doses may need to be targeted to specific groups and individuals. In 2008, HHS and the U.S. Department of Homeland Security (DHS) jointly published *Guidance on Allocating and Targeting Pandemic Influenza Vaccine*—a draft plan that aimed to communicate which groups and individuals would likely be vaccinated first, and individuals targeted for earlier vaccination differed by pandemic severity. The plan was heavily predicated on the premise that pandemics of varying severity would all pose a risk to the nation’s critical infrastructure workforce. However, in the case of the 2009 H1N1 pandemic, DHS determined that critical infrastructure was not at significant risk, and thus the CDC Advisory Committee on Immunization Practices (ACIP) made a determination to establish public health and medical priorities based on the epidemiology of the disease and

³⁰ A detailed listing of the recommendations from these reports can be found here: President’s Council of Advisors on Science and Technology. (August 2010). Report to the President on Reengineering the Influenza Vaccine Production Enterprise to Meet the Challenges of Pandemic Influenza. August 2010. Available online at: <http://www.whitehouse.gov/sites/default/files/microsites/ostp/PCAST-Influenza-Vaccinology-Report.pdf> Last accessed. December 2010 and HHS. (August 2010).; and The Public Health Emergency Medical Countermeasures Enterprise Review. August 2010. Available online at: <https://www.medicalcountermeasures.gov/documents/MCMReviewFinalcover-508.pdf> Last accessed. November 2011..

³¹ Currently, no licensed influenza vaccines in the U.S. contain adjuvants; although several are licensed outside of the U.S. and are used for seasonal and pandemic influenza.

developed target group recommendations accordingly.³² This change in approach, although warranted by the characteristics of the pandemic, created confusion among some critical infrastructure sectors that were not prioritized by ACIP. This supports reconsideration of the current pandemic vaccine use guidance, the development of guidance for allocating pre-pandemic vaccine that is stockpiled by HHS, and the development of a system to execute prioritization plans which will include a transparent process for refining priority groups as needed. Due to the confusion about which age groups could be vaccinated with the four different 2009 H1N1 vaccines in 2009, harmonization of the indicated age groups for both seasonal and pandemic influenza vaccines is needed for influenza pandemics. Clinical studies with antigen-alone and adjuvant-containing influenza vaccines for all age groups should be performed, if no data are available, to support access under EUA in an emergency.

Develop improved awareness of and communication about vaccine production, distribution, and coverage

During the 2009 H1N1 pandemic, there was a strong demand for information, and in some cases real-time information, on vaccine production, distribution, and coverage (at the national and priority group level). Awareness of vaccine production and availability for the U.S. during an influenza pandemic has important operational implications as witnessed during the H1N1 vaccination campaign. It requires a number of components feeding into a near-to-real-time information system that inform vaccine distribution based upon continually updated estimates of vaccine supply. These components include an accurate assessment of manufacturers' vaccine production, lot release from FDA and distribution by the manufacturers, and effective and ongoing coordination and communication across federal, state and local partners, the private sector, and the public. There is room for improvement in all of these areas. Information regarding both the movement of vaccine through the distribution supply chain as well as data on how many individuals actually received vaccine will be required during the next pandemic response. A system is needed that captures real-time information on vaccine location across the entire vaccine spectrum from dose availability at the manufacturers to administration.

Develop improved methods to quickly distribute, deliver, and administer vaccine

Responding to an influenza pandemic poses challenges that heighten the critical need to be able to quickly provide an effective vaccine to the public. At the time of the pandemic, there was no centralized national infrastructure for the distribution of non-routine childhood vaccines, a characteristic rendered necessary by the federal financing of the vaccination campaign. As a result, instead of a direct manufacturer-to-state/local health department distribution model, which had been the focus of previous pandemic planning, the 2009 H1N1 response used the vaccine ordering system that is used by CDC's Vaccine for Children (VFC) program. With some effort, it was scaled up for use, allowing for the consolidation of distribution operations to a single vendor. This also permitted state health departments to maintain control of ordering and allocation within their state.

Once vaccine is available, rapid delivery and administration through vaccination clinics and other means are critical, especially to identified target groups in instances of real or projected

³² The 5 initial target groups were pregnant women, household contacts and caregivers for children younger than 6 months of age, healthcare and emergency services personnel, individuals aged 6 months to 24 years, and persons aged 25-64 with health conditions associated with higher risk of complications.

vaccine shortages. However, during the 2009 H1N1 pandemic, it was difficult to establish new relationships with certain providers to reach priority groups recommended for initial vaccination by ACIP. To first reach priority groups and then the general population, a number of vaccination strategies were used, including school-located vaccine clinics, delivery through neighborhood and “big box” retail pharmacies, mass vaccination clinics, and private provider dispensing. Each of these approaches had their own unique benefits and challenges and these models should be further explored and refined with the assumption that the use of everyday systems in an emergency is often the most efficient and effective approach due to familiarity. The successful implementation of these delivery models is dependent upon many factors including available medical materiel, clear communication of priority groups for vaccination, effective immunization information systems, and strong collaboration between government and the private sector.

