An HHS Retrospective on the 2009 H1N1 Influenza Pandemic to Advance All Hazards Preparedness

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EXECUTIVE SUMMARY

This report is intended to stimulate discussion within HHS, with other federal departments and across relevant organizations—both governmental and non-governmental—about how to build upon the successful elements of the response and concretely address areas that warrant improvement. Every function, activity, role, and area of responsibility involved in the response, no matter how successful, represents a potential area for improvement. It is important to keep a sense of balance in mind, in that even successes can be improved upon, and even areas identified for improvement often had positive attributes. Discussions, accompanied by careful analysis of scientific evidence, can inform concrete actions to improve pandemic and all-hazards preparedness. This report represents an early step in a multifaceted improvement process that will require continued participation by the public, and health and preparedness officials at all levels, both public and private.

On April 15, 2009, the Centers for Disease Control and Prevention (CDC) in partnership with the Department of Defense (DOD) detected an influenza A in a 10 year old participating in an evaluation of a prototype point-of-care influenza diagnostic device, and that could not be subtyped by the study device; subsequent testing revealed an influenza virus never identified before. Two days later, a second California child who was participating in an influenza surveillance project was also found to have a very similar strain of influenza virus. These two new strains of influenza were, however, radically different from other known circulating seasonal influenza strains. They contained genes from at least two viruses of swine origin that were not known to be circulating among any herds of swine in the United States. An intensive and extensive epidemiological investigation was launched and by Thursday, April 23, additional cases were reported in Texas and California, along with recognition of earlier cases in Mexico. By the following Saturday, April 25, cases had been detected in Kansas, Ohio, and New York. By the end of the month, it was clear that the novel new strain of influenza also contained genes from an avian flu strain. This strain had crossed hosts from swine to humans and appeared to have the potentially dangerous capability of human-to-human transmission.

The 2009 H1N1 influenza pandemic, which was declared by the World Health Organization (WHO) in June 2009 and officially ended in August 2010, provided an important test of our nation's preparedness activities and our ability to respond and adapt to a large-scale, protracted public health emergency with the potential for enormous health consequences. For the first time since 1968, we faced the prospect of a pandemic influenza virus that could have had an enormous impact on morbidity and mortality, as well as on our nation's economy. The pandemic occurred at a time when a severe economic downturn was stretching public and private resources. In addition, the federal government was in the midst of transitioning to a new administration, adding further challenges to the pandemic response.

It is appropriate for the Department of Health and Human Services (HHS) to step back and examine which aspects of our preparedness and response worked well and which did not, as well as which elements of our preparedness were not stressed in our response to the 2009 H1N1 pandemic, but could be in a very severe pandemic as experienced in 1918. A comprehensive retrospective examination can help the nation learn from its experiences and improve its

response capabilities before it confronts the next pandemic or other public health emergency. This report is one step in the process—describing the results of a review by key participants in the 2009 H1N1 response and identifying key successes and opportunities for improvement. This review drew on multiple data collection methods (i.e., document review, electronic survey, key participant interviews, and webinars), allowing a wide range of federal and non-federal participants with designated roles in the response to share their perspectives.

This document is meant to serve as a springboard for dialogue. These perspectives and views are recorded as reported and have not been prioritized; the sequential numbering of the Retrospective's lists of Successes and Opportunities for Improvement are not intended to be interpreted as being in priority order. The retrospective relied on a convenience sample to gather the personal anecdotes and perceptions of individuals involved in the response to stimulate discussions that will improve not just future pandemic responses, but all-hazards preparedness as well. An evaluation team recorded but did not audit or study the activities discussed.

The results of the review are organized according to the following four areas of focus, (referred to as "pillars") as outlined in the *National Framework for the 2009 H1N1 Influenza Preparedness and Response* (the Framework) issued by the White House:

- Surveillance
- Mitigation Measures
    - Addressing Medical Needs
    - Community Mitigation Measures
    - Medical Countermeasures
- Vaccination
- Communications and Education

In addition, the review includes activities that cut across pillars, such as coordination and funding.

Surveillance

As defined in the Framework, surveillance involves enhanced efforts to achieve timely and accurate situational awareness of evolving disease and its impact on critical sectors in order to inform policy and operational decisions. The following are key successes and opportunities for improvement.

Successes

1. The CDC laboratory, in partnership with DOD, rapidly identified and characterized the new 2009 H1N1 virus strain in the first cases in the U.S. and on an ongoing basis assessed viral isolates for evidence of antigenic change and antiviral resistance, providing International Health Regulations (IHR) notification to the WHO as required.
2. The Real Time - Polymerase Chain Reaction (RT-PCR) diagnostic test received rapid regulatory authorization.
3. The CDC laboratory rapidly produced and distributed RT-PCR test kits to U.S. state and international laboratories and made protocols available to all countries and test developers within two weeks of identification of the first case.

4. A system of pre-existing multiple surveillance platforms (some of which were enhanced during the pandemic) together with international relationships, provided a strong foundation for ongoing reporting of the extent of illness, hospitalizations, and deaths.
5. Communication of surveillance information across government agencies and with the public was timely, transparent, and comprehensive.
6. The United States Government (USG) was well poised to obtain and contribute to global influenza surveillance.
7. The identification of risk groups for severe disease, as well as non-risk groups, occurred early in the response and provided a picture as to which segments of the population were likely to be most affected.

Opportunities for Improvement

1. The high volume and pace of demand for surveillance data of various types created challenges in communicating clearly about the different data available and required considerably more time from both surveillance and communications staff than anticipated. Data was reported at intervals across seven time zones encompassing U.S. states and territories, with later time zones reporting data in the following reporting interval. Although communication of surveillance information across government agencies and the public was comprehensive, due to the volume of information there were challenges with timeliness and wide distribution.
2. National-level surveillance information was often not sufficiently granular to characterize rapid changes in influenza-like illness or hospitalizations at the community level or to meet the information needs and demands of local responders and citizens. There may have been missed opportunities to quickly leverage existing sources of surveillance information. It should be noted that the value of the surveillance information from these sources gathered during the early days of a pandemic will be limited due to sparse cases, possibly against the backdrop of ongoing seasonal influenza circulation. However, despite these factors, increased capacity for state and local surveillance is necessary to supplement and contribute to national-level systems.
3. The time needed to collect, validate, summarize, and disseminate surveillance data is challenging. Some requests for data could not be met within a desired time period. This is especially important considering that during the pandemic it proved difficult to incorporate data from multiple sources and techniques to compensate for the limitations of surveillance that were unseen prior to the emergency. Continued, proactive enhancement of existing surveillance systems and development of new systems that rapidly incorporate data would improve the capacity for informed decision making and enable the USG to better address expectations for more timely data.
4. In the early weeks of the pandemic, the surveillance case definition was adjusted in response to increasing knowledge about the 2009 H1N1 virus. These changes were appropriate to improve surveillance for cases of pandemic influenza, but use of case definitions primarily for surveillance rather than clinical care was not communicated clearly to the clinical practices community. Additionally, diagnostic tests for accurately detecting influenza, especially for confirming 2009 H1N1, were not accessible and led to

frustration within the clinical community due to their lack of availability. The low sensitivity of commercially available rapid antigen detection tests led to misdiagnosis and under-treatment of people with 2009 H1N1 influenza. In addition, frequent changes in the case definition created challenges in data collection and interpretation.

5. Monitoring use of clinical care services at a national level was challenging. Surveillance systems to perform this kind of surveillance, especially in a time frame that can inform decision making regarding management of the public health response or clinical care, are underdeveloped and need to be in place prior to a more severe pandemic. Although some desired an assessment of health care system stress at the national level, health care system monitoring information was largely available at the local level and supported local decision making. Not all data needed at the local level is necessary for decision making at the national level. Further work should identify the national level information needs regarding health care system stress.
6. Modeling efforts have inherent limitations but still contributed to decision making. Closer collaboration among modelers, decision makers, interagency operational units, and data collectors may produce models better informed by real data. In turn, this would allow specific policy questions to be addressed more directly.
7. The 2009 H1N1 pandemic highlighted the need for continued work to close gaps in the capability of the global surveillance network to detect emerging novel human pathogens.
8. Reviewing the 2009 H1N1 pandemic response is an opportunity for the USG to better define the roles and responsibilities of federal agencies regarding surveillance, situational awareness, and communication with government leaders, including Congress and the White House. The roles and responsibilities for communicating with the DOD and Departments of State (DOS) and Homeland Security (DHS) during a public health emergency could also benefit from clarification.
9. There is a need for more timely, data-driven clinical guidance regarding the best methods of treatment for seriously ill, hospitalized patients in an evolving public health emergency. HHS attempted to use existing intensive care unit research networks to obtain near real-time data on the clinical course of seriously ill hospitalized patients. However, during 2009 H1N1 many proposals for emergency research presented for consideration to IRBs were relatively incomplete, frequently failing to distinguish between identifiable and deidentifiable data and causing delays in approval. Mechanisms might be considered to address the need for rapid IRB approval for clinical research in the future, which might include a single national IRB during public health emergencies.

Mitigation Measures – Addressing Medical Needs

The mitigation pillar includes interventions to slow the spread of illness and reduce the impact of infection and illness on individuals and communities. As defined in the Framework, addressing medical needs involves ensuring that science-based guidelines and operational capabilities are in place to enable communities to provide for the medical needs of the population in a potentially resource-constrained setting.

Successes

1. The Centers for Medicare & Medicaid Services (CMS) issued guidance and approved the first Section 1135 waiver request within 24 hours of the President's declaration of an emergency under the National Emergencies Act on October 23, 2009. Section 1135 waivers relaxed certain medical care provider requirements in the event health care facilities became overwhelmed.
2. HHS rapidly developed a complete inventory of all available ventilators nationally, and was able to determine there was an ample supply of ventilators to meet national need with respect to the severity of the pandemic. The inventory included information about which ventilators could be used for small children, since this group was potentially at high risk for needing ventilators and not all ventilators can be used for them. The inventory revealed that there were sufficient pediatric-capable ventilators nationwide for the severity of the 2009 pandemic; however, regional quantities varied dramatically so some regions could have been vulnerable to pediatric ventilator shortfalls had the pandemic severity changed. Federal contingencies for such circumstances were developed due to these actionable inventory data. HHS also made available online training regarding how to use the ventilators in the Strategic National Stockpile (SNS), should they be needed.
3. The Institute of Medicine (IOM) letter report, *Guidance for Establishing Crisis Standards of Care for Use in Disaster Situations* (IOM, 2009), was an important step in development of plans for use should needs exceed available resources. The report was made available to ASPR and was used to help facilitate overall crisis planning.
4. Although the medical care guidance for clinicians was high quality, consistent and based on scientific evidence, frequent updates may have caused some confusion among patients and clinicians, and may have contributed to less than optimal use of antiviral drugs.

Opportunities for Improvement

1. Clinical triage algorithms for medical providers were disseminated in the provider community. The "H1N1 Flu Self-Evaluation," designed to help individuals choose whether to seek medical care or stay home if they had symptoms consistent with 2009 H1N1, was made available on flu.gov. Further analysis of self-assessments such as the "H1N1 Flu Self-Evaluation" is needed to determine their utility.
2. The 2009 H1N1 pandemic did not fully test the health care system's ability to meet a surge in demand for care. There was no national-level, real-time system in place to assess facility stress and track/monitor resources. Attempts made to retro-fit HAvBED, a national bed tracking system, to assess facility stress need further evaluation. The amount and kinds of data required from local communities for federal decision making should be re-evaluated.
3. The 2009 H1N1 experience highlighted the need for more complete medical surge guidelines and standards for health care providers, particularly for communities to develop vetted plans for the provision of high quality, safe clinical care in a resource-constrained environment appropriate to state and local circumstances.

4. Two declarations are necessary before the Secretary of HHS may invoke her authority to grant 1135 waivers under the Social Security Act, one by the Secretary of a public health emergency under the Public Health Service Act, and a second by the President of an emergency or disaster under the Stafford Act or National Emergencies Act.

Mitigation Measures – Community Mitigation Measures

As noted above, the mitigation pillar focuses on slowing the spread of illness and mitigating the impact. In particular, community mitigation involves the promotion of measures, such as social distancing, aimed at reducing disease transmission.

Successes

1. Guidance for a range of community mitigation measures was released quickly and coordinated across multiple federal agencies.
2. Guidance on school closure was responsive to changes in the understanding of the pandemic severity.
3. Prior relationships and planning between the health and education sectors, both within the USG and at the state, local, and tribal levels, facilitated the response.
4. Congruent with WHO recommendations, the quick USG decision to keep borders open and minimize travel restrictions avoided disruptions of travel and trade, avoided panic and stigma, and conserved resources.
5. The USG raised awareness about respiratory etiquette and hand hygiene and surveys indicated that use of these behaviors increased.
6. CDC and the Department of Education (ED) developed a system to collect information on school closures related to 2009 H1N1 influenza.
7. While some states had limited capacity for storing antiviral medications and personal protective equipment (PPE) deployed from the SNS, this did not appear to hinder storage. Ultimately, states were able to accommodate SNS supplies.

Opportunities for Improvement

1. 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, 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—in large part because only the more severe cases are initially visible—a PSI Framework needs to remain flexible enough so that accurate and appropriate mitigation measures may be taken at times of uncertain severity. Evidence to inform policy decisions related to community mitigation measures is limited, and a stronger evidence base is needed.

2. Although information on school closures was available, systems to track workplace or school absenteeism due to 2009 H1N1 influenza do not exist. To determine the full impact of a more severe pandemic, a system to monitor its effect on the workforce is needed.
3. The evidence base to support guidance on the appropriate level of respiratory protection (N95 respirators or surgical masks) to prevent occupational acquisition of 2009 H1N1 influenza by health care workers was insufficient. This lack of evidence made developing science-based guidance difficult and controversial. In some cases, the PPE that was delivered was different from what those recipients were familiar with, therefore requiring that users undergo time-consuming fit testing with the new product.

Mitigation Measures – Medical Countermeasures

Medical countermeasures, as defined in the Framework, include the appropriate use of antiviral medications and respiratory protection. Vaccines and diagnostics, also medical countermeasures, are addressed separately.

Successes

1. Antiviral medications were administered at a higher rate than ever before.
2. Antiviral medications were rapidly distributed from the SNS to states and territories.
3. Guidance on the appropriate use of antiviral medications was timely and evidence-based, and changed as new information became available.
4. Emergency use authorizations (EUAs) for the antiviral medications oseltamivir (Tamiflu®) and zanamivir (Relenza®) that expanded their age and patient population indication were issued in a timely fashion.
5. FDA issued an EUA authorizing the use of the unapproved intravenous antiviral medication peramivir in certain hospitalized patients with known or suspected 2009 H1N1. Peramivir development is part of the ASPR Office of Biomedical Advanced Research and Development Authority (BARDA) pandemic preparedness.
6. With the exception of pediatric suspensions, the commercial distribution system in the U.S. was generally capable of keeping up with demand for antiviral medications.

Opportunities for Improvement

1. The national supply of antiviral medication in a form optimal for pediatric populations (i.e., premixed suspension), including that in the SNS, was insufficient, especially given the epidemiologic profile of the 2009 H1N1 pandemic.
2. It is important to develop a monitoring and research system adequate to support the study of uptake, safety, and efficacy of antiviral medications after release from the SNS to public providers, or by states from their own stockpiles.
3. Research is important to produce interpretable information on safety and efficacy of antivirals before and during a pandemic. There were limited mechanisms to study the safety and efficacy of the medications made available under an EUA. As a result, while the approximately 2100 treatment courses of the intravenous antiviral medication

peramivir were distributed, there is insufficient information regarding its effectiveness against severe 2009 H1N1 influenza to support approval. Other factors contributing to the lack of information regarding peramivir effectiveness included: the lack of protocols and clinical trials consortia prepared to implement the collection and analysis of information regarding the efficacy of peramivir; restrictions on follow-up peramivir research because of contractual agreements associated with the antiviral medication, and no mechanisms were in place to conduct research on these types of products during an emergency event before the pandemic occurred.

4. States used different models to distribute antiviral medications received by the SNS. These different approaches in distribution resulted in greater availability and timeliness of antiviral drugs in some states compared with other states. The absence of an accurate and comprehensive monitoring system across the nation for antiviral drug distribution from state and local stockpiles prevented determination of the effectiveness of this mitigation measure and provides an opportunity to develop such a system to collect data in real time during public health emergencies.
5. A policy for international deployment of oral and intravenous antiviral medications had not been developed in advance of the 2009 H1N1 influenza pandemic, creating challenges for the deployment process.

Diagnostics

Accurate diagnosis is a critical element of clinical management. During the 2009 H1N1 pandemic, there was a great demand for testing. Highly sensitive and specific reference diagnostic tests were available at public health laboratories and were used for surveillance of the 2009 H1N1 pandemic. These tests were able to meet the initial surge and provide confirmatory laboratory testing for clinical specimens. CDC supplied reagents to these laboratories for confirming initial cases, many of which were detected by Polymerase Chain Reaction (PCR) tests. During the course of the pandemic, CDC also provided reagents for monitoring prevalence and virus changes, monitoring disease characteristics, and reporting results for specimens referred by clinical laboratories. Because of the time delay in shipping specimens to these reference laboratories and the overwhelming number of tests being requested, a more widely available sensitive and specific test would have helped meet the clinical demand for testing.

Successes

1. In order to meet the need for diagnostic tests for the detection of the 2009 H1N1 influenza virus, FDA authorized 18 such tests through the Emergency Use Authorization mechanism. Laboratory test developers were able to configure new assays to identify infections caused by 2009 H1N1 influenza viruses while manufacturers were able to receive EUAs for the assays, enabling distribution to multiple labs. The first EUA for the CDC RT-PCR assays was available almost immediately for use in public health labs already performing seasonal influenza subtyping using the same test system. As a result of the EUAs, more diagnostic tests became available and the public health laboratories were able to concentrate their efforts on surveillance activities.
2. Some of the authorized tests were developed by clinical laboratories for their own use. These tests are known as laboratory developed tests (LDTs). Test systems receiving later EUAs became available after July 2009 and were used primarily during the second wave

in the fall. EUAs were issued for some LDTs later during the fall of 2009. With the exception of the EUA for the CDC RT-PCR assays, other EUAs were not available during the peak demand in the late spring and early summer of 2009.

3. During the first week of May 2009, many laboratories were able to develop new assays for 2009 H1N1 virus using sequence information quickly released by the CDC. Many of these laboratories collaborated with public health laboratories to exchange information and to validate test results from these newly developed tests.
4. Experimental point-of-care diagnostic devices under development with support from BARDA and CDC detected the first cases of 2009 H1N1 in the U.S.

Opportunities for Improvement

1. Accessible point-of-care diagnostic tests for 2009 H1N1 influenza were not sufficiently sensitive for accurately diagnosing influenza in patients with respiratory symptoms.
2. The greatest diagnostic challenge remains at the point of clinical care. The absence of readily available, rapid, simple, and highly sensitive diagnostic tests which could detect the 2009 H1N1 virus made infection control more difficult.
3. Testing accuracy for detecting a novel influenza virus such as 2009 H1N1 is a concern both in terms of reliability for use in surveillance and as a diagnostic tool.

Vaccination

The vaccination pillar includes actions to develop, secure, and deliver safe and effective vaccines and to make ready a national vaccination program that enables the U.S. to begin voluntary immunization if recommended, as well as to monitor the use, impact and safety of vaccines in the population. This pillar also includes those actions taken to deploy vaccine internationally.

Vaccine Development and Production

Successes

1. Once the virus causing the initial pandemic was known, development of a vaccine candidate virus and its distribution to manufacturers progressed rapidly, both domestically and internationally.
2. HHS' large investments in pandemic preparedness, including existing contracts and ongoing relationships with vaccine manufacturers, enabled manufacturers to develop and establish the safety and immunogenicity of the 2009 H1N1 vaccine in fewer than six months, and in quantities sufficient for the U.S. population—the stated goal of pandemic planning.
3. HHS quickly established and used a stepwise process to create and then implement a centralized program to distribute vaccine. The process was flexible and was adjusted as the situation evolved.
4. HHS used a rigorous decision-making process and made well-informed decisions as it pertained to stockpiling adjuvant, ultimately deciding not to use adjuvant in the vaccine.

5. The National Institutes of Health (NIH) and BARDA-supported vaccine manufacturers rapidly conducted clinical studies as soon as vaccine was available, providing valuable information needed to approximate required doses before the vaccination program began, as well as insights into the vaccine's safety profile.
6. The 2009 H1N1 vaccine had a similar safety profile to seasonal influenza vaccines. Under the auspices of the National Vaccine Advisory Committee (NVAC), federal public health officials created the H1N1 Vaccine Safety Risk Assessment Working Group and implemented a multifaceted, rigorous, and transparent program that included frequent public communications of its findings.
7. The Food and Drug Administration (FDA) rapidly approved monovalent 2009 H1N1 vaccine as a "strain change" under the established regulatory framework for licensure of influenza vaccines.
8. As recommended by senior public health leaders following the 1976 swine flu episode, many public advisory boards (including the National Biodefense Science Board, NVAC, Advisory Committee for Immunization Practices, and Vaccines and Related Biological Products Advisory Committee) were utilized successfully during the 2009 H1N1 pandemic for consultation on numerous vaccination policy and logistics issues.