Refine mechanisms for vaccine safety monitoring and effectiveness studies

During the pandemic, the vaccine safety monitoring system was enhanced to provide more robust monitoring and reporting of the safety of 2009 H1N1 vaccine than during a typical influenza season.³³ In parallel with the intensified review of data from all components of the federal vaccine safety monitoring system, the H1N1 Vaccine Safety Risk Assessment Working Group (VSRAWG) was established as a Working Group of the National Vaccine Advisory Committee (NVAC) with membership from several federal advisory committees for an independent review of the data. The VSRAWG was regularly briefed by the federal agencies involved in vaccine safety monitoring, evaluated safety data provided by the agencies, and opined and advised NVAC, which then advised HHS on 2009 H1N1 vaccine safety. Status reports on vaccine safety were regularly reported to the public through the NVAC and significant information was published in scientific literature.³⁴ Beyond the enhancements made during the 2009 H1N1 pandemic, efforts should continue to strengthen every day vaccine safety monitoring systems, leverage advances in electronic health records and electronic communications, build additional vaccine safety monitoring infrastructure and build scientific expertise—all of which will position HHS and the U.S. government to effectively and efficiently respond to future pandemics and other public health emergencies involving a large-scale vaccination program.

Improve Seasonal Influenza Vaccination Coverage

Annual vaccination is the most effective method for preventing seasonal influenza and its related complications. Annual vaccination is currently recommended for all persons aged 6 months or older for whom it is not contraindicated. Overall, nationwide influenza vaccination coverage remains suboptimal, especially coverage for children, pregnant women, minorities, and healthcare workers. Increasing seasonal influenza vaccination rates is an important component of pandemic influenza preparedness for several reasons. Seasonal influenza vaccines provide an opportunity to strengthen and maintain the system for providing vaccine from manufacturers to vaccine providers, and individuals who routinely obtain seasonal influenza vaccine may be more likely to actively seek vaccine during an influenza pandemic. To improve vaccination coverage

³³ During the vaccination campaign, over 80 million Americans were vaccinated for 2009 H1N1 influenza within approximately four months. Rates of adverse events for the 2009 H1N1 vaccine were comparable to seasonal influenza vaccines.

³⁴ Black S, Eskola J, Siegrist CA, Halsey N, Macdonald N, Law B, Miller E, Andrews N, Stowe J, Salmon D, Vannice K, Izurieta HS, Akhtar A, Gold M, Oselka G, Zuber P, Pfeifer D, Vellozzi C. (2009). ³⁴ Black S, Eskola J, et al. Importance of background rates of disease in assessment of vaccine safety during mass immunization with pandemic H1N1 influenza vaccine. *The Lancet*, 2009 Oct; 374 (9707): 2115-2122.

in medical and nonmedical settings, specific strategies should be implemented or expanded to encourage annual influenza vaccination.

Summary of Key Priorities

- Develop a process to provide transparent and realistic vaccine output range projections, in conjunction with vaccine manufacturers, for federal officials, state and local vaccine planners, and the public (HHS lead: ASPR/BARDA and CDC; Target Date: June 2012);
- Encourage influenza vaccine manufacturers interested in developing pandemic vaccines to study pandemic vaccine candidates in children to determine safety and immunogenicity. (HHS lead: ASPR/BARDA and FDA; Target Date: Dec 2013);
- Refine policies and plans related to pre-pandemic vaccine distribution modalities (pre-pandemic vaccine allocation guidance, utilization strategies, stockpiling goals, and communications plans) (HHS lead: ASPR/BARDA and CDC; Target Date: October 2013);
- Review and refine as necessary the pandemic vaccine prioritization strategy and implementation plans, including communications plans (HHS lead: ASPR/OPP, OASH and CDC; Target Date: October 2013);
- Increase partner participation in planning for the administration of vaccine, including government health officials, community planners, providers, schools, employers, pharmacists, and distributors (HHS lead: CDC; Target Date: October 2012);
- Refine ancillary supply and distribution strategies, including exploring options for new and efficient dose delivery systems (HHS lead: ASPR/BARDA; Target Date: October 2012);
- Implement the recommendations of the President's Council of Advisors on Science and Technology influenza vaccinology report and the HHS Public Health Emergency Medical Countermeasure Enterprise Review to develop improved influenza vaccines and manufacturing technologies that shorten the timeframe for first and last dose availability (HHS lead: ASPR/BARDA, NIH, CDC, and FDA; Target Date: September 2013).³⁵
- Improve methods for preparing and calibrating reagents for vaccine potency testing (HHS Lead: FDA; Target Date: December 2013);
- Refine and expand the use of immunization information systems among all providers, including non-traditional providers. (HHS lead: CDC; Target Date: January 2013);
- Increase the percentage of persons receiving annual influenza vaccinations, and develop guidance to be used when limited vaccine availability requires targeted vaccination of persons with high-risk conditions (HHS lead: CDC; Target Date: March 2013);
- Evaluate approaches and develop recommendations for using adjuvanted vaccines to enhance current and future vaccination campaigns (HHS lead: ASPR/BARDA, FDA, and CDC ; Target Date: June 2013);

³⁵ A detailed listing of the recommendations from these reports can be found here: President's Council of Advisors on Science and Technology. (August 2010)., Report to the President on Reengineering the Influenza Vaccine Production Enterprise to Meet the Challenges of Pandemic Influenza. August 2010. Available online at: <http://www.whitehouse.gov/sites/default/files/microsites/ostp/PCAST-Influenza-Vaccinology-Report.pdf> Last accessed November 2010; and HHS. (August 2010). The Public Health Emergency Medical Countermeasures Enterprise Review. August 2010. Available online at: <https://www.medicalcountermeasures.gov/documents/MCMReviewFinalcover-508.pdf> Last accessed December 2011.

- Develop a state-of-the-art fast, flexible and adaptive vaccine tracking system suited for pandemic and other vaccine-preventable emergencies, capable of providing real-time information on vaccine location across the entire vaccine spectrum from dose availability at the manufacturers to administration, with near term priorities focused on allocation adjustment, dose requesting, and distribution tracking. (HHS lead: CDC, FDA and ASPR/BARDA; Target Date: June 2015); and
- Enhance and facilitate use of post-market vaccine safety monitoring systems, conduct influenza vaccine safety studies in vulnerable/special populations (e.g., pregnant women), and explore opportunities to improve awareness of vaccine adverse events and reporting by clinicians and other vaccine providers (HHS lead: OASH, CDC, FDA, ASPR/BARDA, and NIH; Target Date: January 2014).

CHAPTER 7: COMMUNICATIONS

Introduction

Effective emergency risk communication helps the public improve decision making during a pandemic by explaining the risk and how people can reduce their risk. It is critical to ensure that credible and accurate information is communicated rapidly, effectively, and consistently to the public and other stakeholders. Communication will always be one of the biggest challenges during a pandemic due to high levels of uncertainty at the onset; the rapidly evolving nature of the event; the number and complexity of messages; the many information channels used by the public to receive information; and the diversity of the U.S. population and their unique information needs. Coordinating communication activities within and among federal, state, local, stakeholder organizations, and international partners is a major responsibility that requires considerable advanced planning. Key areas of emergency risk communications include (1) communications preparedness; (2) partnerships; and (3) communications channels.

Building and maintaining a strong network among state, local, international public health partners, and broad sectors of society is integral to the success of efforts in preparing for and responding to a pandemic. In order to broaden the reach of messages, it is important to work with diverse organizations that can carry influenza information to those with unique communication needs or limited access to traditional communication channels. Partnership activities can work to promote health and empower diverse groups. Any influenza communication strategy must aim to reach as many people as possible. Print and broadcast communications have long been the norm, but in recent years the Internet and its social media platforms have become effective pathways for reaching diverse audiences for seasonal and pandemic influenza messaging. Examples of specific communication challenges experienced during the 2009 H1N1 pandemic include:

- Prior pandemic preparedness efforts and the resulting pre-developed communications messages and materials were based largely on a scenario of severe human illness caused by highly pathogenic avian influenza and therefore were of little use when a less severe pandemic scenario unfolded;
- Priority groups for 2009 H1N1 influenza vaccine recommended by the ACIP differed from those recommended for seasonal flu vaccine;

- Vaccine demand varied across the country and decreased as the pandemic progressed and supply increased; and
- Low awareness among the public regarding the availability of influenza antiviral medications and among clinicians regarding CDC’s recommendations for their use during an influenza pandemic.

Lessons Learned

The 2009 H1N1 Retrospective highlighted opportunities for communications improvement, including:

- Some communications with both the public and participants were too complex and did not use plain language;
- Communications did not adequately reach all desired minority, disadvantaged, and other hard-to-reach populations; and
- Rapidly changing information on 2009 H1N1 challenged the capacity to provide consistent public health information.