Opportunities for Improvement

1. The U.S. has depended on egg-based technology that has been in use since the 1950s for the production of influenza vaccines. Although generally reliable, due to unpredictable virus growth this technology may not produce timely vaccine for influenza pandemics. In addition, completing the manufacture and distribution of 2009 – 2010 seasonal influenza vaccine contributed to delays in production and delivery of 2009 H1N1 pandemic vaccine. As a result, even though the six-month goals for initial vaccine delivery were met, most of the vaccine arrived too late to vaccinate much of the public before the pandemic peaked. High vaccine production yields, more modern vaccine design, potency testing and production technologies (such as cell-based vaccines and recombinant vaccines) are essential to accelerate the speed of production and increase the vaccine yield. The speed and reliability of vaccine production is an important consideration for the future; this is especially important when novel strains occur. Improvements—which will take several years to accomplish and were underway but not yet completed when the pandemic occurred—have been mandated by the Pandemic and All Hazards Preparedness Act (2006) and by other statutes and Executive Branch directives.
2. Early projections from BARDA regarding timing of vaccine supply changed frequently and were inaccurate. This led to public confusion and temporary erosion of confidence in the federal government, and created challenges for the planning and execution of local vaccine administration efforts. However, as the just in time system began to function better, later BARDA projections – which were based on information supplied weekly from the vaccine manufacturers themselves – increased in accuracy.
3. Vaccinators had to work with multiple formulations of vaccine, as well as with different age and risk group indications. In addition, vaccines with different age and risk group indications arrived at different intervals. While this was an unavoidable by-product of

the effort to use all existing seasonal influenza vaccine manufacturing platforms, available fill/finish lines, and approved indications to make as much vaccine available as quickly as possible, it resulted in confusion and challenges in planning a mass vaccination program.

Vaccine Allocation, Distribution, Administration, and Monitoring

Previous definitions of priority populations to receive initial vaccine when supply was limited were not applicable to the epidemiology of the 2009 H1N1 pandemic. Because of this, the Advisory Committee on Immunization Practices (ACIP) identified priority groups early in the pandemic, and CDC supported consistent messaging regarding priority groups. Pandemic planning guidance had suggested that some 'mission essential' federal workers and other critical infrastructure personnel would also be prioritized for early vaccination in order to maintain essential services.

Successes

1. Building on the existing Vaccines for Children (VFC) Program vaccine distribution process, CDC implemented a federally financed and controlled distribution process that was scalable and used procedures and systems already familiar to many providers. Over 126 million doses of monovalent 2009 H1N1 vaccine were delivered to nearly 70,000 locations, over 330,000 total shipments, with 95 percent of orders received within 48 hours of ordering. The number of providers enrolled to offer vaccine, greater than 120,000, was nearly triple the number enrolled in the VFC Program.
2. The decision for the USG to purchase all 2009 H1N1 vaccine for the American public provided greater control over vaccine distribution.
3. The vaccine safety monitoring system was strengthened to provide more robust monitoring of the safety of 2009 H1N1 vaccine than had previously been possible. Status reports on vaccine safety were regularly reported to the public through the NVAC review process. The resulting safety monitoring and reporting system was effective and benefited from strong collaboration across agencies.
4. State and local health departments used approaches to vaccine delivery that had been piloted and used effectively during previous influenza seasons, including the use of school-located clinics and retail pharmacies. The pandemic response resulted in valuable new information about opportunities and challenges in this type of interface between public health and other public and private organizations.
5. There were higher immunization coverage rates among children and pregnant women—two critical priority groups—than during past seasonal influenza epidemics. ACIP recommended 2009 H1N1 vaccine priority groups, which were supported by high quality data, remained in place for the duration of the pandemic, and were well-received by the public. The ACIP also provided a sub-prioritization plan that could be adapted to local circumstances.

Opportunities for Improvement

1. Because vaccine supply was initially limited, local health departments needed to make decisions about sub-prioritization of groups based upon ACIP guidance regarding these

groups. As a result, there was considerable local variation regarding eligibility for vaccine, creating confusion among the public.

2. Information collected during and after the pandemic response indicated that racial and ethnic minorities were vaccinated at comparatively lower rates than other groups—a serious, ongoing issue for seasonal influenza vaccination, especially in adults. Because of its impact on morbidity and mortality, this disparity merits continued evaluation and action by federal, state, tribal, local, and territorial authorities.
3. As one method of estimating coverage, telephone surveys were used to produce periodic national estimates of vaccine coverage. However, due to limited sample sizes these estimates did not provide information at the state level until late in the vaccination program. State level estimates by age and risk subgroups were provided to CDC leadership and states in January 2010. New analysis techniques are now available to provide earlier release of more reliable state level estimates in future outbreaks.
4. During the pandemic, health care workers had relatively low rates of vaccination. This is consistent with historic data collected on health care workers during seasonal influenza. While there have been gradual improvements, this remains an area in need of continued action and evaluation.
5. During the pandemic, real-time information on the population that had actually received 2009 H1N1 vaccine was limited to weekly national estimates of the proportion of children, adults, and persons in ACIP target groups versus other groups; estimates by race and ethnicity were available in October 2009. Additionally, state level data were available monthly based on the BRFSS sampling design.
6. A policy and plan for recovery, donation and, if necessary, disposal of unused pandemic vaccine had not been developed in advance of the 2009 H1N1 pandemic.
7. Although the federal government considered using the SNS Points of Dispensing (POD) model for vaccine distribution, it decided to build upon the Vaccine for Children (VFC) program. Local and state health officials expressed concerns that the public health care infrastructure would be unable to support the vaccination campaign without substantial participation from the private sector.
8. The HHS Pandemic Influenza Plan did not formally address drug delivery devices such as needles and syringes as critical components of a vaccination campaign. As a consequence, there were no existing requirements for ancillary supplies until after the pandemic had begun.

Communication and Education

This pillar involves the development and implementation of a coordinated campaign to promote unified action across all levels of government, the private sector, the health care sector, faith-based and community-based organizations, and individuals.

Successes

1. Communications with the public were regular, balanced, transparent, and unified, which built confidence and trust with much of the public. Flu.gov was an excellent centralized source for those with access to online services.

2. Communication, information sharing, and coordination across response organizations overall were very good but offer opportunities for improved efficiencies.
3. Social media and networking were used to disseminate messages to broad audiences.
4. The simple "wash your hands, cough in your elbow, stay home if sick" flu prevention message was enormously effective in raising awareness about the importance of handwashing in preventing the spread of germs. Its public acceptance may have, however, limited recognition and compliance with vaccine messages that followed.
5. There were frequent and open lines of communication related to various aspects of the 2009 H1N1 pandemic among a wide range of participants.

Opportunities for Improvement

1. Some communications with both the public and participants were too complex and did not use clear and simple language.
2. Communications did not adequately reach all desired minority, disadvantaged and other hard-to-reach populations.
3. There were ongoing questions about the severity and seriousness of the pandemic that affected public perceptions, especially since the second wave of the pandemic was not as severe as predictions circulating in the media. This led to some public skepticism about the seriousness of the pandemic and the need for vaccination.
4. Rapidly changing information on 2009 H1N1 influenza challenged the federal government's ability to provide consistent public health information and to support clinical practice.
5. Different components of HHS awarded contracts for media campaigns to promote vaccination. The campaigns had different themes but in some cases resulted in duplicated efforts. Consideration should be given to designating one clear lead for media campaign activities on behalf of the Department in the future.
6. State partners need to be informed about federal media campaign plans much earlier and updated regularly on their status, so they can integrate these plans effectively with their own efforts and access products from the federal campaign more quickly.

Selected Cross-cutting Issues

A wide array of activities and issues associated with the response to the 2009 H1N1 influenza pandemic cannot be neatly associated with a single pillar. Rather, they cut across several or all of the pillars. These include, but are not limited to, issues around planning, coordination, funding, staffing, and federal workforce protection.

Successes

1. Prior pandemic preparedness planning, including the Public Health Emergency Preparedness (PHEP) cooperative agreements and other work to build capacity of state and local public health departments, laid the foundation for an effective response to the 2009 H1N1 pandemic at federal, state, territorial, tribal, and local levels.

2. Overall, communication, information sharing and coordination across response organizations were very good, but offer opportunities for improved efficiencies.
3. The pillar structure used to organize the response functioned effectively at the operational level and helped avoid information and decision silos.
4. Utilization of pre-established relationships with international partners was instrumental in sharing information and coordinating international aspects of the response to the 2009 H1N1 pandemic.
5. HHS was able to rapidly notify WHO of the 2009 H1N1 virus as a potential Public Health Emergency of International Concern (PHEIC) under the IHR (2005).
6. From the beginning of the pandemic, HHS communication with WHO was effective and enabled coordination on issues such as international vaccine deployment.
7. Early in the pandemic, ASPR, OGHA[1], and HSC recognized problems associated with not having policies in place to guide international deployment of medical supplies and equipment, and cooperated to rapidly develop the Homeland Security Council sub-Interagency Policy Committee on Supporting H1N1 International Requests and Engagement (SHIRE) Framework that provided principles, criteria, and a decision-making process for international deployments.
8. HHS successfully deployed nearly 17 million doses of H1N1 vaccine to the WHO to assist in the international response to 2009 H1N1.

Opportunities for Improvement

1. While there was extensive planning for many areas of the pandemic, one area that requires additional planning is the operational aspects of vaccine administration, as opposed to simple dissemination to communities. Going forward, such planning, which must be done in partnership with state, local, tribal and territorial partners, will be critical.
2. Federal and state mechanisms for obtaining and distributing public health emergency funds to state and local governments were burdensome. In particular, the requirement of multiple separate applications with separate guidelines for each state to obtain Public Health Emergency Response (PHER) grants, and the time required for federal approval of the applications, affected states' capacity to respond effectively.
3. The many federal entities involved in USG workforce protection efforts experienced challenges in the early stages of the response, which may have generated disparities in protective actions across departments and job types.
4. The extended response placed a heavy burden on the workforces at the tribal, local, state, and federal levels.
5. Although coordination with international partners was successful in many ways, the pandemic exposed significant areas for improvement in coordination among federal entities for planning and communication with these international partners.

[1] The Office of Global Health Affairs (OGHA) became the Office of Global Affairs following the 2009 H1N1 Pandemic.

6. In some cases, coordination across all levels of government, private sector and emergency health response organizations was challenging.
7. Given the uncertainty regarding the severity and the ultimate impact of the H1N1 pandemic, decisions regarding the appropriate level of funding were challenging, particularly as they had to be made in the first days and weeks of the pandemic. At the outset, a consensus emerged that a vigorous, federally-funded response was needed. As the pandemic unfolded through the summer and fall of 2009 and the epidemiology of infection with the 2009 H1N1 virus became clear—high attack rates in children and much lower virulence than pandemic planning scenarios—the uncertain risk of mutation of the 2009 H1N1 virus to a more virulent form remained. With hindsight, it is easy to question whether the pandemic response was too costly, forgetting that current science had limited capability to foretell the final course of the pandemic. Better communication regarding our uncertainty in predicting how public health emergencies evolve might help reduce this type of retrospective assessment. Moving forward, planning should include a framework for the types of resources that may be needed and a range of estimated costs.
8. Prior to the start of the pandemic, USG did not have in place policies or staff sufficient to guide its responses for international requests for assistance. Requests for vaccine, antivirals, diagnostic kits, and medical assets and supplies were received by multiple federal departments and agencies, but the USG did not have a centralized process in place to coordinate the requests.
9. The provision of international assistance was complicated by a variety of legal, export, regulatory, and funding issues.
10. HHS received a number of bilateral requests for vaccine from other countries, and HHS did deploy vaccine to the WHO. However, although the U.S. was a global leader in 2009 H1N1 international vaccine deployment, there were few established policies and principles to guide international deployment in advance of the 2009 H1N1 pandemic. Policies and principles are needed to guide international deployment sharing of available medical countermeasures, including pandemic vaccine, and systems for rapid exchanges of safety and efficacy data, during emergency conditions.
11. Policies and principles to guide international deployment of medical countermeasures, including pandemic vaccine, are needed. In addition, strategies to increase international access to pandemic vaccine and decrease dependence on donations need to be further developed and implemented.

Conclusion

The overall HHS response to the 2009 H1N1 influenza pandemic was successful. There is a range of specific areas for performance improvement to ensure the nation's ability to prepare for, respond to, and recover from a future pandemic or other public health emergency.

Prior investments in pandemic preparedness and response and established relationships with key institutional partners at all levels of government facilitated the success of the response. Several of the investments laid out in the plan paid off in concrete ways, including strengthening key capacities and capabilities, such as domestic influenza vaccine manufacturing capacity, stockpiling and distributing antiviral medications; streamlining and improving the clarity of

public communications; defining roles and responsibilities; building important relationships within and across organizations; distributing RT-PCR reagents and supplies to public health labs; and releasing sequences for use by developers and other laboratories.

Some elements of existing plans, including the May 2006 National Strategy for Pandemic Influenza Implementation Plan (Homeland Security Council, 2006), were more strategic than operational, and others were too locked into specific planning assumptions, such as the severity of the disease.

The 2009 H1N1 pandemic tested some aspects of the nation's response capabilities yet did not address others. For instance, many children, young adults, and individuals with chronic health issues experienced serious health issues to a higher degree than during seasonal influenza epidemics. Had the virus strain been more virulent, difficulties in responding to these issues could have posed major public health, economic, and societal problems.

This report may serve as the foundation for the next stage of pandemic planning, which is already underway. It is important to understand that the occurrence of the 2009 H1N1 pandemic has not reduced the risk of a future, severe pandemic or altered the timeframe on which it may occur. For that reason, acting now on lessons learned through this and other reviews of the 2009 H1N1 pandemic experience is imperative.

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CHAPTER 1: INTRODUCTION

During a 48-hour period in April 2009, two California children living 130 miles apart were separately identified by the Centers for Disease Control (CDC) in partnership with the Department of Defense (DOD) as having very similar strains of a new subtype of influenza virus. One child happened to be participating in a clinical study on influenza, and the second child was part of an influenza surveillance project. The two strains of virus were radically different from other known circulating seasonal influenza strains, containing genes from at least two viruses of swine origin and one virus of avian origin. These influenza strains, however, were not known to be circulating among any known herds of pigs in the United States.

The epidemiological investigation that followed found that by Thursday, April 23, additional cases were reported in Texas and California, along with recognition of earlier cases in Mexico. By that weekend, cases had been reported in Kansas, Ohio, and New York. By the end of the month, it was clear that a novel new strain of influenza had crossed hosts from swine to humans, and had the alarming potential for human-to-human transmission.

The 2009 H1N1 pandemic provided an important test of our nation's ability to respond to a large-scale public health emergency. For the first time in a generation, we faced the prospect of a pandemic influenza virus that could have had an enormous impact on morbidity and mortality, as well as on our nation's economy. The pandemic also occurred at a time when public and private resources were being stretched due to a severe economic downturn.

As is the case with many events of historic proportions, the 2009 H1N1 pandemic presented both challenges and opportunities. On the one hand, the pandemic immediately raised questions and issues that had the potential for enormous health consequences. Could its spread be minimized through social distancing and other strategies while safe and effective vaccines were being produced? Would vaccines be produced in sufficient time and quantities to meet national—let alone worldwide—demand? How well did pandemic planning in recent years prepare us to respond promptly and effectively?

Conversely, the pandemic provided an opportunity to apply lessons learned from past pandemics and other public health emergencies to prevent or mitigate potential problems. Largely as a result of the accelerated investment in public health emergency preparedness following the events of September 11, 2001 and the subsequent anthrax attacks, as well as the rapid global spread of the highly lethal H5N1 virus, the nation has invested heavily in the infrastructure necessary to confront a myriad of health threats. Over the last half-decade, the United States Government (USG) allocated large amounts of time, energy, funding, and resources to prepare for a severe influenza pandemic—albeit a different one than occurred in 2009. As a result, the federal government had an explicit strategy and implementation plan in place when the 2009 H1N1 pandemic emerged. Taken together,

the expertise garnered through experience, explicit planning, exercises, and relevant resources acquired in recent years significantly increased the likelihood of a robust response.

Nevertheless, it is appropriate to step back and examine which aspects of the 2009 H1N1 pandemic response worked well, in addition to which aspects of the response offer opportunities for improvement and warrant further interagency discussion. A comprehensive retrospective examination can help the nation learn from its experiences and improve its response capabilities before the next pandemic or public health emergency. This report is one step in the process; it describes results of a review of the 2009 H1N1 pandemic response—conducted from January 2010 through June 2010—to identify key successes and opportunities for improvement as perceived by a range of participants. The purpose of this report is not to establish facts or recommend policy changes, but to serve as a springboard for a performance improvement dialogue with the interagency and appropriate partners in order to enhance our preparedness going forward. Thus, the sequential numbering of the Retrospective's lists of Successes and Opportunities for Improvement are not intended to be interpreted as being in order by priority.

Methods and data sources

This section describes the analytic framework used to guide the 2009 H1N1 Retrospective, and the various data sources utilized during the course of the analysis.

Methods

The National Framework for 2009 H1N1 Influenza Preparedness and Response (the Framework, White House 2009), developed by the federal government and released in July 2009**,** served as a guide for organizing The Department of Health and Human Services' (HHS) efforts during the 2009 H1N1 pandemic. Consequently, to maintain consistency, it was also used to guide the data collection efforts and analysis conducted for this report.

The Framework outlines a relatively short list of near-term response activities, organized under four focus areas (referred to as "pillars"): Surveillance, Mitigation Measures (Addressing Medical Needs, Community Mitigation Measures, and Medical Countermeasures), Communication and Education, and Vaccination.[2] Thus, the evaluation of HHS's activities is organized in accordance with these pillars. Activities associated with two or more pillars were considered cross-cutting issues and addressed in the evaluation as such. The Framework defines the pillars as follows:

- **Surveillance**: Enhanced efforts to achieve timely and accurate situational awareness of evolving disease and the impact on critical sectors to inform policy and operational decisions.

[2] Of note, the November 2005 U.S. National Strategy for Pandemic Influenza (NSPI) and the associated May 2006 NSPI Implementation Plan are organized under a different set of "pillars," but the 2009 Framework does not reference the previous strategy or plan, including the previous pillars.

- **Mitigation Measures**: Interventions to slow the spread of illness and reduce the impact of infection and illness on individuals and communities. This pillar subsumes the following strategies:
    - **Addressing Medical Needs:** Appropriate management of the medical needs of patients within the community and after they present to the health care system.
    - **Community Mitigation Measures:** Promote social distancing in an effort to reduce disease transmission.
    - **Medical Countermeasures:** Appropriate use of antiviral medications and respiratory protection.
- **Vaccination**: Actions to develop, secure, and deliver safe and effective vaccines and to ready a national vaccination program to enable the U.S. to begin voluntary immunization if recommended, and to monitor use, impact and safety of vaccines in the population.
- **Communication and Education**: A coordinated campaign to foster a convergence of action across all levels of government, the private sector, the entire health care sector, faith-based and community-based organizations, and individuals.

In addition to collecting information associated with each of the pillars described above, relevant data were gathered on incident management; funding; legal authorities; research, planning, and execution of a national, voluntary immunization program; and coordination and other interactions among federal, state, local, tribal, territorial, and international governments.

Data Sources

To understand both the multiple strengths and areas for improvement associated with HHS's response to the 2009 H1N1 pandemic, a variety of data sources available from January 2010 through June 2010 were reviewed. Sources included a review of available after-action and other reports related to the response, an electronic survey of federal officials knowledgeable about the pandemic and the response, a series of in-depth interviews with key participants, and a set of webinars held with a wide range of participants. Each of these data sources is described briefly below.

Literature Review

As of April 2010, only a limited number of after action-reports, progress reviews and summaries were available for review. Consequently, the literature review was based primarily on several reviews (ASTHO 2010; Li et al. 2010; DHS 2010) and two key reports (PCAST 2009; TFAH 2009b). In addition to these documents, the literature review included media reports, peer-reviewed journal articles, Government Accountability Office (GAO) reports, and tabletop exercises specific to H5N1 or pandemic influenza that had relevance for the federal 2009 H1N1 response.

Electronic Survey

The tool used to field the survey, ExpertLens, is an online method for conducting expert panels. The ExpertLens approach consists of eliciting opinions of experts through an online tool that combines idea generation, estimation, and discussion rounds.