A successful pandemic response also requires a strong and solid infrastructure for emergency and risk communications. Communications staff with subject matter knowledge and experience with influenza and influenza-related topics provide the greatest efficiency and effectiveness in pandemic influenza communications. Investments made in program communications and activities prior to the 2009 H1N1 pandemic greatly contributed to the rapid production of core content and key messages related to the emerging pandemic. Established relationships among communicators and subject matter experts are critical to a rapid, credible, and science-based communications response. Unless existing staff are augmented prior to the pandemic, surge staff will likely be needed, and it will take time before they are able to contribute effectively to the communications response. During a pandemic, there is great demand for communications materials—from toolkits for physicians to plain language materials for the public. Tremendous advantages can be gained by leveraging the communication strategies for seasonal influenza to that of a pandemic, since both have many overlapping issues. The timely development and clearance of culturally appropriate and plain language materials for public audiences is essential. Development of clear communication materials can only be achieved with a strong evidence base and implementation guidelines for message development that adhere to health literacy principles.

While it is important to identify new partners, existing collaborations must be nurtured to ensure relationships carry over to the next response. In the 2009 H1N1 pandemic, maintaining two-way communication with state and local public health partners was critical to staying abreast of events in the field as well as for dilemma sharing and joint problem solving. Many of the partnerships strengthened and formed during the 2009 H1N1 pandemic, such as those with the Association of State and Territorial Health Officials; the National Association of City and County Health Officials; the National Public Health Information Coalition; professional organizations such as the American College of Obstetricians and Gynecologists; employers and business groups; and faith-based and community organizations, need to be maintained and strengthened.

The 2009 H1N1 pandemic also highlighted the opportunity and value of broadening the approach and practices used to further integrate public awareness, perceptions and attitudes into the response framework. Through creating bi-directional communication channels, social, behavioral, and compliance practices and trends can be assessed in an effort to ensure accurate, proactive, time-sensitive, and real-time messaging. By adapting and implementing tools using social media, social science, and consequence analysis, the nation's reaction to the response can aid outcomes through more effective communications. HHS can create tools that can be leveraged, implemented, or modeled on the state and local levels through embarking on these efforts. These activities can further support community resilience by creating avenues for broader community engagement in responses.

Summary of Key Priorities

- Develop an approach, definitions, tools, and models for a risk communications response plan (HHS lead: ASPA, ASPR, SAMHSA, and CDC; Target Date: March 2013);
- Develop mechanisms to further integrate social media and other communication tools into preparedness activity (HHS lead: ASPA and CDC; Target Date: August 2012);
- Continue to ensure internal operation plans for pandemic influenza communication are updated, exercised, evaluated, and improved for effective communication strategies (HHS lead: CDC and ASPR; Target Date: September 2012);
- Work with international partners to share communications strategies and harmonize communication messages (HHS lead: ASPA and ASPR; Target Date: October 2012);
- Improve sharing public health emergency messages, and translated and culturally appropriate materials with non-English speaking communities across the U.S. (HHS lead: ASPA, CDC, and CFBNP; Target Date: November 2012);
- Refine and implement partnership strategies to improve communications with hard-to-reach/at-risk populations, including identification of key community spokespersons prior to a pandemic (HHS lead: ASPA, SAMHSA, and CDC; Target Date: November 2012);
- Develop procedures that ensure the timely development and dissemination of culturally appropriate public education materials in plain language, and that define and clarify roles and responsibilities across HHS (HHS lead: ASPA; Target Date: November 2012);
- Develop plans to ensure the availability of adequate communications staff to handle rapidly changing information during a pandemic and to provide both consistent and accurate public health information (HHS lead: CDC, ASPR and ASPA; Target Date: November 2012);
- Increase capacity for developing plain language and easily understood materials for public audiences (HHS lead: ASPA and CDC; Target Date: December 2012);
- Develop procedures to ensure that information is provided in accessible and alternative formats in future pandemics (HHS lead: ASPA and CDC; Target Date: December 2012);
- Strengthen and maintain existing relationships and communications with governmental and non-governmental agencies, as well as the media and other trusted entities (HHS lead: ASPA, CDC, and IEA; Target Date: December 2012); and
- In support of the U.S. government MOU with WHO, support capacity building for the Risk Communications Core Capacity under the International Health Regulations (HHS lead: ASPA and CDC; Target Date: December 2012).

CHAPTER 8: CROSS-CUTTING PREPAREDNESS ISSUES

Introduction

Preparedness for and resiliency in the face of health threats requires smoothly operating routine response capabilities and supporting functions that do not delay or create barriers to an effective emergency response. Without proper planning, legal barriers, administrative and workforce constraints, and delays in access to funding may hinder an organization's ability to efficiently and effectively respond to an emergency event. HHS and state and local governments across the country experienced varying degrees of challenges related to these issues, and since then, a significant emphasis has been placed on developing new plans and procedures to overcome those challenges.