To gather relevant data from federal agency officials who played an active role in the response to the pandemic, a series of electronic surveys were fielded. The first survey presented a set of open-ended questions to 59 federal employees representing a wide range of agencies involved in the 2009 H1N1 influenza pandemic preparedness and response activities. The main objective of the survey was to elicit their perceptions of important successes and areas for improvement in the responses of HHS and other federal agencies to the pandemic. Answers from 32 participants in the idea-generation round were used to formulate close-ended questions for subsequent rounds of the survey.

In the second survey round, a much larger group of participants was asked to evaluate the level of success associated with 63 components of the 2009 H1N1 response activities, using a seven-point scale. In the third round, participants were presented with a statistical summary of the group responses, their own answers to the previous round, and an opportunity to discuss their impressions of the results via anonymous, online discussion boards. In the final round, they were asked to re-evaluate and finalize second round ratings.

Overall, 399 federal agency officials, representing a large number of agencies involved in the 2009 H1N1 influenza pandemic preparedness and response activities, were invited to participate in the ExpertLens process. Of those, 145 submitted their answers in round two, 42 participants contributed to the discussion in round three by starting 10 discussion threads and posting 91 comments, and 75 participants answered round four questions.

Key Interviews

To complement the ExpertLens process, a series of in-depth interviews was conducted with a convenience sample of federal officials from multiple departments and agencies. The purpose of the interviews was to understand in more detail the issues that surfaced in the literature review and the ExpertLens process and to identify any additional issues. In a sense, while the ExpertLens process gathered opinions on *what* did or did not go well during the 2009 H1N1 pandemic, the key interviews focused on *how* and *why* successes or challenges occurred.

A semi-structured interview protocol, organized according to the four pillars, was used to guide the interviews, which typically ran between 30 and 60 minutes. Participants were asked questions related to the successes and areas for improvement associated with each of the four pillars. In addition, participants were asked a set of questions pertaining to coordination and integration, agency roles and responsibilities, public health emergency preparedness funding, statutory authorities, and domestic and international participant engagement.

A total of 154 individuals were interviewed between May 4 and June 25, 2010. Ten interviews were conducted in person and the remainder by telephone.

Participant Webinars

The final data source contributing to this analysis was a series of webinars held with a broad range of participants who played an active role in the response to the pandemic. Participants included federal, state, territorial, tribal, and local officials; representatives from private sector firms; critical infrastructure businesses; and other participants who were closely involved with some aspect of the 2009 H1N1 response. Over 330 individuals participated in 12 webinars held between May 11 and June 15, 2010.

During the webinars, participants received a briefing on the goals and objectives of the 2009 H1N1 evaluation, and were provided with a sample of key successes and opportunities for improvement that corresponded to the four pillars. They received similar information relating to response coordination and integration. Throughout the webinars, participants were given the opportunity to add to the lists of successes and opportunities for improvement, as well as to express their views on other matters related to the response. For large webinars, participants used a "chat function" to communicate their thoughts and ideas. In smaller webinars, an open telephone line was used to solicit participant input. Each webinar lasted between 45 and 90 minutes, and extensive notes were recorded. In addition, to allow for greater input from the participants, webinar participants were encouraged to share any additional comments, stories, and/or relevant documents via email. Over 50 participants took advantage of this opportunity and provided additional information.

Data synthesis

Using the data sources described above, the evaluation team synthesized findings, extracted cross-cutting themes, and compiled lessons learned from the 2009 H1N1 pandemic, focusing on issues that, when addressed, will leave the nation better prepared to respond to a broad range of public health threats. To aid in this effort, qualitative analysis software (ATLAS.ti) was used to code and sort notes, organizing them according to the four pillars and other topics of interest. Two reviewers were assigned to examine all qualitative data for each pillar and develop a list of successes and opportunities for improvement. Reviewers selected issues for inclusion in the report that were mentioned multiple times and/or were thought to have a large impact on the response.

Limitations of methods

This review gathered information and garnered perceptions from a convenience sample of participants, often with divergent views. The evaluation team aggregated and summarized these views and identified key themes. The evaluation team did not evaluate, audit, or study the activities discussed. The report is intended to be a hypothesis-generating activity for further review, not an enumeration of 'facts' about what happened.

Report organization

The remainder of this report is organized as follows: Chapters Two through Seven present findings corresponding to the pillars set forth above—Surveillance, Mitigation Measures (Addressing Medical Needs, Community Mitigation Measures, and Medical Countermeasures), Vaccination, and Communication and Education. Chapter Eight discusses cross-cutting themes that emerged during the course of the analysis, and Chapter Nine presents concluding thoughts.

CHAPTER 2: SURVEILLANCE

Public health surveillance is "the ongoing, systematic collection, analysis, interpretation, and dissemination of data about a health-related event for use in public health action to reduce morbidity and mortality and to improve health" (Thacker 2000). It represents the traditional cornerstone for public health detection and response to endemic and emerging diseases, used both to monitor trends and detect aberrant patterns.

A well-established network of sentinel influenza reporting surveillance sites and the location of pilot testing of advanced laboratory technology converged fortuitously with the occurrence of the first cases in the United States (U.S.) of 2009 H1N1. Coincidentally, and conveniently, H1N1 emerged at the end of the normal October-May influenza season in locations with Real Time- Polymerase Chain Reaction (RT-PCR) subtyping capability and with either ongoing strengthened surveillance, or with clinical evaluations with protocols coordinated with public health to verify findings. Nonetheless, the U.S. surveillance experience with the 2009 H1N1 pandemic revealed both successes and further opportunities to strengthen the surveillance system.

The Framework (White House 2009) delineates the Surveillance Pillar as "Enhanced efforts to achieve timely and accurate situational awareness of evolving disease and the impact on critical sectors to inform policy and operational decisions". The Framework focuses on enhancing surveillance both globally and within the U.S.:

> Appropriate implementation of public health interventions and utilization of medical countermeasures requires situational awareness of disease characteristics and activity. Real time, accurate insight into global influenza activity can help guide decisions to implement mitigation measures and initiate a targeted vaccination program, as appropriate. And there is a requirement for surveillance and analysis of key aspects of domestic disease patterns to assess quickly the extent and severity of disease, and to target and refine our response strategies more effectively.

Timeline of events

While it is now known that cases of 2009 H1N1 influenza had emerged and were spreading in Mexico beginning in March 2009, the first U.S. cases were reported by the Centers for Disease Control and Prevention (CDC) in the April 24 edition of its *Morbidity and Mortality Weekly Report* (MMWR), made available online on April 21 (CDC 2009a). The first two reported cases occurred in children ages nine and ten in different Southern California counties, with onsets of illness on March 28 and 30, respectively. CDC, which is a WHO Collaborating Centre for the Surveillance, Epidemiology and Control of Influenza, was notified of the first case by the San Diego health department on April 13 and received a specimen on April 14. CDC received the specimen from the second case on April 17 from the DOD Naval Health Research Center, which was an investigative site in this study and provided reference testing as well as other advanced testing. CDC quickly confirmed the identification of a novel influenza virus and also genetically characterized its

origins. The point-of-care advanced development effort and the deployment of the CDC RT-PCR reagents was part of an overall increased investment in pandemic preparedness.

By April 26, the World Health Organization (WHO) had been notified of 20 laboratory-confirmed cases in five U.S. states as well as 18 laboratory-confirmed cases from Mexico, with suspected cases in 19 of Mexico's 32 states by that time (WHO 2009a). The Acting Secretary of HHS declared a public health emergency on April 26, 2009. The WHO Collaborating Center on Influenza elevated its pandemic alert level from three (sporadic human cases) to four (small clusters of human-to-human transmission) on April 27. The first recognized laboratory confirmed 2009 H1N1 death in the U.S. occurred on April 29. That same day, the WHO elevated its pandemic alert level from four to five, indicating larger clusters of human-to-human transmission and the increased likelihood of a coming pandemic(Li et al. 2010).

Over the ensuing weeks, the WHO issued 43 nearly daily official updates (WHO 2009b) and on June 11 elevated its pandemic alert to its highest level (six), indicating pandemic status, with nearly 30,000 confirmed cases reported from 74 countries (WHO 2009c). U.S. 2009 H1N1 influenza activity peaked during the week of October 24, with 49 of 50 states reporting geographically widespread disease. The 2009 H1N1 virus accounted for the overwhelming proportion of laboratory confirmed influenza cases during the 2009-2010 influenza season (CDC 2009b). By January 2010, overall influenza activity had declined substantially (CDC 2009b).

Identification and characterization of new 2009 H1N1 virus strain in first U.S. cases

As described above, the CDC laboratory received specimens of what proved to be the first U.S. cases on April 14 and 17, and within two days identified and genetically characterized the novel 2009 H1N1 strain. In a serendipitous occurrence, the earliest U.S. cases arose after the normal influenza season peak and in specific parts of California where a new point-of-care test with subtyping was evaluated under an FDA-approved IDE, and the study protocol was coordinated with public health laboratories, through a CDC/BARDA advanced development contract. DOD and CDC routinely monitor influenza viruses year-round. DOD identified six of the first eight U.S. cases through four components of its surveillance network. The Navy laboratory in San Diego was participating in the pilot testing trial and performed critical tests on early U.S. cases using the new CDC test. They were able to quickly determine that those patients were infected with unsubtypable influenza A viruses, and sent samples to CDC for confirmatory testing.

Over the ensuing months, CDC characterized the genome sequences of over 4,000 samples of the 2009 H1N1 virus to monitor for mutations. Meanwhile, the NIH supported the sequencing of more than 2,000 H1N1 viruses and deposited the sequences in GenBank. Mutation of the virus would likely have been associated with significant changes in epidemiology, clinical profile, and antiviral medication and vaccine sensitivity, any of which could have carried important implications for prevention, treatment, and mitigation policy. Fortunately, no such changes were detected through CDC's virus surveillance efforts.

Test kits for U.S. state and international laboratories

Prior to the 2009 H1N1 pandemic, pandemic preparedness efforts had been focused on avian influenza H5N1, which had spread extensively in poultry and affected hundreds of people in countries in the Eastern Hemisphere beginning in late 2003. As part of such preparedness efforts, the Food and Drug Administration (FDA) cleared an avian influenza H5N1 PCR diagnostic test in 2006 and a "Five Target" PCR diagnostic test for detecting Influenza A, A/H1, A/H3, A/H5, and Influenza B in the fall of 2008. After emergence of the 2009 H1N1 virus, CDC quickly updated the PCR test to include detection of the newly characterized 2009 H1N1.

Because FDA and CDC had been working together over the preceding three years on two test approvals, CDC was able to rapidly provide the needed data on test performance to allow FDA to grant an Emergency Use Authorization (EUA)[3]. This authorization allowed CDC to distribute 2009 H1N1 reagents to state public health laboratories. Without this authorization, states would have had to order their own reagents and independently validate their own assays for detection of the novel influenza strain. Because of this preparation and the strong partnership between CDC, FDA, industry, and state laboratories, CDC was able to prepare and ship 372 kits to qualified laboratories under the EUA within one week and to all laboratories within two weeks of the initial detection of 2009 H1N1 influenza virus in Southern California.

Emergency supplemental funds provided to CDC in 2006-2007 were used to establish CDC's Influenza Reagent Resources, which provided a centralized procurement and distribution mechanism for laboratory reagents to test for 2009 H1N1 for all state and public health laboratories in over 100 countries. By providing the diagnostic test kits, reagents, and training to public health laboratories, it was possible to rapidly grow an extensive domestic and international laboratory network that could reliably test for 2009 H1N1infection.

Improving the tools to manage seasonal influenza will improve our response to a pandemic. For example, the implementation of the new H1N1 test was possible because of the pre-positioning of equipment, and training provided to state and other public health labs. In addition, the Influenza Reagent Resource maintained inventories of reagents and other supplies that were quickly released to state public health labs. Further efforts are needed to develop effective rapid diagnostic tests that are more sensitive (to pick up all true cases), more specific (to minimize false positive results), and easy to use. We also need to develop more effective point-of-care diagnostics, to disseminate them widely throughout the health care system (and internationally) and to tie them into surveillance efforts. New technologies might be developed with commonly available testing platforms in mind, so they can be deployed widely and used robustly.

[3] Provision in the Project BioShield Act of 2004 (Public Law 108–276) that fills the need for timely and practical medical treatment under emergency conditions and authorizes the use of an unapproved product or the unapproved use of n approved product for use in an actual or potential emergency. (Nightingale et al, 2007.)

Global influenza surveillance

U.S. policymakers recognized the global implications of a newly emerging influenza virus, not only because of the 1918 pandemic's lethality, but because of the more recent cases of Severe Acute Respiratory Syndrome (SARS) and avian influenza H5N1. Assessment and notification on this event under the International Health Regulations (2005) took place very early on and was notified to the Pan American Health Organization (PAHO) and the World Health Organization (WHO) and regional partners through the Office of the Assistant Secretary for Preparedness and Response (ASPR) IHR Program and the HHS Secretary's Operations Center (SOC) as part of the U.S. National IHR Focal Point structure. Questions arose early about the nature, magnitude, and distribution of cases elsewhere in the world. USG agencies were well prepared to help address such questions. As described above, the existing relationships that CDC, the Office of Global Health Affairs (OGHA)[4] , and the ASPR staff had with counterparts in other countries allowed them quick access to critical official and unofficial information, and in some instances even before information from another country was made public. These relationships were also the basis for the U.S. (through ASPR) to share its own WHO International Health Regulations (IHR, 2005) reporting form with the Mexican Ministry of Health, which used this form for official notification to the WHO. Also, the CDC serves as a WHO Collaborating Centre for the Surveillance, Epidemiology and Control of Influenza designated to perform confirmatory diagnostic testing of novel influenza viruses and which, as described above, rapidly provided 2009 H1N1 diagnostic test kits to international and domestic laboratories.

Prior investments in countries' pandemic planning and enhanced epidemiologic and laboratory capacity allowed for a rapid global response. Beginning in 2005, CDC has provided funding to ministries of health and WHO offices in various countries and regions to establish surveillance for severe acute respiratory infections, to enhance laboratory testing and training, and to build the capacity for rapid outbreak response. Routine measurement and evaluation of these countries' pandemic preparedness progress has demonstrated that most of the over 30 countries had improved their ability to detect, monitor, and respond to a pandemic. This preparedness investment was beneficial for providing improved infrastructure during the pandemic response in 2009-10.

At the start of the pandemic, CDC convened almost daily calls with colleagues in Canada, Mexico, and WHO's Pan American Health Organization (PAHO) regional office to share data and situational awareness. As the pandemic emerged, CDC and ASPR convened with senior leadership from the OGHA on once or twice-weekly conference calls with Global Health Security Initiative (GHSI, comprising of the G7 countries plus Mexico) partners, plus the European Commission and the WHO as an observer. WHO-sponsored conference calls with clinicians, in which CDC, ASPR, and OGHA participated, provided critical clinical and epidemiological information not available at that time in the U.S. Likewise, CDC and ASPR found their frequent consultations with countries in the Southern Hemisphere (e.g., in South America, Australia, New Zealand) particularly informative in

[4] The Office of Global Health Affairs (OGHA) became the Office of Global Affairs following the 2009 H1N1 Pandemic.

understanding the dynamics of 2009 H1N1 pandemic during a winter season (corresponding to the summer months of 2009 in the Northern Hemisphere).

The ability to initially detect emerging new viruses is critical to an effective response, and as such there is a need for strengthening surveillance capabilities in countries around the world—and not just in predictable "hot spots"—consistent with the aims of the revised WHO IHR (2005). Limitations in laboratory capacity in some countries resulted in delays as confirmatory testing occurred outside the country.

There was a lack of synchrony of the WHO pandemic alert "phases" and USG planning "stages," as well as challenges posed by the WHO's definition and announcement of "pandemic." A major difficulty with the use of the WHO pandemic phases is that the phases are based on the number of cases without regard to the severity of the pandemic. Although there is always variability inherent within the larger epidemiological picture, differences across countries in reporting cases to the WHO also contributed to confusion and lack of data comparability.

U.S. technical support, through global and USG initiatives, remains an important mechanism to assist countries and other international partners in strengthening their core detection, surveillance and response capacities, consistent with the IHR (e.g., epidemiology, laboratory diagnosis and biosafety/biosecurity). Reviewing the 2009 H1N1 pandemic response may be an opportunity for the USG to better define the roles and responsibilities of federal agencies regarding surveillance, situational awareness, and communication with government leaders, including Congress and the White House. The roles and responsibilities for communicating with DOD, DOS and DHS could also benefit from clarification.

Surveillance systems

A long term goal for the U.S., and indeed the world, is a biosurveillance system that integrates multiple sources of information, provides current, just-in-time information for decision making, and facilitates the accurate projection of what can be expected. Regardless of the system in place, there is always a level of uncertainty in addressing severity at the beginning of an outbreak or pandemic. More information is always necessary, and it can be challenging for senior leaders to effectively make decisions, formulate plans, and take actions during the early days of a public health event when data are limited and incomplete.

U.S. states have the primary responsibility to protect public health through state and local health departments and, as a result, take primary responsibility for conducting influenza and other disease surveillance. CDC coordinates the longstanding system for routine domestic influenza surveillance, which includes seven complementary components. Information is reported to CDC weekly. These components capture laboratory test results, laboratory-confirmed pediatric hospitalizations and deaths, outpatient illness, total and respiratory disease mortality, and overall assessment by state and territorial epidemiologists regarding the degree of influenza activity in their jurisdiction.

Prior to the 2009 pandemic, most states had existing syndromic and hospital surveillance systems in place to help track outbreaks of seasonal flu or other diseases. One state did not have an electronic surveillance system in place and had to rely on faxing information instead. Most states also had in place patient bed tracking systems to monitor suspect H1N1 cases at hospitals, and this bed status was reported regularly. Some states, such as New York, supplemented clinical surveillance systems with data from pharmacies. At times, the Department of Education acted as the first line of surveillance because some outbreak epicenters were schools. Several states used pharmacies and schools to identify potential new cases and track outbreak trends.

Thus, U.S. influenza surveillance and the synthesis and evaluation of these data that make the products meaningful for decision maker resulted in a composite picture drawn from several sources of information. Because nearly all information is based on sampling rather than exhaustive reporting, the data represent trends in person, place, and time, and can help detect pandemics of influenza-like illness (ILI) or pneumonia/influenza deaths by virtue of exceeding established threshold values.

It is important to note that early characterization of the emerging pandemic was done using existing surveillance systems and other methods. Given the geographically focal aspect of early disease clusters, it was imperative for CDC and state public health partners to deploy multiple teams of epidemiologists to conduct rapid impact assessments through field data collection. Early evaluations of transmission and clinical severity, for example in neighborhoods in Chicago and at the University of Delaware (where the disease had been identified and local health departments were able to support investigations), provided valuable information on the attack rate, transmission characteristics, and clinical picture of 2009 H1N1 disease in communities and households. These data were posted on the CDC website and were published in the *New England Journal of Medicine* approximately two weeks after first recognition of the new influenza strain. This two-week period was significantly faster than the usual publication cycle for medical journals.

The longstanding routine influenza surveillance system that was in place when 2009 H1N1 emerged was the basis for the platform that was adapted for the pandemic response. In addition, the "Distribute" surveillance system – a system that aggregates ILI syndromic information from emergency departments and submits these data to local and state health departments – allowed for the monitoring of one-third of hospital emergency department visits by October 2009. This system was built upon a partnership between CDC, the International Society for Disease Surveillance, and the Public Health Informatics Institute. As of October 6, 2009, 19 states and five local health departments were participating and provided further characterization of geographic- and age-specific disease trends.

In September 2009, CDC added a new ILI module for influenza to the longstanding Behavioral Risk Factor Surveillance System (BRFSS), through which phone interviews in English and Spanish collected further population-based data regarding occurrence of ILI and vaccination with seasonal and 2009 H1N1 vaccine. These efforts provided new dimensions to U.S. influenza surveillance and exemplified flexibility in adding robustness to situational awareness as the pandemic evolved.

Situational awareness entails both vertical (local to state to federal) and horizontal (hospital to hospital; agency to agency) communication and status reporting. Public health departments must communicate clearly with hospitals and other medical providers, and vice versa, to facilitate situational awareness on arising surge issues and response capacity. During the H1N1 outbreak, interagency collaboration between ASPR, CDC and other HHS agencies and divisions allowed a high level of situational awareness to be maintained, which contributed to the federal government's ability to rapidly update guidance as the situation required. Hospitals were able to supply data input for states' syndromic surveillance system, providing them with situational awareness on the status of the outbreak at the hospital level. States must also receive appropriate guidance from the federal level in order to facilitate the local emergency response. Regional collaboration facilitated information sharing of H1N1 status of states in close proximity, such as between the health departments of New York and New Jersey, which met regularly. Oklahoma surveyed hospitals, which reported that they received enough information from the state, but interstate communication was a challenge. Other states utilized information sharing sessions organized by the Association of State and Territorial Health Officials (ASTHO) to obtain situational awareness horizontally on the H1N1 outbreak in their region, both to inform decision making and to share promising practices throughout the response.

States took efforts to disseminate information to appropriate partners, such as holding daily Incident Command Center (ICS) briefings with hospital associations, providers, and regional medical systems. However, several states felt that they had become overwhelmed with emails, conference calls, and meetings that often included redundant information. In addition, states had to adapt to constantly changing federal guidelines throughout the response. One state suggested examining the frequency of updates to make it more manageable for all states to disseminate information.

In the realm of international communications, the U.S. quickly brought in other members of the GHSI Communicators Network within the first days of the pandemic to provide awareness of the U.S. situation and to allow them — for the first time — to have access to the internal communications discussions among U.S. federal agencies. This unprecedented action resulted in an earlier alert to other GHSI countries about how the U.S. was communicating its experiences—allowing our international partners to better prepare their communications regarding the unfolding situation.

Pre-existing relationships between CDC, OGHA, and ASPR staff and counterparts in Mexico; South American countries; Australia; the North American Leaders Summit; the WHO, including PAHO; and the countries of the GHSI (comprising the G7 countries and Mexico, the European Commission and WHO, as a technical advisor) facilitated surveillance and information sharing. Staff language and diplomatic skills helped facilitate coordination of international communications and mitigation measures, including early access to information about cases in these countries.

ASPR, OGHA, and CDC participants described distinct communications nodes, including their own strong relationships with international partners. Other federal departments (e.g.,

DOS) also had relationships and information sharing systems with international partners. Given the importance of clear and aligned communications, these disparate systems may offer the opportunity to determine whether there is redundancy or overlap on the international side as a result of incoming communications from CDC, ASPR, and other federal departments (e.g., DOS and DOD), and to examine how notifications are triggered among them for information sharing. Coordination of USG surveillance-related communications with international partners should be further developed.

CDC communicated surveillance information broadly across federal, state, and local government agencies and to the public. The U.S. public health system was able to draw upon pre-existing secure communications systems to exchange sensitive information as the 2009 H1N1 pandemic emerged and spread. These included Epi-X (for health departments) and the Health Alert Network (which also included clinicians and provider organizations). Not only surveillance information, but also rapidly changing recommendations and guidelines, could be transmitted through these channels.

Routine passive surveillance for infectious diseases is designed to monitor trends and detect unusual events at the macro population level, based on sampling, aggregated data, and a typical weekly reporting frequency. Information is needed rapidly to detect inflection points, and timely information may result in better decision making.

There are clearly opportunities to improve surveillance including improving timeliness through electronic health records, developing sufficiently sensitive and specific rapid tests at point of care (i.e., improve the accuracy of the simple Rapid Influenza Detection Tests to diagnose influenza), developing timely serosurveys, and improving electronic data flow between hospitals, state health departments, and CDC. However, these strategies were not part of routine CDC influenza surveillance in 2009. Further, the individual components of the current U.S. influenza surveillance system each provide only a small snapshot of a given condition at a given point in time. Stitching these pieces together, integrating them to support decision making, and balancing the data limitations with pressing information requirements will improve situational awareness during an incident. Such an effort may require new analytic technologies. During the 2009 H1N1 pandemic, new surveillance components were added. Some information sources were useful and others less so, while some data sources were available but not used.

During the early weeks and months of the 2009 H1N1 pandemic, there was tremendous interest in understanding the evolution of the pandemic. There were expanding requests for geographically specific, timely and precise characterizations of the disease around the country, as well as the nature of the local response, including timely information on the availability of medical resources such as hospital beds and ventilators.

Regarding surveillance and situational awareness overall, there was a lack of available (i.e., sufficiently precise) surveillance information for specific local areas, and sometimes at the state and regional level. There was an absence of sufficiently precise data for minority populations or high-risk areas such as along the U.S.-Mexico border. There was a lack of available surveillance information on the availability of medical resources, vaccine

distribution and administration, and adverse events. These shortfalls offer opportunities for rethinking the goals of surveillance, as well as the sampling design and intensity of routine surveillance in certain areas and considering how these might be enhanced quickly enough when a new threat arises.

Opportunities may exist to leverage existing sources of surveillance information such as the population-based near real-time electronic health record (EHR) system within one agency of HHS itself—the Indian Health Service (IHS). IHS representatives reported they quickly adapted their system for surveillance purposes, initially monitoring epidemiologic and clinical patterns, but later using it to monitor vaccinations as well. They uploaded data nightly from their health facilities across the country and thus had timely situational awareness of 2009 H1N1 within the American Indian/Alaska Native (AI/AN) populations nationwide. They generally provided these data to specific state health departments, with particular interest in demonstrating that AI/AN populations were another important risk group to be considered for vaccine allocation purposes. Two other federal agencies providing direct health care also have electronic medical record systems—DOD and the Department of Veterans Affairs (VA). DOD collects syndromic surveillance from Military Treatment Facilities across the country and breaks down illnesses by zip code, and the data are collected and analyzed as part of CDC's BioSense program.

As the nation moves towards fuller implementation of electronic medical records, close examination of electronic health record (EHR) systems may yield promising opportunities to improve surveillance. Innovations in this area would be done in full accordance with federal protections under HHS HIPAA and the Privacy Act protective provisions. In particular, the EHR systems of IHS, DOD, and VA may be examined, as they are all established, population-based, and nationwide systems, and include clinical as well as detailed demographic data for the populations each agency serves. Other EHR systems, such as those funded through CMS' EHR Incentive Program, may also provide valuable surveillance data. The increasing investment in health information technology (HIT) nationwide may offer new opportunities for better and more timely surveillance and would add robustness to local level data.

Surveillance posed a large burden on reporting sources such as hospitals, state health departments and CDC during a high operational tempo period. Detailed reporting of cases and resource availability was very labor intensive and difficult to manage in settings where the demand for medical services was surging. States also experienced a burden in reporting, including multiple requests for similar information ("information request overload"). Reporting compliance with new surveillance requirements was good (regional and hospital buy-in occurred because of previously established relationships and novel influenza was already a nationally notifiable disease); however, there may have been under-reporting and/or delays. Hospitals and states may be reluctant to share with the federal government data that may impact their competitive edge, data ownership, or organizational rivalries.

Earlier evidence from routine surveillance indicates that even routine reporting compliance is less than desirable. For example, only about one-third of approximately 2,200 sentinel

providers submitted most required reports in timely fashion during 2005-2006. Further examination may identify incentives that should be provided and/or barriers that must be overcome to ensure better reporting compliance for routine and emergency-related surveillance.

Although communication of surveillance information across government agencies and the public was very comprehensive, there were challenges with timeliness and wide distribution due to the volume of information. CDC influenza surveillance staff experienced the burden of high volume of information and high demand for that information. The CDC surveillance team, like many others across all levels of government, was highly capable but had been thinly staffed with almost no relief for several months into the pandemic. The capability to meet the high demand was also influenced by the different times when different states would report information to CDC on case numbers. U.S. states and territories span across seven time zones, creating enormous pressure on epidemiologists and other staff who worked through the night against deadlines to provide ongoing and timely data from all states. More automated provision of information could help harmonize the reporting.

Clinical surveillance systems

Information about clinical aspects of the disease was important for purposes of developing and tailoring clinical management guidelines, assessing the effectiveness of treatment regimens, planning for medical resource needs, and triggering community mitigation measures. Yet, at the outset, only one of the routine components of U.S. influenza surveillance in place in April 2009 provided adequate information on the clinical severity of disease—the CDC's Emerging Infections Program, which collects patient-level information from laboratory-confirmed influenza hospitalizations in ten population centers in the U.S. This system provides detailed clinical information on severe influenza cases on a weekly basis and is published in the MMWR and on the CDC website. From the provider side, it was challenging for clinicians charged with patient care to take the time to provide detailed clinical information requested by the government. A number of studies designed to glean clinical information were implemented. These studies used data collection strategies other than surveillance for characterizing clinical profiles, including clinical severity. For example, chart reviews of hospitalized H1N1 patients suggested risk groups (e.g., 60-80 percent of patients had pre-existing conditions). Also, clinical research protocols organized quickly by the National Institutes of Health (NIH) by September 2009 led to several harmonized observational cohort studies in centers around the world, which permitted multi-center analysis and querying capability for specific clinical conditions.

Hospitalization rates among minority groups were consistently more than double those of White, non-Hispanics (CDC 2010). In the spring, hospitalization rates were highest for Black, non-Hispanics, while during the fall, rates were highest for American Indians/ Alaska Natives (CDC 2010). The reasons for these disparities are unknown, although issues related to access to care, prevalence of underlying health conditions among certain ethnic or minority groups, and self-care or care-seeking behaviors may play a role. Understanding the underlying causes may inform communications and outreach strategies for these populations and help to overcome community-level or system-wide barriers.

In another effort, ASPR and CDC partnered with NIH to establish a registry of critically ill patients with novel influenza. The effort leveraged existing clinical research networks with sites across the country—the Acute Respiratory Distress Syndrome Network (ARDSNet) for adults and the Pediatric Acute Lung Injury and Sepsis Investigators (PALISI) network for children—to gather and rapidly analyze clinical data to better understand the burden of disease, the severity of illness, the clinical course, and the resource utilization needed for optimal care.

However, national standards and expectations for the protection of human subjects must always be scrupulously respected, even under emergency or disaster circumstances. During 2009 H1N1, the ability to collect information, particularly epidemiological and clinical information from patients that can inform emergency public health response and clinical management, may have been slowed by the need to obtain approval at each network site by Institutional Review Boards (IRBs). The delay in IRB approvals were in large part due to many proposals for emergency research being relatively incomplete, frequently failing to distinguish between identifiable and deidentifiable data. There is a need to streamline the process in some way that maintains critical human subject protections, but also allows data collection and analysis in a timely way to support an emergency response. Additional dialogue is required on the need for a central USG review board dedicated to emergency care research to eliminate delays from state, local, and hospital review boards.

Case definition

In the early weeks and months of the 2009 H1N1 pandemic, the case definition included laboratory confirmation of individual reported cases. Case definition changed rapidly in the early months. As the number of cases grew, it became both impractical and, for central policy purposes, less epidemiologically warranted to test every case. However, the transition from a case definition requiring laboratory confirmation to syndromic clinical reporting may have created confusion with regard to who should be tested and what should be reported. Changes in recommendations regarding if and when to test for 2009 H1N1 were nuanced and challenging to convey to physicians. The frequency of the changes to recommendations and the complexity of the scientific issues involved led to a saturation of messages that made reaching every provider in America a challenge despite comprehensive outreach efforts. Moreover, CDC gave states the choice of reporting laboratory confirmed cases or ILI, which compromised comparisons across states and over time, before and after September 1, 2009. Close collaboration between the federal government and states and other partners in planning for and exercising such transition could improve efficiency and reduce confusion in future large-scale pandemics.

Workplace and school absenteeism monitoring

Routine influenza surveillance does not capture workplace or school absenteeism. Several federal agencies expressed confusion or difficulties regarding surveillance among their employee workforce, citing violation of patient privacy (when it became publicly known which employees were ill), the stigma and reluctance on the part of employees to report their illness, and delayed and/or unclear guidance regarding what was to be reported and to

whom. With children identified early as a risk group for 2009 H1N1, there was particular interest in monitoring school absenteeism. While national-level health and education officials worked well together, health professionals across the country did not necessarily understand the importance of working with their counterparts in local departments of education for monitoring school absenteeism. It is of note that HHS and the Department of Education did coordinate a comprehensive education campaign, which included an Influenza Summit (in concert with DHS) for state and local public health, emergency response, and education officials.

Modeling efforts

CDC not only examined its routine surveillance data sources and elements in the customary manners, but also in new ways as well (e.g., transmission dynamics to determine primary and secondary attack rates), and worked with modelers inside and outside of government in an effort to anticipate the burden of disease and potential social disruption. Other federal agencies and organizations also conducted modeling activities. There was great variability in the types of models and their estimates. Some surveillance-based models were actually very useful in planning while other models were less so.

Modeling was aided by rich surveillance data sources and recent research. Surveillance information informed priorities for vaccination, treatment, and mitigation measures. For example, surveillance for 2009 H1N1 identified distinctly different risk groups—especially children and pregnant women—who quickly became, and remained, priority subgroups for prevention and mitigation measures, including vaccination and school closures.

Although modeling efforts have inherent limitations, models contributed to decision making. Closer collaboration among modelers, decision makers, interagency operational units, and data collectors may produce models better informed by real data. In turn, this would allow specific policy questions to be addressed more directly.

Chapter 2 Summary

Successes

1. The Centers for Disease Control and Prevention (CDC) laboratory, in partnership with the DOD, rapidly identified and characterized the new 2009 H1N1 virus strain in the first cases in the U.S. and on an ongoing basis assessed viral isolates for evidence of antigenic change and antiviral resistance, providing IHR notification to the WHO as required.
2. The RT-PCR diagnostic test received rapid regulatory authorization.
3. The CDC laboratory rapidly produced and distributed RT-PCR test kits to U.S. state and international laboratories, and made protocols available to all countries and test developers within two weeks of the identification of the first case.
4. A system of pre-existing, multiple surveillance platforms (some of which were enhanced during the pandemic) together with international relationships, provided a strong foundation for ongoing reporting of the extent of illness, hospitalizations, and deaths.

5. Communication of surveillance information across government agencies and with the public was timely, transparent, and comprehensive.
6. The USG was well poised to obtain and contribute to global influenza surveillance.
7. The identification of risk groups for severe disease, as well as non-risk groups, occurred early in the response and provided a picture as to which segments of the population were likely to be most affected.

Opportunities for Improvement

1. The high volume and pace of demand for surveillance data of various types created challenges in clearly communicating about the different data available and required considerably more time from both surveillance and communications staff than anticipated. This was exacerbated by reporting from seven time zones encompassing U.S. states and territories. Although communication of surveillance information across government agencies and the public was comprehensive, due to the volume of information, there were challenges with timeliness and wide distribution.
2. National-level surveillance information was often not sufficiently granular to characterize rapid changes in influenza-like illness or hospitalizations at the community level or to meet the information needs and demands of local responders and citizens. There may have been missed opportunities to quickly leverage existing sources of surveillance information. It should be noted that the value of the surveillance information from these sources gathered during the early days of a pandemic will be limited due to sparse cases, possibly against the backdrop of ongoing seasonal influenza circulation. However, despite these factors, increased capacity for state and local surveillance is necessary to supplement and contribute to national-level systems.
3. The time needed to collect, validate, summarize, and disseminate surveillance data is challenging. Some requests for data could not be met within a desired time period. This is especially important considering that during the pandemic it proved difficult to incorporate data from multiple sources and techniques to compensate for the limitations of surveillance that were unseen prior to the emergency. Continued, proactive enhancement of existing surveillance systems and development of new systems that incorporate data rapidly would improve the capacity for informed decision making and enable the USG to better address expectations for more timely data.
4. In the early weeks of the pandemic, the surveillance case definition was adjusted in response to increasing knowledge about the 2009 H1N1 virus. These changes were appropriate to improve surveillance for cases of pandemic influenza, but use of case definitions primarily for surveillance rather than clinical care was not communicated clearly to the clinical practices community. Additionally, diagnostic tests for accurately detecting influenza, especially for confirming 2009 H1N1, were not accessible and led to frustration within the clinical community due to their lack of availability. The low sensitivity of commercially available rapid antigen detection tests led to misdiagnosis and under-treatment of people with 2009 H1N1

influenza. In addition, frequent changes in the case definition created challenges in data collection and interpretation.

5. Monitoring use of clinical care services at a national level was difficult. Surveillance systems to perform this kind of surveillance, especially in a time frame that can inform decision making regarding management of the public health response or clinical care, are underdeveloped and need to be in place prior to a more severe pandemic. Although some desired an assessment of health care system stress at the national level, health care system monitoring information was largely available at the local level and supported local decision making. Not all data needed at the local level is necessary for decision making at the national level. Further work should identify the national level information needs regarding healthcare system stress.
6. Modeling efforts have inherent limitations but still contributed to decision making. Closer collaboration among modelers, decision makers, interagency operational units, and data collectors may produce models better informed by real data. In turn, this would allow specific policy questions to be addressed more directly.
7. The 2009 H1N1 pandemic highlighted the need for continued work to close gaps in the capability of the global surveillance network to detect emerging novel human pathogens.
8. Reviewing the 2009 H1N1 pandemic response is an opportunity for the USG to better define the roles and responsibilities of federal agencies regarding surveillance, situational awareness, and communication with government leaders, including Congress and the White House. The roles and responsibilities for communicating with the Departments of Defense (DOD), State (DOS) and Homeland Security (DHS) during a public health emergency could also benefit from clarification.
9. There is a need for more timely, data-driven clinical guidance regarding the best methods of treatment for seriously ill, hospitalized patients in an evolving public health emergency. HHS attempted to use existing intensive care unit research networks to obtain near real-time data on the clinical course of seriously ill hospitalized patients. However, during 2009 H1N1 many proposals for emergency research presented for consideration to IRBs were relatively incomplete, frequently failing to distinguish between identifiable and de-identifiable data and causing delays in approval. Mechanisms might be considered to address the need for rapid IRB approval for clinical research in the future, which might include a single national IRB during public health emergencies.

CHAPTER 3: MITIGATION MEASURES – ADDRESSING MEDICAL NEEDS

As discussed in the previous chapter, the "Framework" delineates the strategy for addressing medical needs, relevant to the Mitigation Measures pillar, as "appropriate management of the medical needs of patients within the community and after they present to the health care system" (White House 2009). This area comprises a wide range of activities including generating medical surge capacity, and protecting patients and health care workers within medical facilities. This includes timely communication of clinical care guidelines and algorithms to health care providers and measures to ensure that patients can be managed safely in the community or can safely defer care for a period of time. The rapid transmission of accurate, up-to-date information on appropriate care for ill individuals is essential to ensure that providers' treatment approaches keep pace with changes in clinical guidelines.

Medical surge refers to the capacity, despite a rapid increase in demand for medical care, to ensure sufficient supplies, staff, space, and pharmaceuticals to provide care to the greatest number of people while maintaining acceptable standards of care. Planning for medical surge must take into account such matters as federal reimbursements to hospitals; alternative care sites; increase in the number of clinical providers; triggers for activating and de-activating surge protocols; deviation from normal medical practice standards, if warranted; mechanisms for shifting non-urgent care away from emergency departments and hospitals to home settings and primary care providers; and ways to address surge demand for mental and behavioral health care in response to an incident. In addition, protecting patients and health workers within facilities involves measures such as hospital infection control and use of isolation facilities.

Medical care guidance for clinicians

CDC developed and disseminated medical care guidance for clinicians on a variety of topics including, but not limited to identifying and caring for patients, care of pregnant women, and care of young children.

CDC guidance was both developed and disseminated quickly based on the best scientific evidence available at the time. The list below illustrates how quickly the initial guidance was disseminated:

- April 28, 2009: CDC releases Guidance for Clinicians: Prevention and Treatment of Swine-Origin Influenza Virus Infection in Young Children
- April 29, 2009: CDC releases Guidance for Infection Control for Care of Patients with Confirmed or Suspected Swine Influenza A (H1N1) Virus Infection in a Health Care Setting
- April 29, 2009: CDC releases Guidance for Clinicians: Children and Pregnant Women Who May Be Infected with Swine Flu

The initial guidance was quickly updated as new data became available. It may be of benefit to highlight new or changed information.

Guidance was disseminated through multiple channels. For example, ASPR worked with the American College of Emergency Physicians to issue guidance for physicians through its communication channels, including additional websites. In addition to using the internet to disseminate medical care guidance, CDC also conducted real-time communication and outreach with the provider community through direct email communications and conference calls held by the CDC's Clinician Outreach and Communication Activity (COCA). These calls provided an opportunity for providers to ask topic-specific questions. To further increase their reach, CDC transcribed the calls and made them available on their website. ASPR also hosted specific conference calls with clinical providers, alternating between adult and pediatric issues and allowing medical care providers to share experiences and provide information for the development or modification of medical care protocols. CMS also conducted outreach to providers through a variety of mechanisms including conference calls, web conferences, and Question and Answer documents. The Division of Oral Health within CDC's National Center for Chronic Disease Prevention and Health Promotion created guidelines for dental providers on 2009 H1N1 infection control measures (found at http://www.cdc.gov/oralhealth/infectioncontrol/factsheets/2009_h1n1.htm), as well as made a presentation on 2009 H1N1 at a national conference; it also worked with the American Dental Association to circulate its guidance through that association's newsletter. There were, however, challenges in communicating with physicians, as there is no one system for reaching all physicians.

It will be beneficial to explore the extent to which guidance was beneficial and conduct research aimed at gaining a better understanding of how clinicians interpret and implement guidelines, an effort which may be adaptable for multiple disease situations.