This section discusses five important support areas: scientific research, response and preparedness; budget and financial preparedness; policy preparedness; legal preparedness; and public health workforce surge. Ensuring solid preparedness planning in these areas is as critical as preparing for the direct response effort itself.

Lessons Learned

Scientific Research, Response, and Preparedness

Traditional scientific research routinely requires planning, coordination, and a lengthy process of experimentation and validation of results. Emergency responses, however, frequently contain only a brief period of time to organize and conduct scientific research that may both immediately benefit those affected by the event and also improve responses to future disasters. The 2009 H1N1 pandemic contributed to the realization that the nation would be better served if protocols and other preparations to conduct research during emergency events were ready in advance. During a pandemic, it is critical to quickly understand the scientific and clinical components of the disease as it unfolds, including the effectiveness of approved countermeasures against the circulating strain, and how any new treatments, especially those used under EUA, IND and IDE, may work.

During the 2009 H1N1 pandemic, the National Institute of Allergy and Infectious Diseases (NIAID) within HHS's National Institutes of Health (NIH) conducted several clinical trials through its longstanding Vaccine Treatment and Evaluation Units (VTEUs). Trial data offered key scientific evidence essential for public health decision making, including the determination of optimal dosage and number of doses for individuals of different ages and for specific high risk groups, such as pregnant women. NIAID clinical trials with adjuvanted vaccine (which was not used in the public vaccination program) also showed that the adjuvant was safe and could have been utilized to stretch the vaccine supply. The information and experience that was gained from all of these clinical trials has bearing beyond H1N1 and the current influenza season. Challenges related to conducting research during emergency events still remain, however. For example, approximately 2,100 treatment courses of the intravenous antiviral medication peramivir were distributed during 2009 H1N1 and made available under EUA, but there was not a plan in place to gather information on the drug's effectiveness against severe 2009 H1N1 influenza. This resulted in a lack of information regarding peramivir's benefit for the treatment of severely ill 2009 H1N1 patients.

Current federal efforts seek to identify, better utilize, and integrate research activities into standard operating procedures for all-hazards response, and these efforts are bolstered by a 2011 report issued by the National Biodefense Science Board (NBSB), a federal advisory committee which advises the HHS Secretary on issues related to public health emergencies and biodefense. The NBSB report, *Call to Action: Include Scientific Investigations as an Integral Component of Disaster Planning and Response*, emphasizes the need to improve the nation's ability to mount a comprehensive and rapid mobilization of its scientific resources in the investigative response to disasters that threaten public health. The report includes recommendations for preparing in advance for activities to generate and collect informative data to enable the evaluation of the effectiveness of specific countermeasures in real-world situations, including preparation during non-emergency periods of protocol templates that could be rapidly adapted when an emergency arises.³⁶ Advance preparations to quickly mobilize scientific resources during an emergency, including a pandemic, are important at the federal, state, and local levels, as well as in the academic and private sectors. Ultimately, data and improved scientific understanding obtained through these efforts will be applied to improve future emergency responses and enhance medical, public health, and societal outcomes. Efforts are underway to create a central USG Institutional Review Board (IRB) that can approve protocols both in advance and after the onset of a pandemic or disaster, as well as establish a clinical research network, analogous to the VTEUs which can “turn-on” clinical research data collection, with a designated rapid analytical capability.

Budget and Financial Preparedness

Preparing in advance for potential budgetary and financial needs during an emergency can help to ensure timely access to and distribution of funds at all levels of government, which is necessary for an efficient and effective response. For example, at the onset of the 2009 H1N1 pandemic, time was required to determine budget needs and submit a request to Congress for supplemental funding. Compiling budget information in advance, using available information and plans, could save time at the beginning of an emergency and strengthen the response.

Determining the appropriate administrative mechanisms for using and distributing funds for response and relevant research activities can be time consuming during a response. This is true at all levels of government, none of which were immune to the challenges of getting funding out the door quickly to the responding organizations that needed it during the 2009 pandemic response. Authorities and mechanisms for distributing and using funding can be investigated before an emergency to ensure that the appropriate processes are in place to distribute and use funds rapidly during emergency events. This is part of a larger effort defined as administrative preparedness.³⁷

Policy Preparedness and Urgent Decision Making

³⁶ National Biodefense Science Board. (April 2011).³⁶ *Call to Action: Include Scientific Investigations as an Integral Component of Disaster Planning and Response*. A Report from the National Biodefense Science Board. April 2011. Available online at: <http://www.phe.gov/Preparedness/legal/boards/nbsb/Documents/nbsbrec14.pdf> Last accessed. August 18, 2011.