The Centers for Medicare & Medicaid Services (CMS) guidance and requests for Section 1135 waivers

Section 1135 of the Social Security Act permits the HHS Secretary to temporarily waive or modify certain Medicare, Medicaid or Children's Health Insurance Program (CHIP) requirements for health care providers in response to certain emergencies. The requirements that may be waived or modified include certain requirements under the Emergency Medical Treatment and Labor Act (EMTALA) and the Health Insurance Portability and Accountability Act (HIPAA).

The language of the waiver specific to the 2009 H1N1 influenza pandemic stated the intent of the waiver was to:

> "ensure that sufficient health care items and services are available to meet the needs of individuals enrolled in the Medicare, Medicaid and CHIP programs and to ensure that health care providers that furnish such items and services in good faith, but are unable to comply with one or more of these requirements as a result of the 2009 H1N1 influenza pandemic, may be reimbursed for such items and services and exempted from sanctions for such noncompliance, absent any determination of fraud or abuse" (HHS 2009b).

After the Secretary invokes section 1135, health care providers may ask for 1135 waivers in response to particular needs, and only within the geographic and temporal limits of the emergency declarations.

Examples of waiver requests include:

- Hospital requests to set up an alternative screening location for patients away from the hospital's main campus (requires waiver of sanctions for certain directions, relocations, or transfers under EMTALA).
- Hospital requests to effect transfers normally prohibited under EMTALA of individuals with unstable emergency medical conditions when the transfers are necessitated by the circumstances of the declared emergency (flu.gov 2009).

Both a Secretarial and a Presidential declaration are necessary to trigger use of 1135 waivers. CMS provided guidance to help providers understand the 1135 waiver and reviewed 1135 waiver requests (CMS 2009). In all, 16 waivers were requested from 13 states, six of which were approved and the remaining ten being resolved under current laws and regulations.

The CMS guidance issued in August 2009 helped to clarify the conditions under which the provisions of EMTALA could be relaxed. The clarification that there was some flexibility within EMTALA helped alleviate concerns of hospitals and health care providers who were trying to address a public health emergency and the resulting crush of patients while complying with EMTALA. CMS also provided information about their programs to other federal agencies.

To help work through the Section 1135 decision-making process, CMS convened a cross-regional workgroup to develop criteria by which waiver requests could be evaluated. The group decided jointly whether a waiver should be issued under the 1135 authority. The 1135 waiver workgroup was viewed as a success as it brought together 1135 waiver and localized experience. CMS was asked to report weekly on the number of waivers requested and granted, as well as the time it took to turn them around. The workgroup was able to act quickly, with waiver requests being turned around within 24 hours.

In many cases, CMS was able to effectively resolve issues with facilities without issuing the waiver. In these situations, the leadership within facilities thought they needed regulatory relief, but found after discussion with CMS that they could modify operations under existing policy and regulations without fear of sanctions. For example, for some waiver requests CMS did not need to grant 1135 waivers for EMTALA once the facility understood requirements and flexibilities within current regulations.

It should be noted that *both* the Secretary and the President must issue separate declarations to trigger use of 1135 waivers under the Social Security Act: the Secretary must declare an emergency under the Public Health Service Act, and the President must declare an emergency or disaster under the Stafford Act or the National Emergencies Act.

The H1N1 Flu Self-Evaluation Tool

The H1N1 Flu Self-Evaluation Tool is a communication and education tool developed to help the public determine if they needed to seek medical care for their flu-like symptoms to prevent overloading medical care facilities with "worried well" patients. This tool was rapidly developed during the 2009 H1N1 pandemic response and was viewed as being quite helpful. (In the end stages of development, the question arose as to whether the tool was actually a medical device, which would make the tool subject to FDA regulation.) The Self-Evaluation tool might now serve as a foundation from which to build other tools. The tool, developed in collaboration with the Emory University School of Medicine, is available online at http://www.flu.gov/evaluation/.

The H1N1 Flu Self-Evaluation Tool asks participants a series of questions about their clinical symptoms and underlying medical conditions. After responding to these questions, the participant is given information about seeking medical care. For example, people who report severe flu-like symptoms receive this message: "People who answer like you did might be very sick. They should: Call their doctor now. Tell their doctor they might be very sick. Ask if they need to be seen right now. If they need to be seen right now, ask their doctor where to go (doctor's office, walk-in clinic or the emergency room). When they see the doctor, ask if they need medicine for the flu." People who do not reply with flu-like symptoms are told: "People who answer like you probably don't have the flu, but they may be sick from something else. If they are worried about their health, they should call their doctor. If they do not have a doctor, they should go to a walk-in clinic. If they think they have an emergency, they should call 9-1-1."

There is potential for further development of online triage tools such as the Flu Self-Evaluation Tool, including development of more specific criteria to determine when individuals not in priority groups should seek medical treatment. Tools of this sort are best developed in advance to allow for adequate testing and evaluation before they are used in a pandemic; these tools should be evaluated for utilization and impact.

Clinical triage algorithms

In addition to the H1N1 Flu Self-Evaluation Tool, CDC, in coordination with multiple partners including AAP, CSTE, IDSA, and Emory University School of Medicine, developed and disseminated 2009-2010 Influenza Season Triage Algorithms for adults (CDC 2009d) and for children (CDC and AAP 2009). These algorithms were different from the H1N1 Self-Evaluation Tool in that they were meant for use by physicians and those under their supervision, not by the general public. These algorithms were disseminated after HHS participated in the Institute of Medicine's (IOM) September 2009 workshop on *Clinical Algorithms to Inform and Empower Health Care Professionals and the Public: Assessing the Severity of Influenza-Like Illness*. Further objective assessment of the triage algorithms may be warranted.

Hospital resource tracking

There was no way to measure precisely whether and how the pandemic affected the health care system across the entire U.S., because the pandemic was not severe enough to seriously stress the system. Although there were individual cases of hospitals having increased workload, no devolution of patient care capabilities emerged. There was a gap in surveillance for monitoring disruption to the medical care delivery system, and the gap was particularly notable for inpatient hospital care.

There was a poor understanding of health care system stress during the 2009 H1N1 pandemic which impaired the ability to rigorously evaluate needs for, and utilization of, intensive care resources, such as extracorporeal membrane oxygenation equipment (to augment respiratory capacity in severely ill patients), and to make informed policy decisions about local additions to such resources. A clearer picture of health system stress at the community level is needed, and regardless of which level of government is responsible for data collection, the data need to be collected and analyzed in near "real time" so resources can be shifted quickly.

In the absence of a system specifically designed to assess health care system disruption and stress, ASPR tried to adapt the National Hospital Available Beds for Emergencies and Disasters (HAvBED) System, which is designed to collect data on hospital bed availability in communities during emergencies. The system was augmented by asking hospitals to report on additional resources such as ventilators. ASPR was able to receive and analyze the data quickly. The HAvBED data appear to have been a reasonable proxy for hospital system stress as well as a timely indicator of disease prevalence, subsequently confirmed by surveillance. However, there were limitations and reporting challenges with the system. The HAvBED system was not immune to the more generalized problems of ad hoc system adaptations (i.e., the retrofitting of existing systems for new purposes) that created challenges across the response. Going forward, better and more timely information is needed to be able to effectively manage medical care resources in a large-scale emergency. Determining what the federal government needs to know and what data are needed to inform each decision and action is essential.

In addition to expansion of the HAvBED system, HHS worked to obtain better information on the number of ventilators available in the health care system. HHS partnered with the American Association for Respiratory Care (AARC) to conduct a national ventilator inventory and developed information on the number and types (e.g., adult, pediatric, full feature) of ventilators in the nation. Institution-specific information was made available to state health officers and aggregate data by state was available on flu.gov. This effort provided a much clearer picture of ventilator resources than had been available previously, provided information needed by policy makers to manage the response, and reduced anxiety about whether there were sufficient numbers of ventilators to manage the pandemic if its severity were to increase.

Surge capacity-related issues also may not have received adequate attention in pandemic planning over the years prior to the emergence of the 2009 H1N1 strain. If the pandemic had been more severe, the health care system may not have been able to handle the surge in

demand, raising ethical issues around the allocation of scare medical resources. Dealing with hospitalizations or attended care in a more severe pandemic that involved many communities may have been challenging, as there were certain areas that were significantly taxed in the 2009 H1N1 pandemic. The nation must be better prepared to address these types of issues before another, more severe public health emergency occurs.

There are inherent difficulties in planning for and implementing medical surge capacity. The responsibility for medical surge is diffuse—spread across elected officials, medical providers, and public health officials. This diffusion creates uncertainty regarding surge responsibilities and a lack of accountability.

At the same time, there were successes in addressing medical surge capacity issues. For example, a recent description of Hospital Preparedness Program grantees' response to 2009 H1N1 indicated that most of the grantees interviewed had activated a portion of their pandemic flu plan and used various, usually pre-identified, methods to manage the increase in demand for care in the Emergency Department (ED) (e.g., setting up a triage tent outside of the hospital for people with flu-like symptoms) (Booz Allen Hamilton, 2009). It is not clear whether the health care facility stress caused by 2009 H1N1 was sufficient to warrant widespread implementation of surge capacity plans.

CDC updated the clinical guidance as new data were received, and keeping up with frequent changes may have been challenging for clinicians. For example, guidance for clinical care of pregnant women with 2009 H1N1 was issued on April 28, May 1, June 30, September 18, and October 23. Guidance for antiviral use was issued on April 28, May 6, September 8, September 18, October 14, October 16, October 19, October 23, and October 26. It may have been very challenging for clinicians to locate portions of the guidance that were clinically relevant to their needs. In the future, it may also be beneficial to highlight and maintain a dated archive of previous guidance and other documents.

Provision of high quality, safe clinical care in a resource-constrained environment

The 2009 H1N1 pandemic raised the prospect of a significant surge in demand for health care. Although the surge was not as large as feared and there was no need to implement crisis standards of care, there is still a need to further develop guidelines and standards of medical care in surge situations – particularly in transitioning to crisis standards of care. CDC-led stakeholder meetings included, a) Integrating Primary Care Providers into Community Pandemic Influenza Planning: Stakeholder Meeting, August 24-26, 2009; b) Long Term Care Provider Response to Pandemic (H1N1) 2009 Influenza: Stakeholder Meeting, August 27-28; and c) Pediatric Healthcare Response to Pandemic (H1N1) 2009 Influenza: Stakeholder Meeting, September 9-10, 2009. Some states may lack vetted plans for providing high quality, safe clinical care in a resource-constrained environment during times of medical surge. Few states have developed disaster or crisis standards of care as part of their broader medical surge planning. Although various federal agencies have published guidance on medical surge—including alternative or crisis standards of care – to date there have been few incentives or unified efforts to help states develop and test such measures. Additionally, there is no federal clearinghouse to share information on best practices for medical surge, including provision of high quality, safe clinical care in a

resource-constrained environment. There is a need to invest to improve strategies and infrastructure for surge response capability, including the development of tools and templates for this type of planning.

In recognition of this planning gap, ASPR requested that the IOM "develop guidance that state and local public health officials and health-sector agencies and institutions can use to establish and implement standards of care that should apply in disaster situations—both naturally occurring and manmade—under scarce resource conditions" (IOM 2009). In late September 2009, the IOM issued a letter report entitled "Guidance for Establishing Crisis Standards of Care for Use in Disaster Situations" (IOM 2009). The report was made available to ASPR and was used to help facilitate overall crisis planning. The key elements, as requested by ASPR, include standards of care protocols, identification of potential triggers, and a template matrix that can be used by public health officials at the state and local level as a framework for developing specific crisis standards of care for health care providers. There is an opportunity for states, as well as the federal government, to build upon the IOM work to enhance surge planning and preparedness at state and hospital levels.

Chapter 3 Summary

Successes

1. CMS issued guidance and approved the first Section 1135 waiver request within 24 hours of the President's declaration of an emergency under the National Emergencies Act on October 23, 2009. Section 1135 waivers relaxed certain medical care provider requirements in the event health care facilities became overwhelmed.
2. HHS rapidly developed a complete inventory of all available ventilators nationally, and was able to determine there was an ample supply of ventilators to meet national need with respect to the severity of the pandemic. The inventory included information about which ventilators could be used for small children, since this group was potentially at high risk for needing ventilators and not all ventilators can be used for them. The inventory revealed that there were sufficient pediatric-capable ventilators nationwide for the severity of the 2009 pandemic; however, regional quantities varied dramatically so some regions could have been vulnerable to pediatric ventilator shortfalls had the pandemic severity changed. Federal contingencies for such circumstances were developed due to these actionable inventory data. HHS also made available online training regarding how to use the ventilators in the Strategic National Stockpile (SNS), should they be needed.
3. The IOM letter report, *Guidance for Establishing Crisis Standards of Care for Use in Disaster Situations* (IOM, 2009), was an important step in development of such plans for use should available resources exceed the needs. The report was made available to ASPR and was used to help facilitate overall crisis planning.
4. Although the medical care guidance for clinicians was high quality, consistent and based on scientific evidence, frequent updates may have caused some confusion among patients and clinicians, and may have contributed to less than optimal use of antiviral drugs.

Opportunities for Improvement

1. Clinical triage algorithms for medical providers were disseminated in the provider community. The "H1N1 Flu Self-Evaluation," designed to help individuals choose whether to seek medical care or stay home if they had symptoms consistent with 2009 H1N1, was made available on flu.gov. Further analysis of self-assessments such as the "H1N1 Flu Self-Evaluation" is needed to determine their utility.
2. The 2009 H1N1 pandemic did not fully test the health care system's ability to meet a surge in demand for care. There was no national-level, real-time system in place to assess facility stress and track/monitor resources. Attempts made to retro-fit HAvBED, a national hospital bed tracking system, to assess facility stress need further evaluation. The amount and kinds of data required from local communities for federal decision making should be re-evaluated.
3. The 2009 H1N1 experience highlighted the need for more complete medical surge guidelines and standards for health care providers, particularly for communities to develop vetted plans for providing high quality, safe clinical care in a resource-constrained environment appropriate to state and local circumstances.
4. Two declarations are necessary before the Secretary of HHS may invoke her authority to grant 1135 waivers under the Social Security Act, one by the Secretary of a public health emergency under the Public Health Service Act, and a second by the President of an emergency or disaster under the Stafford Act or National Emergencies Act.

CHAPTER 4: MITIGATION MEASURES – COMMUNITY MITIGATION

The Framework describes the Mitigation Measures pillar as "Interventions to slow the spread of illness and reduce the impact of infection and illness on individuals and communities" (White House 2009). One group of mitigation strategies relates to the use of community mitigation measures (CMM). CMM encompass interventions designed to reduce disease transmission, blunt or delay the peak of the pandemic, and reduce overall disease burden, excluding pharmaceutical products such as antiviral medications or vaccine. Some refer to such strategies as "non-pharmaceutical interventions" (Aledort et al. 2007).

Although CMM are especially critical prior to the development of vaccine and can minimize the impact of a pandemic until medical countermeasures are deployed, many social distancing and personal hygiene measures remain important throughout the response. Examples of CMM include staying home from school or work when sick, school closures, respiratory etiquette such as covering coughs and sneezes, and constraints on mass gatherings (e.g., cancellation of parades and sporting events).

Some CMM are likely to produce social and economic disruption. However, planning for their implementation well in advance of a pandemic can help to anticipate and limit the nature and scope of the disruptions. Key planning activities include federal collaboration with states to address legal challenges associated with public health interventions; exercising border control and traveler screening; and providing guidance for voluntary isolation of ill adults and children, school closures, and reductions in social contacts and community mixing. During the 2009 H1N1 response, many community mitigation activities were implemented, including guidance on what individuals could do to prevent illness (e.g., voluntary isolation at home when ill), school closures, and travel warnings.

The Framework notes that to be effective, interventions must be instituted early in the pandemic and reflect trends in the severity of disease, virus characteristics, feasibility, and acceptability. It calls for "community flexibility" to adapt to changing conditions as more surveillance data become available. The Framework also recognizes that community mitigation measures may be challenging to implement since they have secondary effects, including potential loss of income for parents who cannot work because they need to care for their children during school closures.

Guidance for a range of community mitigation measures

On April 26, with confirmed cases of 2009 H1N1 continuing to increase in the U.S., the Acting Secretary of HHS declared a Public Health Emergency. On April 29, WHO raised the influenza pandemic alert from phase four to five, signaling multiple large clusters of human-to-human transmission of a novel virus and the likely escalation to pandemic level. At that time, WHO requested that all countries immediately activate their pandemic preparedness plans and be on high alert for unusual epidemics of influenza-like illness and severe pneumonia.

By leveraging pre-established policies and strategies for non-pharmaceutical interventions[5], the CDC quickly developed and released guidance on community mitigation measures such as travel advisories, school closure, respiratory etiquette, advising the sick to stay home, and separating those with flu-like symptoms from others.

Starting just days after confirming the first U.S. cases of 2009 H1N1, CDC released several types of community mitigation guidance, including the following:

- Guidance to assist airline flight deck and cabin crew in identifying passengers who may have 2009 H1N1 influenza (April 28, 2009);
- Updated guidance on school (K-12) dismissal and childcare facilities (May 1, 2009);
- Interim Novel Influenza A (H1N1) guidance for cruise ships (May 2, 2009);
- Interim guidance for colleges, universities, and post-secondary educational institutions (May 6, 2009);
- Interim guidance for public gatherings (May 10, 2009);
- Interim guidance for day and residential camps (June 15, 2009); and
- Updated guidance for schools for the fall flu season and issuance of the toolkit Preparing for the Flu: A Communication Toolkit for Schools (Grades K-12) (August 7, 2009).

Guidance on school closure

Biological, social, and maturational factors make children disproportionately more likely to transmit influenza than older individuals. Since children are together at school for a significant portion of the day, schools serve as amplification points of seasonal community influenza epidemics (CDC 2007). Not surprisingly, evidence suggests that school closure can interrupt influenza spread (Aledort et al. 2007; CDC 2007). Thus, it was one of the leading community mitigation measures used in the 2009 H1N1 response.

In response to the 2009 H1N1 pandemic, the ACF's Office of Child Care (OCC) worked closely with the CDC to issue a letter providing information to child care providers about 2009 H1N1 infections throughout the country, as well as recommendations for preventing the spread of influenza in child care settings. This letter, and links to the CDC website http://www.cdc.gov/h1n1flu/, was distributed to the Child Care and Development Fund (CCDF) grantees in April 2009. OCC subsequently hosted a call with its CCDF state and tribal administrators in September 2009 to discuss updated flu guidance from CDC for preparing for H1N1 infections, to field questions, and to hear about outreach efforts being implemented by states, tribes, and communities across the country. OCC and ACF regional offices collaborated to collect and aggregate information regarding closure of

[5] CDC released the "Interim Pre-Pandemic Planning Guidance: Community Strategy for Pandemic Influenza Mitigation in the United States" in February 2007. This document introduced the Pandemic Severity Index to characterize the severity of a pandemic, provided planning recommendations for specific interventions that communities may use for a given level of pandemic severity, and suggested triggers for initiating non-pharmaceutical interventions and duration of implementation.

child care facilities due to 2009 H1N1 and the number of children impacted by those closures, and reported that information on a weekly basis to the Department.

As more data became available suggesting the clinical illness associated with the 2009 H1N1 was less severe than first assumed, the initial school closure strategy from April 2009 (that recommended a low threshold for school closure based on the Pandemic Severity Index (PSI)) seemed unnecessarily disruptive. Accordingly, in May 2009, CDC issued more relaxed guidelines on school closures. This updated guidance provided a menu of tools from which school and health officials could choose based on conditions in their area.

There were challenges despite the overall sense of success related to school closure. For example, many employers did not have policies in place to deal with the secondary effects of school closures, including workplace absenteeism.

Recommendations encouraging sick individuals to stay home from work and school may not match the economic reality of many families. The Family and Medical Leave Act (FMLA), which allows employees to take unpaid sick time due to serious illness, only applies to 60 percent of the private sector workforce, and although in some circumstances may be taken for cases of ordinary seasonal flu, does not cover less severe communicable diseases in every circumstance. In addition, there is the issue of lost income for those who cannot afford to take unpaid leave, or who are at risk for loss of employment if they do not report to work (TFAH 2009b).

Prior relationships and planning between the health and education sectors, both within the USG and at the state and local levels

The Secretaries of HHS and ED released school-related guidance together, and staff from CDC and ED spoke regularly and met in person several times to coordinate activities during the response. Partnerships between HHS and ED resulted in the availability of toolkits by summertime for schools and summer camps to guide social distancing measures. The recommendations balanced the needs of disease mitigation with social disruption very well. HHS and ED collaborated to provide guidelines that worked for education and public health. Specific pre-pandemic planning activities that contributed to relationship building between the health and education sectors at the local level included multiple school and health department tabletop exercises and meetings.