³⁷ “Administrative preparedness” is the process of ensuring that fiscal and administrative authorities and practices that govern funding, procurement, contracting, and legal capabilities necessary to mitigate, respond, and recover from public health threats and emergencies can be accelerated, modified, streamlined and accountably managed at all levels of government.

Every emergency response has unique circumstances that require rapid strategy and policy development. The response to 2009 H1N1 emphasized the need to strengthen the Department's infrastructure for this decision making during a public health emergency. HHS is strengthening the linkage between its response operations and strategy and policy development, and working to create a predictable and transparent process to better integrate them during emergency responses. This process should also integrate after action reviews and subsequent reports to identify and implement policy changes that could facilitate and improve future emergency responses. Government at all levels and other stakeholders who engage in response activities should continually examine the connection between their own policy deliberations and response operations, and strive to improve the linkages between their own policy and strategy development and response operations.

Legal Preparedness

Legal authorities, along with financial, personnel (workforce surge), and administrative policies and procedures play an essential role in a jurisdiction's ability to respond in a timely manner to emergency public health situations. Ideally, statutes should provide jurisdictions with flexibility to respond to the needs of emergencies that cannot be predicted in advance; however, many current authorities may not be as nimble as one would hope. Considerations for current legal authorities, which will vary by level of government and jurisdiction, should be integrated into emergency response planning, including those for a future influenza pandemic. The effects of differing legal authorities that may impact an efficient pandemic response are broad and include those related to the use of emergency declarations, vaccination requirements, informed consent, licensure and credentialing requirements, social distancing, school closures, quarantine and isolation orders, legal frameworks for information sharing. Governments at all levels (federal, state, and local) should understand and plan to address any legal barriers to effective public health preparedness and response that may exist.

Public Health Workforce Surge

During a public health emergency, the public health workforce at the federal, state and local levels will be called upon to go above and beyond their routine responsibilities. This workforce will likely need to (1) expand their laboratory and epidemiology capacity; (2) perform incident command and control; (3) expand disease tracking, including monitoring of hospitals and other healthcare facilities; and (4) increase capability and capacity for mass vaccination and mass countermeasure dispensing, among other duties. During an influenza pandemic, the ability to vaccinate a large number of individuals as quickly as possible in pharmacies and clinic settings, in schools and workplaces, and in other venues is especially important. If healthcare facilities are overwhelmed, public health can assist in a number of ways, including educating healthcare providers to provide care in outpatient settings and assisting in moving care of the less-ill away from emergency rooms to more appropriate outpatient facilities.

The additional effort required during an influenza pandemic will most likely be beyond what current public health personnel can handle even working extra hours. Therefore, respite coverage will also be important to prevent staff burn-out and to help ensure a healthy, productive workforce. Public health agencies at all levels of government should have mechanisms in place to be able to quickly bring on additional temporary, qualified staff during public health emergencies, including future pandemics. The need to prepare to surge with extra staff is

especially critical now, as state and local public health departments have lost over 44,000 positions since 2008.^{38, 39}

Summary of Key Priorities

- Identify tactics for advanced preparation that will allow all levels of government and the academic and private sectors to quickly mobilize scientific resources during any emergency (HHS lead: ASPR; Target Date: April 2013);
- Develop and implement recommendations to expedite the use and distribution of federal funds during any emergency (HHS lead: ASFR and ASPR; Target Date: August 2012);
- Develop, and refine as necessary, a mechanism and accompanying standard operating procedure for collaboration during an emergency for HHS leadership to identify and resolve policy issues and to ensure coordination, integration, and follow up of policy, budget, legislative, and external communication strategies (HHS lead: ASPR; Target Date: July 2012);
- Identify and develop a plan to address any legal barriers to effective federal public health preparedness and response (HHS lead: ASPR; Target Date: March 2013);
- Develop mechanisms to quickly surge federal, state, and local staffing levels during any emergency and provide respite opportunities to staff (HHS lead: ASPR, CDC, and FDA; Target Date: June 2013); and
- Promote budget, financial, legal, and other administrative preparedness concepts at the state and local government levels to include identifying barriers and challenges to hiring; contracting and the procurement of necessary resources; and identifying and/or putting in place statutory authorities that can be used during an emergency to implement response activities using available funding (HHS lead: ASPR and CDC; Target Date: October 2012).

³⁸ Association for State and Territorial Health Officials. (December 2010). ³⁸ Impact of Budget Cuts on State and Territorial Public Health Services. Association for State and Territorial Health Officials. December 2010. Available online at: <http://www.astho.org/Display/AssetDisplay.aspx?id=5574> Last accessed..October 18, 2011.

³⁹ National Association of County and City Health Officials. (September 2011).³⁹ Local Health Departments Job Losses and Program Cuts: Findings from July 2011 Survey. National Association of County and City Health Officials. September 2011. Available online at: <http://www.naccho.org/topics/infrastructure/lhdbudget/loader.cfm?csModule=security/getfile&PageID=214308> Last accessed. October 18, 2011.

CHAPTER 9: INTERNATIONAL PARTNERSHIPS AND CAPACITY BUILDING ACTIVITIES

Introduction

Pandemic influenza is a global threat requiring a coordinated global response. Given the almost universal susceptibility of human populations to novel strains of influenza virus, an outbreak of a novel strain that is readily transmissible among humans poses a risk to populations everywhere. The recent 2009 H1N1 influenza pandemic does not lessen the risk of the emergence of a novel human influenza virus in the near future and we cannot predict where or when the next pandemic will emerge. Strengthening global capacities to prepare, identify and respond to an influenza pandemic is a complex effort that requires advances in policy, planning, and technical areas within each country and internationally. HHS has made significant investments in international pandemic influenza preparedness activities in every region of the world and has worked with bilateral, multilateral, and private sector partners to strengthen the ability to detect and mount a coordinated global response to an influenza pandemic. These partnerships and investments have been informed by efforts to respond to the influenza pandemics of the 20th century, to combat the emergence of the H5N1 influenza strain, and have been leveraged most recently to mount an international response to the 2009 H1N1 influenza pandemic.

The United States worked closely with the international community, including the WHO and other countries, to share information, coordinate public communications, provide international assistance, and develop guidance throughout the course of the 2009 H1N1 influenza pandemic. For example, HHS donated nearly 17 million doses of 2009 H1N1 influenza vaccine to the WHO in order to assist developing countries with no access to the vaccine. In addition, CDC experts in influenza epidemiology, laboratory, health communications, and emergency operations—including those involved in the distribution of supplies and medications, information technology and veterinary sciences—were deployed to assist with the international response. HHS is also an active member and co-chair of the Global Health Security Initiative (GHSI) Communicators Network on behalf of the U.S. The Network includes lead communicators from national-level health ministries and departments ensuring that the health agencies of the G7 countries plus Mexico and the European Commission notify one another about public communications related to outbreaks and other health threats. The GHSI network also identifies joint strategies for emergency communication planning and collaboration among member nations.

Lessons Learned

Previous preparedness efforts and USG investments in building capacities to detect and respond to pandemic influenza throughout the world provided the basis for and were critical to the 2009 H1N1 response. These investments have made us better prepared for an influenza pandemic than at any other time in history; however, many gaps still remain. The United States' ability to respond to future influenza pandemics depends on international capacities to prepare, respond to and recover from pandemics caused by novel human influenza viruses.

The recent 2009 H1N1 Retrospective highlighted a number of opportunities for improvement, specifically:

- Gaps in the ability of the global influenza surveillance network to detect novel human pathogens must be addressed in order to more rapidly and effectively identify threats to human health;
- More precise and rapid technical capabilities are needed to quickly identify and categorize emerging threats;
- Bilateral and multilateral partnerships need to be better utilized to obtain medical data on human cases in other countries and their response to medical countermeasures, in order to get the most accurate picture of the threat for creating an appropriate response;
- Better international coordination, specifically in communications and issuance of recommendations across countries, is needed;
- Sustainable approaches are needed to improve self-sufficiency among developing countries in response to an influenza pandemic. Specifically, the development, implementation, and support of strategies to build/increase in-country vaccine and antiviral production capacity is needed to ensure that developing countries are able to produce their own resources to respond to a pandemic;
- Options and resources need to be identified for supporting least-developed countries in responding to an influenza pandemic. The United States should also work with public and private international partners, including the WHO, in order to identify and address barriers to provision and acceptance of international assistance during a pandemic. Logistical, legal and regulatory barriers to the international sharing of medical countermeasures must be addressed to facilitate potential future deployments of pandemic influenza vaccine and antiviral medications; and
- The United States needs to establish a well-coordinated process to receive and share requests for assistance from international partners. In addition, coordination with other donor countries regarding provision of and response to requests for international assistance could be improved.

There is a need to continue working with international partners to build international laboratory capacity at all levels in order to support confirmatory diagnostics of syndromic surveillance and for detection of novel influenza viruses with pandemic potential—a gap noted in the 2009 H1N1 Retrospective and a key component to rapid public health response. A robust research portfolio is needed to improve understanding of international disease burden in various age and risk groups, flu seasonality, virus genetics with a view to develop new candidate vaccines, and clinical development of vaccines, including clinical trials and controlled studies. The research platforms for these activities often do not currently exist or are in need of significant enhancement in a majority of countries.