Relationships created between ASPR, CDC, DHS, and ED that were formed during previous interagency pandemic exercises and other programs conducted prior to the 2009 pandemic were valuable to the actual H1N1 response. For example, prior to 2009 H1N1, the Homeland Security Council (HSC, renamed the National Security Staff [NSS] in 2009) held meetings with the interagency regularly to ensure progress was being made on implementation of the national pandemic strategy and implementation plan, which would help facilitate coordination among federal agencies in the event of a future pandemic. These interagency meetings were continued during the 2009 H1N1 pandemic response. These interagency meetings were credited with making communication and coordination during the H1N1 response easier than it would have been otherwise.

States also benefitted from partnerships and collaborations that were forged during past events or emergency preparedness planning. For example, New York State had standing Memoranda of Understanding (MOUs) with state police and the Department of Corrections. These MOUs helped to ensure that emergency response plans were in place at penitentiaries and court systems, and that proper lines of communication were open between all entities regarding disease surveillance and reporting. The New York State Department of Corrections also provided the state with trucks and drivers to move assets, such as SNS supplies. Alaska collaborated with state troopers to distribute the SNS cache to local clinics in rural areas inaccessible by local roads. South Carolina leveraged existing relationships between the public health department and providers and hospitals to communicate on H1N1 issues (e.g., infection control protocols, sample testing prioritization and procedures, and education of the public). States frequently collaborated with hospital and medical associations to reach health care providers in order to distribute information and guidance through alerts on the CDC's Health Alert Network (HAN).

In addition to leveraging existing relationships, states took opportunities to forge new and novel partnerships. In addition to New York, other states' public health departments formed relationships with their departments of corrections and departments of education to provide guidance and inform those departments about community mitigation strategies such as isolation and screening issues. The New York State Health Commissioner formed relationships with local contacts at the Department of Education to improve communication with the school system on surveillance and school closure issues. New York's hospital labs also increased communication and collaboration with public health labs to educate hospital staff about protocol and prioritization of testing suspected H1N1 cases. These partnerships helped to mitigate confusion about lab surge issues, as well as about who should be tested.

Borders and travel restrictions

One of the major decisions senior health officials faced at the beginning of the pandemic was which actions to take at border crossings and whether to issue travel advisories or alerts as a means of effectively reducing the spread of the virus. Past planning efforts assumed the virus would originate abroad, so implementing travel restrictions and border screening might help delay entry of the virus into the U.S. According to one stakeholder from CDC, planning for border screening "was too heavily emphasized prior to H1N1" due to the assumption that a pandemic virus would emerge outside of North America. When the H1N1 virus emerged within North America, HHS's decisions related to travel were flexible and responsive to the reality of the 2009 H1N1 threat.

In the beginning days of the pandemic, DHS Customs and Border Protection took the step of visually inspecting travelers entering the United States for flu-like symptoms, referring suspected infected persons to CDC quarantine stations or public health officials, and providing travelers information on measures for controlling influenza transmission. As of April 23, 2009 (just prior to the declaration of a public health emergency), CDC guidelines recommended that individuals feeling ill or experiencing flu-like symptoms should not travel, but they did not recommend exit screening at our borders; Customs and Border

Protection did develop a concept of operations for exit screening should it have become necessary to prevent the export of 2009 H1N1. With the raising of the WHO pandemic alert to Phase 4, indicating small clusters of sustained human-to-human transmission, CDC issued a travel warning against non-essential travel to Mexico on April 27. On April 28, WHO issued an update for travelers indicating that it did not recommend restricting international travel, and on May 1 (well before its declaration of a full pandemic), WHO released a statement declaring no public health rationale for travel restrictions. CDC removed its travel health warning to Mexico on May 15th once it recognized the risk of contracting the disease was estimated to be no higher in Mexico than it was in the U.S.

There was an early decision to adapt to the situation at hand and change past planning efforts related to travel restrictions. Restrictions on travel and screening at borders were dismissed early on, having generally been viewed as being unlikely to be effective, having little impact on slowing transmission of 2009 H1N1, and being disruptive as the pandemic progressed. U.S. travel policies in 2009 were relatively unrestrictive when compared to other countries that employed thermal screening at airports with mandatory isolation of febrile passengers to prevent export of 2009 H1N1. CDC provided Traveler Health Alert Notices (THANs) and put up health information posters for arriving travelers at points of entry. DOS informed U.S. citizens of such travel guidance through its website (http://travel.state.gov). In addition, U.S. missions overseas distributed warden messages to locally registered U.S. citizens on the influenza situation in affected countries and identified the best sources of public information, which included updates and alerts from other governments.

Awareness about respiratory etiquette, hand hygiene, and behavior change

Given that the vaccine would not be available until the fall of 2009, non-pharmaceutical methods to reduce disease transmission were critical to the 2009 H1N1 pandemic response. As a consequence, the USG and communities invested substantial effort in developing and implementing risk communication messages about respiratory etiquette, hand hygiene, and staying home when sick.

The pre-existing Pandemic Severity Index (PSI) and triggers for initiation of non-pharmaceutical interventions

In prior pandemic planning, the use of mitigation measures was dependent on the severity of the pandemic and tied to the Pandemic Severity Index (PSI). However, the 2007 PSI used case fatality ratios as the critical driver in categorizing the severity of a pandemic, and the case fatality ratio cannot be calculated early in a pandemic if the denominator of that ratio—the total number of infected persons (severely ill, symptomatic, and asymptomatic)—is unknown. Other factors compromising the accuracy of the PSI were the rarity and potential delay in reporting deaths due to 2009 H1N1, as well as the transmissibility of the disease.

Because these factors compromised the utility of the pre-existing PSI, there is a need for a better and more refined metric other than case fatality rate for defining severity. Further refinement is needed to have faster estimates of severity across populations in order to increase the efficiency of the response. The absence of adequate severity data made it

challenging to make policy decisions about mitigation measures. Furthermore, the impact of the 2009 H1N1 pandemic varied by locality, and local officials did not have the resources to calculate case fatality rates unique to their jurisdictions. In general, it was difficult to practically apply a national severity measure to a local context.

The 2009 H1N1 influenza pandemic could have resulted in greater morbidity and mortality, and the existing plans based on more severe pandemics need to be easily adaptable in order to determine the optimal time to implement mitigation measures. The PSI should be re-designed to effectively guide implementation of mitigation measures.

Policy decisions related to community mitigation measures

Consistent with previous reviews of the science behind non-pharmaceutical public health interventions (Aledort 2007), survey and participant interview data for this retrospective identified the lack of an adequate evidence base to inform community mitigation as an area for improvement. Studies of the utilization and effectiveness of mitigation measures during the 2009 H1N1 pandemic have been conducted, but many results are still pending. Further efforts might be undertaken to determine if this information would contribute to a public health response.

Research and policy efforts should focus on both the public health outcomes of community mitigation and the social disruption CMM triggers, in order to develop balanced guidance and remove obstacles to effective implementation. Since limited evidence was available to inform implementation of CMM, more research is needed on the effectiveness of CMM, their secondary effects, public acceptability of the measures, and likely compliance with them. Better data on the impact of various community mitigation approaches in improving health outcomes would encourage states, territories, tribal, and local communities to implement federal guidance. Also, additional research on CMM could further support policy development.

Real-time information on school and work absenteeism

As described in the Surveillance chapter, routine influenza surveillance does not capture school absenteeism because the data are difficult to gather and interpret. Further efforts might be undertaken to determine if this information would contribute to a public health response. Information on school attendance may have been useful in monitoring disease trends across the country, but it is unclear whether such information would meaningfully add to other surveillance efforts. Further, it is difficult to track absenteeism without already having established systems in place and most schools and school districts are not capable of (or funded for) providing these data to their education or health agencies in real time. Furthermore, to detect increases in absenteeism, baseline data on usual levels of absenteeism must be assembled.

A national effort was mounted during the pandemic to track information on school closures. This system demonstrated that local jurisdictions were responsive to federal guidance on school closures, and that the majority of school closures occurred in the fall when school closure was no longer recommended to mitigate the pandemic, but rather was used as a reactive measure to school absenteeism.

Personal Protection Equipment (PPE) - N95 respirators and surgical masks

Another community mitigation measure is the use of Personal Protection Equipment (PPE), which includes masks and respirators. However, there is a lack of scientific evidence on the effectiveness of respiratory PPE as a mitigation strategy. Also, although updated guidance on the use of PPE had been issued, and caches of PPE from the SNS had been released to states, during the fall of 2009, aspects of the response pertaining to PPE offer some opportunities for improvement. Specifically, it is not clear whether surgical masks offer sufficient protection against influenza viruses, or if N95 respirators or other more stringent respiratory protection may be needed. Additional research in this area is needed.

Some states and localities, including South Carolina, Los Angeles County, and Alaska, reported problems with distribution of N95 respirators. To comply with CDC guidelines recommending health care employees to use N95 respirators, one state reported the need to procure additional respirators. A new vendor filled the supply, causing challenges concerning the need to conduct additional fit testing. Some states have managed to ramp up fit testing and bolster their just-in-time training in response to these challenges. In addition, one state reported that some suppliers put a limit on the number of supplies they were distributing. As a result, they received several calls from clinics, physician offices, law enforcement and EMS asking where they could obtain N95s.

Guidance on the use of PPE in the workplace

Implementation of PPE guidance varied across federal departments, stemming from the fact that different federal agencies released different sets of recommendations on the appropriate PPE to protect against the 2009 H1N1 influenza virus. It would be desirable in the future for the federal government to disseminate a single, consistent set of recommendations.

Priorities for PPE use may have been too narrowly focused on health care providers while overlooking other frontline workers also at risk for occupational exposure to the 2009 H1N1 virus. The guidance on PPE could also have targeted law enforcement workers. There is a need for ongoing discussions regarding the full scope of personnel that should be prioritized for PPE use in future emergency situations linked to the severity of the pandemic.

Some forms of PPE, such as respirators, need to be properly fitted and some need to be periodically refitted in order to ensure that they are providing proper protection. It is always a challenge to write guidance on fit testing for PPE that require fit-testing (i.e. respirators) that is realistic given practical constraints of real-world clinical and other occupational settings. There was great demand for respirators, but insufficient resources to provide rapid fit testing for everyone who required such testing in accordance with federal government standards.

PPE deployed from the SNS

In some cases, PPE that was released was not the preferred or previously fit-tested brand, did not fit, or required training for use. Some masks deployed from the SNS were different brands and required different training for proper use. Because of unique training and fit testing requirements for each brand of mask, standardizing the brand of PPE available from the SNS and soliciting input from states into decisions about purchases for the SNS contents should be considered.

Chapter 4 Summary

Successes

1. Guidance for a range of community mitigation measures was released quickly and coordinated across multiple federal agencies.
2. Guidance on school closure was responsive to changes in the understanding of pandemic severity.
3. Prior relationships and planning between the health and education sectors, both within the USG and at the state, local, and tribal levels, facilitated the response.
4. Congruent with WHO recommendations, the quick USG decision to keep borders open and minimize travel restrictions avoided disruptions of travel and trade, avoided panic and stigma, and conserved resources.
5. The USG raised awareness about respiratory etiquette and hand hygiene, and surveys indicated that use of these behaviors increased.
6. CDC and ED developed a system to collect information on school closures related to 2009 H1N1 influenza.
7. While some states had limited capacity for storing oral antiviral medications and PPE deployed from the SNS, this did not appear to hinder storage. Ultimately, states were able to accommodate SNS supplies.

Opportunities for Improvement

1. 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 the response. As a follow-up to this, 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—in large part because only the more severe cases are initially visible—a PSI Framework needs to remain flexible enough so that accurate and appropriate mitigation measures may be taken at times of uncertain severity. Evidence to inform policy decisions related to community mitigation measures is limited, and a stronger evidence base is needed.
2. Although information on school closures was available, systems to track workplace or school absenteeism due to influenza do not exist. To determine the full impact of a more severe pandemic, a system to monitor its effect on the workforce is needed.

3. The evidence base to support guidance on appropriate level of respiratory protection (N95 respirators or surgical masks) to prevent occupational acquisition of 2009 H1N1 infection in health care workers was insufficient. This lack of evidence made developing science-based guidance difficult and controversial. In some cases, the PPE that was delivered was different from what those recipients were familiar with, therefore requiring that users undergo time-consuming fit testing with the new product.

CHAPTER 5: MITIGATION MEASURES – MEDICAL COUNTERMEASURES

Within the context of the National Framework, mitigation associated with medical countermeasures includes the appropriate use of antiviral medications for prevention and treatment of influenza infection. Although the Framework allows for use of antiviral medications for both prevention and treatment, antiviral medications were deployed only for treatment in the 2009 H1N1 response.

Immediately following the official announcement of the first U.S. cases of H1N1 on April 24, 2009, HHS quickly took actions to dispatch medical countermeasures from the SNS to states and to prepare for their large-scale use in response to the 2009 H1N1 pandemic. A timeline of key actions related to medical countermeasures is described below.

CDC and FDA considered certain off-label uses of the antiviral medications oseltamivir (Tamiflu®) and zanamivir (Relenza®) relative to ages, dosage, time for usage, and severity of disease acceptable to consider during the declared pandemic emergency. On April 26, 2009, FDA issued EUAs authorizing the use of Tamiflu® and Relenza® for wider segments of the public beyond those for whom the medications were approved. The EUAs allowed for expanded use of oseltamivir to include hospitalized patients and patients less than one year of age, and allowed for both oseltamivir and zanamivir to be dispensed by a wider range of health care workers, including volunteers. Accordingly, relevant Public Readiness and Emergency Preparedness (PREP) Act declarations were amended or issued by the Secretary to extend liability protections to use these medications to prevent or treat 2009 H1N1 influenza. On the same day, HHS deployed SNS materiel to high priority states and areas (i.e., those with confirmed cases of H1N1, states along the Southwest border (California, Texas, Arizona), and New York City) (Li et al. 2010).

On April 27, 2009, CDC released guidance on the use of respirators and surgical masks. The following day, HHS disseminated guidance to health care providers on the use of antiviral medications for patients with confirmed or suspected 2009 H1N1 influenza.

As the 2009 H1N1 pandemic progressed, and after careful consideration of federal policies and discussions of global demand, HHS released medical countermeasures to other nations, including Mexico, to which it deployed over 400,000 treatment courses (one percent of the federal government's antiviral stockpile) on April 30, 2009. During the summer of 2009, HHS also deployed 420,000 treatment courses of oseltamivir to the Pan American Health Organization (PAHO) for distribution to several Latin American countries as part of a larger effort to assist countries in the Western Hemisphere in responding to the 2009 H1N1 pandemic.

Towards the end of the summer, HHS geared up for its domestic response in the fall of 2009 by updating and disseminating guidance on the use of antiviral medications. As information on the appropriate use of antiviral medications evolved over the next several months, HHS continued to update and disseminate guidance to health care providers. On September 28, 2009, HHS Secretary Kathleen Sebelius signed a PREP Act declaration for

the investigational intravenous antiviral drug peramivir, extending liability relief to cover its administration and use to treat 2009 H1N1 influenza. The PREP Act declaration was made effective retroactive to April 26, 2009 in order to cover certain uses of peramivir under an investigational new drug (IND) prior to the date of signature. On October 23, 2009, the FDA issued an EUA for peramivir's treatment of 2009 H1N1 influenza in certain pediatric and adult hospitalized patients for whom intravenous therapy was deemed clinically appropriate. An IV formulation of peramivir, under its EUA status, was used in more 1200 patients who were hospitalized with known or suspected influenza. HHS also continued to release caches of antiviral medications from the SNS to states during the fall of 2009. While certain aspects of the response related to PPE offered some opportunities for improvement, those aspects pertaining to antiviral medications were generally viewed as successes.

Supplies of antiviral medications

The national supply of antiviral medications appropriate for adults was adequate throughout the course of the pandemic. This was due in large part to a significant federal government purchase of antiviral medications in 2006, which built up the stockpile and stimulated manufacturers to develop and expand their capacity for manufacturing antiviral medications. Thus, when H1N1 influenza surfaced, the USG had in place both a significant stockpile and knew that there was a robust commercial pipeline from which to procure additional antiviral medications as needed. There were benefits from the USG partnering with the private sector as well. For example, SNS managers and others assembled a consortium of public and private groups to understand the market for antiviral medications, and BARDA successfully elicited the cooperation of leading antiviral manufacturers to reduce gaps in the supply chain.

Although the supply of antiviral medications was adequate for the needs of the 2009 H1N1 pandemic, shortages might have occurred in a more severe emergency that warranted much larger use of antiviral medications. Furthermore, the distributions from the SNS did not adequately address pediatric needs. This issue is discussed in more detail below as an area for improvement.

Antiviral medication distribution from the SNS to states and territories

During the 2009 H1N1 pandemic response there was rapid deployment of antiviral medications from the SNS to states and territories. IOM had published guidance on developing antiviral distribution programs (IOM 2008). However, due to the characteristics of 2009 H1N1, CDC chose to employ a prioritized deployment schedule to allow distribution of SNS assets to high priority areas first. In this prioritized plan, all states received antivirals within seven days for deliveries of the first 25% of stockpiled pandemic influenza countermeasures conducted in the spring of 2009 under the pro-rata distribution plan. CDC had focused on improving medical countermeasure distribution, and H1N1 provided a useful opportunity to evaluate progress made.

Unfortunately, because there is limited information available as to whether individuals who received antivirals belonged to risk groups or had severe presentations of the disease, it is challenging to evaluate whether antiviral distribution was optimized during the

response. Antivirals may have had a stronger impact earlier in the pandemic if there had been fewer limitations on the use of the drugs, especially during the second wave of 2009 H1N1 influenza and before the vaccine became widely available. Although fewer limitations on use of the antiviral drugs may have stemmed the incidence of infection for a short time, containment would have been impossible due to the spread of the virus at the time of its detection.

IHS used a central distribution system, the National Service Supply Center, to distribute antiviral medications to IHS facilities, rather than relying on state distribution to IHS facilities.

While distribution was timely, there were some instances in which distribution occurred before states had sufficient storage capacity to receive material from the SNS. There is a need to clarify the roles of the federal government and private sector in distribution, as well as to enhance distribution through the private sector. This distribution enhancement may be accomplished by either utilizing existing clinical distribution systems and retail pharmacies, or by identifying or developing a track and trace system capable of locating a single therapeutic dose anywhere along the supply chain from manufacturer to administration to the individual.

Federal models of dispensing medical countermeasures to individuals may benefit from adding the private sector to the distribution systems in planning for medical countermeasures. The current vaccine distribution system is based on the VFC platform, and this system was in place prior to the pandemic (and will be discussed further in the Vaccine Pillar Chapter) and is used in routine public health practice. This may be the model upon which to build a distribution plan.

Guidance on the appropriate use of antiviral medications

CDC guidelines surrounding the use of antiviral medications were appropriately informed by the evidence base and by consultation with participants, including associations of medical professionals. Moreover, gaps in the guidance were addressed rapidly after they were identified (e.g., dosing of antiviral medications for pediatric populations). This guidance recommended antiviral medications for treatment only in most cases, and prophylaxis in more limited situations.

Of course, guidance against use of antiviral medications for widespread prophylaxis may not result in uniform compliance by clinicians. It is always challenging to communicate rapidly changing guidance in a clear and timely manner to providers. Special mechanisms for reaching pediatric providers included webinars and CDC hotlines staffed by experts.

Emergency Use Authorizations for certain antiviral medications

The FDA may issue Emergency Use Authorizations (EUAs) during public health emergencies to allow the use of drugs, biologics, and devices (including diagnostics) for non-approved indications, if certain criteria are met. Use of a product under an EUA differs from that of a clinical trial in which several issues related to human subject considerations arise, especially for multi-site research activities. In certain circumstances,

an EUA may place conditions for the collection of information regarding the safety and efficacy of an unapproved product with respect to the product's emergency uses during the period when the authorization is in effect, limiting the ability to garner useful information during a public health emergency that could help inform further development of that product.

During the 2009 H1N1 pandemic response, the FDA rapidly issued EUAs for the antiviral medications oseltamivir, zanamivir, and the intravenous drug peramivir. The EUA for oseltamivir extended its use to children under one year of age, and the EUAs for both oseltamivir and zanamivir broadened the range of health care workers who could dispense them. The EUA for peramivir was the first ever to be issued for an unapproved drug and allowed for use of peramivir in critically ill, hospitalized patients. In addition, six million treatment courses of zanamivir were purchased to mitigate the risk of the emergence of resistance to oseltamivir prior to the second wave of 2009 H1N1 pandemic strain of influenza. The timely issuance of EUAs was a result of prior pandemic planning, which sought to clarify and streamline the EUA process through better coordination between FDA and CDC.

The EUA authorized the use of peramivir for certain hospitalized patients with known or suspected 2009 H1N1 influenza. However, the EUA did not place conditions for the collection of information regarding the efficacy of peramivir with respect to the product's emergency uses. This may have limited the extent to which the efficacy of peramivir could be further evaluated. However, the EUA made the investigational drug broadly available to people across the country in a short time. There were challenges in the uptake of guidance provided to pharmacists and health care providers at the state and local levels on implementing EUAs for antiviral medications. The guidance may not have been clearly communicated or disseminated to pharmacists and health care providers who are not generally familiar with EUA language, which delayed distribution. Delivering clear, concise guidance on EUAs through communication mechanisms routinely used by pharmacists and health care providers (e.g., through an official federal letter to state pharmacy boards) may have better facilitated their implementation.

The supply of antiviral medication in a form optimal for pediatric populations (i.e., premixed suspension)

Although the overall availability of antiviral medications in the SNS was adequate, the supply of antiviral medications appropriate for use in pediatric populations was insufficient. In one jurisdiction, the average age of youth affected by 2009 H1N1 was 10 years old. However, plans for SNS contents assumed that the average age of youth affected was 18 years old. This highlighted the importance of planning for variability in medical countermeasure needs for pediatric populations across jurisdictions. This suggestion is consistent with the Pandemic and All Hazards Preparedness Act (PAHPA) legislation enacted in 2006 specifying the need to ensure adequate provisions for the care of at-risk individuals, including pediatric populations, in public health emergencies.

As set forth above, FDA issued an EUA to expand the use of Tamiflu® to children under the age of one and released guidance to pharmacists on compounding oral suspension from

capsules. However, it was noted that the guidance, which may be relevant to other drugs when supplies of pediatric formulations are limited, was complicated and difficult to understand. This guidance was last updated on December 1, 2009 and may be found at http://www.cdc.gov/h1n1flu/antivirals/mixing_tamiflu_qa.htm.

Monitoring of the supply of antiviral medications after release from the SNS

Although distribution of antiviral medications was a success, situational awareness of antiviral medications after their release from the SNS to states was limited. The CDC processed and PSC Supply Support Center delivered almost 1400 clinic requests for peramivir (approximately 2100 5-day adult treatment course-equivalents) during the EUA period between October 2009 and June 2010. However, there is no comprehensive system in place to track antiviral medications after they are received by states, or to monitor their safety, efficacy and proper disposal. Bar coding of antiviral medications may facilitate effective medication tracking and monitoring. There was limited visibility of the commercial supply chain, which further complicated tracking actual uptake. The government provision of antiviral medication versus the private supply system needs further clarification.

The CDC/Division of Strategic National Stockpile Dashboard is designed to maintain situational awareness of medical countermeasures at a national level. However, a centralized system is needed to track medical countermeasure activities and effects at the more granular state and local levels. Among other benefits, such a system would help to identify opportunities for performance improvement (e.g., population disparities in antiviral medication use), facilitate redistribution, and support local decision making regarding medical countermeasure distribution.

Another limitation in monitoring antiviral medications was the limited data collection on their safety and effectiveness, particularly those used under an EUA. Informative clinical data is needed to assess whether medications used under an EUA are beneficial or harmful. Therefore advance preparation and appropriate implementation of research protocols would be extremely important to obtain information data on their effects.

At the time of the 2009 H1N1 pandemic, there was insufficient data regarding the effectiveness of the investigational medication peramivir. It is difficult to collect and review clinical data during a response, and more work is needed in this area to develop research protocols and consortia that may be prepared to generate appropriate data on clinical safety and efficacy before and during emergency situations.

States' capacity for storing antiviral medications and PPE

Some states had limited capacity to store antiviral medications and PPE when they were not immediately required by local jurisdictions, a situation that was not immediately apparent in all cases. States had the capacity to store antivirals, but some states did not have the capacity to store the drugs for prolonged periods of time. Because SNS material was released before many states had depleted their own stockpiles, some states had unanticipated excesses of medical countermeasures to store. There is a tradeoff between advanced deployment—requiring storage—and on-demand deployment, and this deserves

further investigation. It should be noted that assessments of states' capacities for long term storage of vaccines had not been done before or during the pandemic.

A review of recommendations for improving the national public health response to the 2009 H1N1 pandemic further underscored the problems associated with the limited capacity of states to store medical countermeasures that were acquired but not distributed over the long term. The review noted the need for guidance and financial assistance from the federal government on how to dispose of and/or re-direct these assets to other activities (ASTHO 2010).

Plans and policies for international deployment of antiviral medications

While HHS successfully deployed hundreds of thousands of treatment courses of antiviral medications to Mexico and PAHO, there were planning challenges and coordination issues across the federal government to support international deployment. These included the specific authority within the USG for international deployment and challenges of coordination regarding deployment of supplies from different USG sources.

Existing policies on antiviral medication deployment focused on containment operations abroad, assuming the pandemic would emerge in Asia, which was not the case in the 2009 H1N1 pandemic. Policies need to be in place regarding the deployment of antiviral medications and PPE to foreign governments once containment strategies are discontinued and mitigation strategies become needed.

Many issues with international deployment applied to vaccine as well as to antiviral medications and PPE. International deployment of vaccine and ancillary supplies are discussed further in Chapter 8: Cross-Cutting Issues.

Diagnostics

Accurate diagnosis is a critical element of pandemic influenza response, both for surveillance purposes and clinical management. As would be expected during a pandemic, demand for testing was high. Highly sensitive and specific reference diagnostic tests were available at public health laboratories and were used for surveillance of the pandemic H1N1 virus. These tests were able to meet the initial surge and provide confirmatory laboratory testing for clinical specimens. Because of the time delay in shipping specimens to these reference laboratories and the overwhelming number of tests being requested, a more widely available sensitive and specific test would have helped meet the clinical demand for testing. With the greatest diagnostic challenge being at the point of clinical care, the absence of readily available, rapid, simple, and highly sensitive diagnostic tests which could detect the 2009 H1N1 virus made infection control more difficult.

Accurate, point-of-care rapid diagnostic tests for detecting probable novel influenza cases were not available. In order to meet the need for diagnostic tests during the 2009 H1N1 influenza pandemic, FDA authorized 18 diagnostic tests through the Emergency Use Authorization, although none of these were point-of-care tests. As a result of these authorizations, more diagnostic tests became available, allowing public health laboratories to concentrate their efforts more towards surveillance activities. Some of the authorized

tests were in fact developed by clinical laboratories for their own use, and are known as laboratory developed tests (LDTs). Certain clinical laboratories submitted validation information on their 2009 H1N1 LDTs to FDA and had their tests authorized, allowing wider availability of these tests to other clinical laboratories and communities. However, while more diagnostic tests received EUAs, only the first diagnostic test submitted to CDC and the July authorization to Focus/Quest contributed to meeting the test demand. Most EUAs were issued in the fall of 2009, and some not until 2010, well after the peak demand for testing. Also, the lack of information on LDTs that may be available during a pandemic response and their accuracy to detect a novel influenza such as 2009 H1N1 creates uncertainty when planning responses regarding their effectiveness as diagnostic tools.

Laboratory surge issues differed across states as well. New York and South Carolina set up protocols to prioritize lab testing samples, while Alaska and Connecticut did not experience surge issues because of low volume. Oklahoma noted that they did not experience a surge in lab testing, but that testing every suspected case in future outbreaks would become a challenge. Alaska experienced a unique challenge due to its geography—lab samples had to be sent to Seattle due to the lack of lab facilities in the state. States leveraged daily conference calls, HAN alerts, and websites to disseminate information regarding lab testing protocol, and lab personnel were often on state conference calls to provide expertise and lab testing information. In general, states have agreed that having proper processes and procedures in place to manage critical supplies and equipment during this phase is important.

Over the next several years, it will be important to sustain and broaden the laboratory diagnostic capabilities for influenza that are now in place. Doing so will maintain the capability to support routine influenza surveillance each year, as well as the capacity for increased testing during the response to a novel virus. In particular, the worldwide spread of the novel 2009 H1N1 virus highlighted the need to sustain planning for the rapid dissemination of authorized diagnostic test reagents to all state public health laboratories and virtually every national public health laboratory in the world. Improved partnerships with commercial laboratories may help in this aspect of the response. The regulatory issues associated with the use and distribution of new diagnostic tools must also be considered as part of these overall preparedness efforts to broadly facilitate the use of these tools. It will also be necessary to improve the availability of reliable diagnostic laboratory tests (especially those that can differentiate among influenza A subtypes) for clinicians at the point of care and to optimize the use of molecular testing for influenza viruses at hospital and commercial laboratories. All of these efforts ultimately reduce the time it takes to detect and recognize an influenza outbreak with pandemic potential.

Chapter 5 Summary

Successes

1. Antiviral medications were administered at a higher rate than ever before.
2. Antiviral medications were rapidly distributed from the SNS to states and territories.
3. Guidance on the appropriate use of antiviral medications was timely and evidence-based, and changed as new information became available.
4. EUAs for additional indications of the antiviral medications oseltamivir (Tamiflu®) and zanamivir (Relenza®) were issued in a timely fashion.
5. FDA issued an EUA authorizing the use of the unapproved intravenous antiviral medication peramivir in certain hospitalized patients with known or suspected 2009 H1N1. Peramivir development is part of the ASPR Office of Biomedical Advanced Research and Development Authority (BARDA) pandemic preparedness.
6. With the exception of pediatric suspensions, the commercial distribution system in the U.S. was generally capable of keeping up with demand for antiviral medications.

Opportunities for Improvement

1. The national supply of antiviral medication in a form optimal for pediatric populations (i.e., premixed suspension), including that in the SNS, was insufficient, especially given the epidemiologic profile of the 2009 H1N1 pandemic.
2. It is important to develop a monitoring and research system adequate to support the study of uptake, safety, and efficacy of antiviral medications after release from the SNS to public providers, or by states from their own stockpiles.
3. Research is important to produce interpretable information on safety and efficacy of antivirals before and during a pandemic. There were limited mechanisms to study the safety and efficacy of the medications made available under an EUA. As a result, while the approximately 2100 treatment courses of the intravenous antiviral medication peramivir were distributed, there is insufficient information regarding its effectiveness against severe 2009 H1N1 influenza to support approval. Other factors contributing to the lack of information regarding peramivir effectiveness included: the lack of protocols and clinical trials consortia prepared to implement the collection and analysis of information regarding the efficacy of peramivir; restrictions on follow-up peramivir research because of contractual agreements associated with the antiviral medication, and no mechanisms were in place to conduct research on these types of products during an emergency event before the pandemic occurred.
4. States used different models to distribute antiviral medications received by the SNS. These different approaches in distribution resulted in greater availability and timeliness of antiviral drugs in some states compared with other states. The absence of an accurate and comprehensive monitoring system across the nation for

antiviral drug distribution from state and local stockpiles prevented determination of the effectiveness of this mitigation measure and provides an opportunity to develop such a system to collect data in real time during public health emergencies.

5. A policy for international deployment of oral and intravenous antiviral medications had not been developed in advance of the 2009 H1N1 pandemic, creating challenges for the deployment process.

Diagnostics

Successes

1. In order to meet the need for diagnostic tests for the detection of the 2009 H1N1 influenza virus, FDA authorized 18 such tests through the Emergency Use Authorization mechanism. Laboratory test developers were able to configure new assays to identify infections caused by 2009 H1N1 influenza viruses while manufacturers were able to receive EUAs for the assays, enabling distribution to multiple labs. The first EUA for the CDC RT-PCR assays was available almost immediately for use in public health labs already performing seasonal influenza subtyping using the same test system. As a result of the EUAs, more diagnostic tests became available and the public health laboratories were able to concentrate their efforts on surveillance activities.

2. Some of the authorized tests were developed by clinical laboratories for their own use. These tests are known as laboratory developed tests (LDTs). Test systems receiving later EUAs became available after July 2009 and were used primarily during the second wave in the fall. EUAs were issued for some LDTs later during the fall of 2009. With the exception of the EUA for the CDC RT-PCR assays, other EUAs were not available during the peak demand in the late spring and early summer of 2009.

3. During the first week of May 2009, many laboratories were able to develop new assays for 2009 H1N1 virus using sequence information quickly released by the CDC. Many of these laboratories collaborated with public health laboratories to exchange information and to validate test results from these newly developed tests.

4. Experimental point-of-care diagnostic devices under development with support from BARDA and CDC were used in the detection of the first cases of 2009 H1N1 in the U.S.

Opportunities for Improvement

1. Accessible point-of-care diagnostic tests for 2009 H1N1 influenza were not sufficiently sensitive for accurately diagnosing influenza in patients with respiratory symptoms.

2. The greatest diagnostic challenge remains at the point of clinical care. The absence of readily available, rapid, simple, and highly sensitive diagnostic tests which could detect the 2009 H1N1 virus made infection control more difficult.

3. Testing accuracy for detecting a novel influenza virus such as 2009 H1N1 is a concern both in terms of reliability for use in surveillance and as a diagnostic tool.

CHAPTER 6: VACCINATION

The November 2005 National Strategy for Pandemic Influenza identifies vaccination as the most important element of pandemic control, and the 2009 National Framework for H1N1 describes vaccine as the most effective medical countermeasure. Thus, very soon after the detection of the new 2009 H1N1 strain, HHS began work to develop a vaccine by isolating the virus and preparing the vaccine strain. The vaccine pillar of the 2009 Framework covers actions to ensure that safe, effective vaccines are available for mass distribution to the public in a timely manner, and includes all major activities from the initial steps of vaccine development through the administration and monitoring of 2009 H1N1 vaccine that began in October 2009 and extended through spring 2010. A mass vaccination program for a new strain of influenza includes: 1) deciding whom to vaccinate given the epidemiology of the disease and the available or projected vaccine supply; 2) determining the amount of funding for vaccine and administration supplies to request from Congress; 3) developing a pandemic vaccine that meets targets for immunogenicity; 4) licensing and approval for manufacturing; 5) advising states to prepare for activation of allocation, distribution, and administration plans; 6) providing forecasts of pandemic vaccine availability from manufacturers; 7) monitoring vaccine supply and distribution; and 8) conducting vaccine-related surveillance such as coverage, safety, and effectiveness.

In this report, vaccination is discussed within the broad categories of vaccine development and production and vaccine allocation, distribution, and administration.

Vaccine Development and Production

Investments in pandemic preparedness/H5N1 planning

One of the goals in the November 2005 National Strategy for Pandemic Influenza was to establish sufficient domestic production capacity to ensure sufficient vaccine to vaccinate the U.S. population within six months of the emergence of a virus with pandemic potential (HSC 2005). Investments in fortifying existing domestic infrastructure and establishing new manufacturing technologies and facilities for pandemic influenza were started in 2007 with a five-year horizon for completion. However, the construction of a new manufacturing facility for cell-based influenza vaccines was not completed until November 2009, and thus it was not operational to produce vaccine during the pandemic. This new facility, which should be operational before the end of 2012, will eventually have the capacity to provide 25% of the national supply of pandemic influenza vaccine and will produce vaccine and adjuvants as needed for influenza pandemics and other emergencies. The Biologics License Application (BLA) for cell-based influenza vaccines is scheduled for submission to the FDA by this manufacturer in late 2011 as expected.

HHS was three years into the five-year plan when the 2009 H1N1 pandemic began. Although supplies of monovalent 2009 H1N1 vaccine were limited initially in the fall of 2009, 2009 H1N1 vaccine was successfully developed and manufactured in less than six

months. In contrast, the current seasonal influenza vaccine requires producing three strains and has a predictable production deadline, requiring a longer production cycle of seven to nine months. The ability to produce vaccine in this time frame, following the completion of seasonal vaccine production, was attributable to large investments in pandemic preparedness since 2006, which had been accelerated due to the emergence and spread of avian influenza H5N1 throughout the Eastern Hemisphere. BARDA investments retrofitting existing domestic manufacturing facilities resulted in increases in U.S.-based influenza manufacturing capacity as compared to 2006. In the context of H5N1 planning, HHS established contractual relationships with manufacturers and improved industrial manufacturing capabilities (such as ensuring a year-round supply of eggs in which to grow vaccine) that allowed the rapid production of 2009 H1N1 vaccine.

Development and clinical testing

Specific planning activities that contributed to rapid 2009 H1N1 vaccine development included the following: 1) developing guidelines and a decision protocol for determining whether a pandemic vaccine could be licensed using the strain change licensure pathway; 2) expanding manufacturing capacity to accommodate routine and surge volume needs; and 3) having contracts in place with manufacturers to enable speedier procurement when needed. Advice from FDA on the licensure pathway, and FDA's decision to license the monovalent 2009 H1N1 vaccine via the strain change pathway—as opposed to the lengthier licensure process for an entirely new product—allowed licensure to proceed more quickly since FDA does not require immunogenicity data or additional safety data for licensure of seasonal influenza vaccine. FDA moved quickly to inspect and license plants and new filling lines. When problems arose, FDA worked closely with BARDA and the manufacturer to resolve them quickly. Also, FDA worked with vaccine manufacturers to release vaccine sooner than usual through the use of electronic lot release submissions. This resulted in decreasing the time of lot release from weeks to days.

NIH and vaccine manufacturers, supported by BARDA, rapidly conducted immunogenicity studies as soon as vaccine was available, providing information needed to determine the dose that generated an adequate immune response. The studies also provided insights into the vaccine's safety profile.

During the 2003-2004 influenza season, there were three manufacturers prepared to produce vaccine for the U.S. market. When 2009 H1N1 was first detected, there were five manufacturers, each having previously-approved products amenable for alteration to the 2009 H1N1 strain, and HHS already had contracts in place with three of the five manufacturers. In addition, HHS had access to carry-over funds that were allocated for the start of vaccine production. Together, these factors allowed the federal government to contract for the production of 2009 H1N1 vaccine in a matter of days. As a result, the U.S. was among the first countries to place orders for vaccine. However, challenges existed in the federal contracting process for vaccine purchasing in that it was time and personnel intensive, and thus there may be opportunities for improvement in the contracting process.

The rapid production of 2009 H1N1 vaccine from seed lot to distribution went according to plan, but early HHS projections of timing of vaccine availability based on previous

experience with other pandemic viruses were overly optimistic. Although vaccine was produced in a record amount of time, it still had to be filled, finished, placed into vials, and shipped, creating delay in disseminating vaccine to the public. Many issues contributed to the vaccine not being widely available until after the peak of illness occurred and thus not having a large public health impact.

Consideration of the use of adjuvant

In the summer of 2009, HHS spent hundreds of millions of dollars on the purchase of additional bulk adjuvant, which could extend the limited vaccine supply and increase the immunogenicity of vaccine. The decision to stockpile adjuvant was a necessary insurance policy during a time of uncertainty.

A series of events that would trigger the use of adjuvant, and decisions regarding the use of adjuvant were revisited at regular intervals throughout the late summer and fall. The ultimate decision not to include an adjuvant was made based in large part on early data from clinical trials indicating that a single unadjuvanted 15-microgram dose of vaccine induced a robust immune response predictive of protection.

Despite immense pressure from the international community and manufacturers, who recommended adjuvants in order to extend the global supply, stockpiled adjuvant was not used. More research is needed on when to use adjuvant, as well as the triggers that would be involved to utilize adjuvant.

It is also important to emphasize that many Americans are unfamiliar with adjuvants. Public communications and education strategies should be developed to increase public (and provider) understanding of their purpose, safety profile, and greater public health good to facilitate better-informed decision making during a future pandemic or other public health emergency.

Egg-based technology for the production of influenza vaccines

One of the greatest challenges for the pandemic response cited was the antiquated, time-consuming, and unpredictable egg-based technology that is currently used to produce influenza vaccines. Unfortunately, the 2009 H1N1 virus grew even more slowly than expected. Despite HHS having spent more than $1 billion to enhance vaccine manufacturing capacity, newer technologies were not sufficiently mature to play a role in the 2009 H1N1 pandemic. The response, therefore, relied on technologies to produce influenza vaccines (i.e., egg-based production lines) that have not fundamentally changed in several decades. The U.S. made the most of an inherently limited technology, and next-generation technologies are under development to make the process faster.

Utilizing certain technologies to shorten response times is desirable. Meeting this goal requires production methods that are not dependent on "growing virus" such as newer technologies to produce recombinant- and molecular-based vaccines. There is a need to remediate those bottlenecks, such as not being prepared to develop seed strains that will adapt to growth in eggs and produce a high amount of antigen when grown by themselves. There is also a need to have techniques that allow for the selection of rapidly growing

vaccine strains. In addition, the current methods for testing influenza vaccines for potency are antiquated and slow. More rapid and sophisticated methods need to be introduced that have the capability to shave four to six weeks off the manufacturing process.

As HHS pursues strategies to improve the current egg-based methods in the short term, more rapid sterility testing and potency testing methods are needed. Moreover, noting that 2009 H1N1 did not grow well in eggs, it was recommended that research to better understand the scientific basis of high-growth conditions for influenza viruses is needed to fine-tune production for the next pandemic, as well as have payoffs for seasonal vaccines as well as for vaccines. It is important to note, however, that such improvements are also needed for vaccines manufactured using other methods, such as cell-based technology. In addition, the successful use of any technology requires additional filling and finishing capacity.