At the national level, robust systems and policies are needed to support a sustained and coordinated response to a global event, such as an influenza pandemic, in addition to geographically limited and short-term emergencies within countries. Building skills and capabilities of public health personnel at all levels and in all relevant areas, including the provision of safe and effective countermeasures and surveillance, will help to sustain strong public health systems that can be leveraged during any type or size of emergency. Additionally, multi-sectoral relationships throughout the international community built around the requirements in the International Health Regulations (2005) ensure robust communication, information sharing, and coordination during public health emergencies. Finally, there is a need

to further emphasize global access to influenza vaccine, including the establishment of sustainable international influenza vaccine production capacity in resource-limited countries.

Summary of Key Priorities:

- Develop strategies to guide the provision and/or receipt of international assistance in order to limit or reduce the negative public health and social impact of an influenza pandemic (HHS lead: ASPR and OGA; Target Date: September 2013);
- Work with international partners to identify and address logistical, regulatory and legal barriers to the international sharing of medical countermeasures (HHS lead: ASPR; Target Date: September 2013);
- Develop strategy/plan and begin implementation to strengthen strategic partnerships focused around the implementation of all eight core public health capacities highlighted in the International Health Regulations (2005) (HHS lead: OGA, ASPR, and CDC; Target Date: October 2013);
- Develop strategy/plan and begin implementation to support partner country systems to identify and share seasonal influenza virus types, subtypes, and information with the global health community (HHS lead: CDC; Target Date: November 2013);
- Develop strategy/plan and begin implementation to assist partner countries to develop new or enhance existing response capabilities to monitor safety, effectiveness, and shortages of MCMs and routinely exercise a multi-sectoral response (HHS lead: ASPR, CDC, OGA, FDA, and NIH; Target Date: November 2013);
- Determine approaches to better support the WHO and WHO Regional Offices in their efforts to prepare for and respond to an influenza pandemic (HHS lead: ASPR, CDC, OGA, FDA, and NIH; Target Date: December 2013);
- Develop strategy/plan and begin implementation to work with international partners to foster development of public health surge capacity in support of pandemic response (HHS lead: CDC; Target Date: December 2013);
- Work with partner countries to enhance their human resource capacity and work toward the establishment of comprehensive national workforce plans (HHS lead: CDC; Target Date: December 2013);
- Develop strategy/plan and begin implementation to collaborate with partner countries in developing or enhancing nationally-supported surveillance systems capable of identifying and responding to an outbreak of influenza caused by a novel virus with pandemic potential (HHS lead: OGA and CDC; Target Date: December 2013);
- Develop sustainable approaches to ensure international access to pandemic influenza vaccine, including collaboration with WHO and other international partners on development of the new Global Action Plan for Influenza Vaccines (GAP II) (HHS lead: OGA, FDA, and ASPR; Target Date: January 2014).

CONCLUSION

As the 2009 H1N1 pandemic demonstrated, influenza pandemics are unpredictable events. Attention to preparedness activities and investments cannot relax simply because the world recently experienced a pandemic. Because pandemics arise infrequently, the place and time of the next pandemic cannot be anticipated, thus it is critical that pandemic influenza preparedness activities continue. The world's more recent influenza pandemics (1918, 1957, 1968, and 2009) demonstrate that time between pandemics can vary widely.

Investments over the last decade provided a solid foundation for the 2009 H1N1 response. Now, post-2009 H1N1, those preparedness strategies and plans need to be adjusted to incorporate real-world experiences and recent technological advances. Influenza virus detection must be strengthened, and work remains to increase the nation's medical and public health surge capacity. Research must continue on novel antiviral drugs and new vaccine technologies. Community mitigation measures need to be refined, and an accompanying decision-making framework needs to be developed. Development of MCMs, including vaccines, must progress and be sustained, and associated utilization strategies need to be continually assessed and updated to reflect sound, data-driven advances. Updated communications strategies and planning are necessary to support a successful response and ensure the public receives timely, relevant, and actionable information. To help ensure the success of these efforts, attention to administrative support areas, and international partnerships and collaboration are essential. All of these activities should be routinely exercised to help ensure familiarity with processes and procedures, and to help strengthen relationships among key response partners. Because pandemic influenza represents not just a health threat, but also a threat to all aspects of our society, a comprehensive whole-of-community⁴⁰ approach to preparedness remains an important component of successful pandemic preparation.

Moving forward, HHS will continue to address the key priorities presented in this plan and aims to have accomplished significant progress by the deadlines listed for each key priority. We cannot accomplish most of these items alone, and will continue to partner with stakeholders at the federal, state, local, tribal and territorial levels, as well as at the private, non-profit, and community levels to achieve these goals. In the near future, a companion implementation plan will be created to guide more detailed and specific planning efforts.

⁴⁰ "Whole-of-community" refers to all levels of government, the private and nonprofit sectors, and individual citizens, including families and communities.