Because both seasonal and pandemic vaccines are produced in the same manufacturing facilities, it is important to understand that the supplies of these vaccines are interdependent. HHS made seasonal influenza vaccine available early and urged the public to be vaccinated ahead of the typical seasonal influenza vaccination schedule, allowing manufacturers to switch to H1N1 vaccine production earlier. In order to integrate efforts to produce seasonal and pandemic vaccine, the decision-making process regarding the timing to produce seasonal vaccine before starting production of a pandemic vaccine at domestic vaccine manufacturers will need to be carefully weighed going forward.

In one instance, a vaccine manufacturer who produced both the 2009 seasonal influenza vaccine as well as the 2009 H1N1 vaccine experienced problems in completing production of the seasonal vaccine. This problem translated to a 45-day delay in switching over to full production of the 2009 H1N1 vaccine. Millions of additional doses of the 2009 H1N1 vaccine would have been made available sooner had the delay not occurred, and media reports on perceived delays were highly critical. Continuing to produce seasonal vaccine seriously affected the timeliness of the delivery of 2009 H1N1 vaccine because there was not enough filling capacity to produce both at the same time.

Projections regarding the timing of vaccine supply

Officials from BARDA provided projections of the vaccine supply early in the course of the response, raising the expectations of the American public and setting the stage for planning at the local level. Early projections were based on manufacturers' past experience producing pandemic vaccines; however, some of the assumptions on which the estimates rested were faulty, and the numbers proved to be inaccurate. Relying on past experiences, in mid-summer 2009 federal officials had predicted that 120 million doses of 2009 H1N1 vaccine would be released by October. By mid-August, however, officials had to scale back that estimate to 45 million doses because manufacturers found that the egg-based production process was not yielding as much virus as expected. As of October 21, only 12.8 million doses had become available. A factor that initially hampered accurate projections was the lack of a good test to measure the amount of vaccine antigen produced of adequate potency. As a result, some manufacturers initially believed they had manufactured far more vaccine than turned out to be the case.

Delays with vaccine delivery

The overly optimistic projections on the vaccine supply represented the most frequently cited area for improvement both within the vaccine pillar and for the response as a whole. Inaccurate projections had several important impacts on the response. A variety of factors may have contributed to poor projections, including delays in the switch over from seasonal to pandemic vaccine production, optimistic projects for new filling systems coming on line to fill pandemic vaccine, testing delays, and the failure to communicate the uncertainties in the vaccine manufacturing process.

The delays associated with pandemic vaccine delivery underscored known deficiencies in U.S. capabilities to manufacture influenza vaccine, and in retrospect reveal shortcomings in communications with the public about the vaccination program.

In terms of vaccine development and production, the observed delays reflected in part the fact that the 2009-H1N1 pandemic occurred before the full maturation of USG efforts to improve and fully expand the domestic vaccine supply. The delays were a consequence of a reliance on dated and inherently slow methods of vaccine production, unusually poor yields of the vaccine seed strains, slow production of seasonal influenza vaccine by one U.S.-based manufacturer, and the decisions of some nations to claim priority access to vaccine manufactured at the facilities of U.S. suppliers located in these countries.

Largely as a result of the delays in vaccine production, Secretary Sebelius called for a review of the entire medical countermeasure enterprise. This review, completed in August 2010, identified the need for flexible, nimble manufacturing to rapidly make a countermeasure against a novel infectious threat, including a new pandemic strain. The review also made a series of recommendations for strengthening the enterprise, and these are currently being implemented. Further, steps have since been taken to minimize the likelihood that these factors could contribute to similar delays in the future. These include:

- Supporting the advanced development of next-generation recombinant- and molecular-based influenza vaccines with shorter production times, greater scalability than current vaccines, and no dependence on the growth and production yields of influenza vaccine virus seeds;
- Supporting development of universal influenza vaccines;
- Completion of studies supporting U.S. licensure of adjuvant-containing influenza vaccines that can expand U.S. pandemic vaccine surge capacity multi-fold;
- Completing efforts to enhance domestic influenza vaccine manufacturing capacity at large, new dedicated facilities (such as the Novartis facility in Holly Springs, North Carolina) for production of cell-based and adjuvant-containing influenza vaccines and other vaccines, as needed;
- Establishing, for use in emergencies, domestic surge vaccine manufacturing capacity for pandemic influenza and other emerging diseases at BARDA's Centers for Innovation in Advanced Development and Manufacturing using flexible and innovative manufacturing processes with state-of-the-art vaccine technologies (this

recommendation was part of the Secretary's Medical Countermeasure Review);

- Optimizing methods to produce influenza vaccines to shorten manufacturing timelines through development of vaccine virus seed strains with high yields, better potency assays that take days, not weeks, to render results, and shorter sterility assays;
- Establishing a network of U.S.-based fill finish manufacturers to expand vaccine surge capacity; and
- Replacing the legacy vaccine ordering system used by states to place orders on behalf of providers with a web-based system that can be used directly by vaccine providers as well as by states and give states and providers real time communication about order shipment status.

Given the complexities of vaccine manufacturing and uncertainties about the timing of the epidemic, public officials should have done more to temper public expectations that vaccine would be delivered prior to the fall wave. These expectations resulted in a public outcry and loss of government credibility when expected vaccine supplies failed to meet the initial demand for the vaccine. Efforts to recalibrate public communications about the vaccination program to accommodate the prediction of an early fall wave and short supply of initial vaccine occurred too late to have an appreciable effect. In the future, anticipatory public messages about vaccine supply and delivery must be couched in terms that prepare the public for potential shortfalls during the periods of peak transmission. These public messages should be better integrated with messaging about steps that individuals and communities can take to reduce their risk and improved guidance for clinicians about the use of influenza diagnostics and antiviral medications.

Multiple formulations of vaccine with different age and risk group indications

In the fall of 2009, two types of 2009 H1N1 vaccine became available (i.e., nasal spray/live attenuated and injectable (inactivated) vaccine). In the injectable vaccine category there were a variety of formulations for different age and risk groups. This was a direct consequence of the decision to contract with every manufacturer of seasonal influenza vaccine to produce the 2009 H1N1 monovalent vaccine. The number of preparations and the varying age indications presented challenges for communications as well as logistics.

The fact that the live attenuated influenza vaccine (LAIV) was the first type of vaccine to become available posed unique challenges because it was inappropriate for use in several of the target populations (e.g., pregnant women, children under two, and those with chronic illnesses). It is important to note, however, that differences in safety and effectiveness may stem from differences in manufacturing processes and whether the vaccine is live or killed. Therefore, despite efforts to standardize, some differences among the available vaccines will likely continue.

Vaccine Allocation, Distribution, Administration, and Monitoring

The Advisory Committee on Immunization Practices identified priority groups early in the pandemic

In July 2009, The Advisory Committee on Immunization Practices (ACIP) determined its recommendations for 2009 H1N1 vaccine priority groups. These were based on a review of epidemiologic and virologic data identifying those at highest risk of infection and influenza-related complications. These recommendations, which were supported by high-quality data, remained in place for the duration of the pandemic, and were well received by the public. The ACIP also provided a sub-prioritization plan that could be adapted to local circumstances. There were communications regarding the target groups to providers and the public and that provide a clear rationale for prioritization. ACIP recommendations were flexible and allowed local public health departments to make changes based on their supply of vaccine.

State health departments took a variety of approaches in allocating vaccine to local health departments and provider categories. Also, because vaccine supply was initially limited, state and local health departments needed to make decisions about sub-prioritization of groups. As a result, there was considerable local variation regarding eligibility for vaccine, possibly creating confusion among the public. While telephone surveys were used to produce periodic national estimates of vaccine coverage, due to limited sample sizes estimates did not provide information at the state level until late in the vaccination program.

At times, the ACIP's risk-based priority scheme was divergent from some business continuity plans (i.e., the personnel they had identified as essential for business continuity, including law enforcement and non-health care first responders, were not covered under ACIP's scheme). It should be noted, however, that at the time the priority groups were announced in the summer of 2009, Native Americans were not known to be at higher risk for contracting the virus than the general population. Communication strategies should reflect the reality that the priority groups for receiving vaccinations may change both prior to and during a pandemic response.

The 2008 HHS and DHS *Guidance on Allocating and Targeting Pandemic Influenza Vaccine* (2008 Guidance) was drafted by a federal interagency working group whose members represented all sectors of the government through a collaborative process, incorporating input from all interested parties including businesses, community organizations and the general public. Information considered by the working group included rigorous scientific assessments of pandemics and pandemic vaccines, national and homeland security issues, essential community services and the infrastructures and workforces critical to maintaining them, and the perspectives of state and local public health and homeland security experts. The 2008 Guidance identified vaccination target groups along with their estimated populations for three levels of pandemic severity: severe, moderate and less severe. In a less severe pandemic, more emphasis was placed on protecting the health of the general population versus critical infrastructure and key

resources personnel, and this was the case with 2009 H1N1. This is in keeping with the thinking that a less severe pandemic is less likely to cause a threat to national security and social and economic disruption as compared to a severe pandemic, so the emphasis should logically gravitate towards the public health goals of preventing morbidity and mortality in the general population. It is important to note that the ACIP recommendations prioritized healthcare workers, pregnant women, and young children, all of whom were included in the highest priority groups in the 2008 Guidance for all pandemic severities.

Building on existing vaccine distribution systems: Vaccines for Children (VFC) program

The federal government considered using the SNS Points of Dispensing (POD) model, which had been the focus of pandemic vaccination planning at all levels of government for many years. However, concerns expressed by state and local health officials on June 3, 2009 at the National Advisory Committee (NVAC) meeting in Washington, DC, at the June 24-26 Advisory Committee on Immunization Practices (ACIP) meeting in Atlanta, Georgia, and on weekly ASTHO/NACCHO H1N1 vaccine conference calls indicated that the public health infrastructure would be unable to support a vaccination campaign of the magnitude expected for 2009 H1N1 Influenza as had been planned. Based on these concerns, CDC, with assistance from BARDA, began a process to reevaluate and revise pandemic influenza vaccine distribution plans.

Under the VFC Program, CMS and CDC cooperate to distribute recommended pediatric vaccines to children via private providers, with CMS financing the cost of the vaccines through the Medicaid program and CDC distributing the doses to certain state, local, and territorial health departments and agencies. By using the VFC Program as a basis, CDC implemented a federally financed and controlled distribution process that was scalable and used procedures and systems already familiar to many providers. Over 126 million doses of monovalent 2009 H1N1 vaccine were delivered to nearly 70,000 locations, over 330,000 total shipments, with 95 percent of shipments received within 48 hours of ordering. The number of providers enrolled to offer vaccine—greater than 120,000—was nearly triple the number enrolled in the VFC program. The decision for the USG to purchase all vaccine for the American public provided greater control over vaccine distribution, necessary to ensure equity and helpful given the fluid nature of the public health response. States and local health departments and providers were familiar with this system; as a result, the system could be expanded to serve adults as well as children very rapidly.

With McKesson, the private, centralized vaccine distributor contracted for both the VFC program and the 2009 H1N1 response, the vaccination program achieved national cold chain distribution to over 100,000 sites and built relationships with thousands of new providers who had not vaccinated adults prior to the pandemic.

Guidance to local jurisdictions to inform vaccine sub-prioritization

Specific problems identified on local jurisdictions on vaccine sub-prioritizations included a lack of information about the timing of vaccine arrival, how much and what types of vaccine to expect, and mismatches between the vaccine and ancillary supplies received (e.g., syringes and needles). The HHS Pandemic Influenza Plan did not address drug

delivery devices such as needles and syringes as critical components of a vaccination campaign. As a consequence, there were no known identified requirements nor preparedness actions for ancillary supplies at the onset of the pandemic.

As a result, local health departments and providers experienced challenges in planning and advertising for clinics or in confidently promoting the availability of vaccine. Also, the inability to control the type and amount of vaccine providers and local health departments would receive created challenges with storage capacity. In addition, the first available vaccine (i.e., nasal spray) did not align with ACIP recommendations to prioritize pregnant women and young children. Finally, vaccine supplies did not always arrive with vaccine shipments, causing logistical problems for jurisdictions. These issues demonstrate an opportunity for public health officials to improve their communications on prioritization.

Vaccine safety monitoring system

During the vaccination campaign, over 80 million Americans were vaccinated for 2009 H1N1 influenza within approximately four months. Monitoring vaccine safety was done collaboratively through the interagency. Through the NVPO, which is responsible for coordinating federal vaccine activities, the CDC, FDA, HRSA, and NIH worked with their counterparts in the Department of Veterans Affairs and DOD to ensure that the vaccine was being administered safely and monitored for potential adverse effects.

Rates of adverse events for the 2009 H1N1 vaccine were comparable to seasonal influenza vaccines. Significant information was provided in the literature regarding background rates of possible medical events anticipated in the population coincident with a large-scale vaccine campaign, and which may otherwise be assumed to be vaccine adverse events. (An example is *The Lancet* paper "Importance of background rates of disease in an assessment of vaccine safety during mass immunization with pandemic H1N2 influenza vaccines," which was available online in October 2009 before vaccination began.) This information was also important in order to assess potential vaccine safety signals and to help separate legitimate safety concerns from events that are temporally associated with – but not caused by – vaccination.

Concerns about an association between 2009 H1N1 vaccine and Guillain-Barré Syndrome (GBS) were heightened because of the experience with swine flu vaccine in 1976. GBS is a potentially fatal form of paralysis that may leave permanent weakness and disability. An end-of-year analysis from the enhanced safety surveillance for the 2009 H1N1 influenza vaccine suggested there was a weak association between the vaccine and the onset of GBS within six weeks of vaccination. However, investigations revealed that 2009 H1N1 vaccine was linked to only one additional case of GBS per million people vaccinated; by comparison, the 1976 swine flu vaccine was linked to ten cases per million vaccinated people. With the exception of GBS, the strong safety record can be attributed in part to the fact that the pandemic vaccine was produced in much the same way as seasonal vaccine, using the same techniques and production facilities. (More information on the link between 2009 H1N1 vaccine and GBS may be found at http://www.cdc.gov/h1n1flu/vaccination/gbs_qa.htm.)

To establish that the rate of adverse events for 2009 H1N1 vaccine were comparable to that of seasonal influenza vaccines, HHS expanded the existing safety system in which adverse events are reported and safety data are carefully reviewed. Select system strengthening efforts included increased staffing; database improvements; efforts to enhance reporting to the Vaccine Adverse Events Reporting System (VAERS); bolstering the Vaccine Safety Datalink, a large-linked database of managed care organizations; and the creation of Post-Licensure Rapid Immunization Safety Monitoring (PRISM) system. PRISM combines vaccine exposure data from Immunization Information Systems with exposure and outcome data from a group of large health plans covering ten percent of the U.S. population to determine if adverse events were related to immunization in real time. CDC established a collaborative effort within the Emerging Infections Program specifically to assess the potential risk of H1N1 monovalent vaccination on the development of Guillain-Barré Syndrome. Furthermore, a robust network was built to share capabilities from DOD, VA, CMS, state and local public health, and medical and private sector entities. In addition, the Vaccine Safety Risk Assessment Working Group (VSRAWG) was convened to review safety data and report to the National Vaccine Advisory Committee (NVAC). There may also be opportunities for clinicians to receive training on reporting adverse events.

Vaccine delivery by state and local health departments

In order to achieve higher uptake, many local health departments utilized school-located clinics. Other novel approaches to vaccine delivery included occupational clinics, drive-thru clinics, and the use of National Disaster Medical System vaccination teams in states and territories, such as in Delaware and the Virgin Islands. Clinics located at schools were successful, and like many types of vaccination clinics, they benefited from the involvement of Medical Reserve Corps volunteers. Collaboration between schools and health departments can be further leveraged in the future. The partnership with public health and the schools through the 2009 H1N1 experience has opened further opportunities to dispense childhood vaccines in the school setting. However, there were challenges to financing of vaccine and of vaccine administration in a non-pandemic scenario need to be explored.

Mechanisms for ordering vaccine

During the 2009 H1N1 pandemic, the VACMAN Database Management System, routinely used for the VFC program, was used to order 2009 H1N1 vaccine and ancillary supplies from CDC. VACMAN was an older system in the process of being replaced when the 2009 H1N1 pandemic began; however, the transition had not yet occurred. In general, many limitations of the VACMAN system were known to officials at HHS at the outset. In a more severe pandemic, VACMAN would not have functioned appropriately because the larger number of doses available would have stressed the system. Specific problems included issues with duplicate orders and the inability to link vaccine and ancillary supply orders, which resulted in the need for manual calculation on the part of grantees placing orders to ensure sufficient supplies were ordered. Replacing the system with one having greater capacity to handle a larger volume of orders, while considering problems encountered during the 2009 H1N1 response, is an area of further discussion.

Distribution and administration

The distribution system delivered vaccine to states effectively; however, a number of states carried out sub-distribution using health departments and other contracts in order to distribute smaller amounts of vaccine. Although CDC had visibility to distribution done by McKesson, and made this visibility available to states using FluFinder, there was no visibility at the federal level regarding states' sub-distributions. In terms of vaccine administration tracking, because of variations in states' tracking practices and abilities, there was limited information at the national level about how many doses were administered and how many children received needed second doses. The ability of states to track vaccine within their state was further challenged when vaccine was shipped directly starting late December 2009 to pharmacy chains participating in a federal program designed to broaden access to vaccine through pharmacies. Bar code systems, which were not in place during the 2009 H1N1 pandemic, may be necessary to assist federal tracking efforts, but on their own are likely not sufficient to solve this problem.

Vaccination of the federal workforce

Because the vaccine prioritization scheme was based on individual medical risk of severe disease rather than on prioritizing individuals with critical societal functions that ensure continuity of operations, federal workers were subject to the same recommendations as the U.S. public and often sought vaccine in similar settings. However, certain segments of the federal workforce, such as the overseas workforce, received vaccine relatively late. While HHS believes that agencies with overseas workers received their fair allotment based on agency size (and that they could include overseas workers in their total counts), in non-HHS agencies there were logistical issues that impeded overseas workers from receiving vaccine in a timely manner. Shipping vaccine overseas in small quantities was prohibitively expensive and required country clearance from the host nation. Going forward, the unique circumstances of the overseas workforce may be further explored when prioritizing vaccine.

Furthermore, prior to 2009 H1N1, planning had begun for the Department of Veterans Affairs (VA) to vaccinate those members of the domestic federal workforce prioritized based on occupational reasons (including employees from HHS) during a pandemic. However, due to challenges in creating and managing new electronic medical records for non-VA federal employees, contracting challenges, and legal issues, the VA was not able to implement its program until January 2010, relatively late into the pandemic. As a result, the VA vaccinated only a few thousand federal workers.

Vaccinating the federal workforce was further complicated by dual distribution mechanisms. For example, health care workers at the VA received their vaccine allotment directly from CDC while the VA's patients received their allotment through state allocations; consequently, state practices led to uneven distribution throughout the VA.

Vaccination of racial and ethnic minorities

In a pattern similar to that of seasonal influenza vaccine, certain racial and ethnic minorities were vaccinated for 2009 H1N1 at lower rates despite serious efforts to improve vaccine uptake in minority populations. Some disparities in pandemic and seasonal

influenza vaccine uptake may be attributed in large part to distrust of vaccine among these populations, access challenges, and a lack of culturally and linguistically appropriate messaging. Messaging geared towards racial and ethnic minorities can include Q&As that address the myths and misconceptions about vaccines that may be prevalent within a culture. The fact that there was lower uptake of 2009 H1N1 vaccine in certain populations suggests the need for better understanding of the basis of this difference coupled with targeted communications and messaging strategies.

Low uptake also suggests possible deficiencies in distribution strategies. For example, communicators saturated the mainstream media but had problems reaching those who do not access mainstream sources. Furthermore, common vaccination sites, such as big box retailers and private physicians, do not serve all populations equally. H1N1 vaccine was distributed through existing provider networks which do not always reach low-income and minority populations. Community-based, faith-based, and grassroots organizations should be leveraged to reach hard-to-reach populations such as racial and ethnic minorities.

Vaccination of health care workers

According to a *MMWR* from April 2010, as of January 2010 less than 40 percent of health care workers had been vaccinated for 2009 H1N1 (CDC 2009e), but nearly 62% received the 2009-2010 seasonal flu vaccine. Low uptake in this risk group is particularly problematic because their attitudes and behaviors regarding vaccination directly influence the public, who look to providers as a source of information and guidance. Furthermore, health care workers are at high risk of contracting and transmitting disease. While this seems to be improving (during the 2010-2011 influenza season, coverage for influenza vaccination among health care workers was estimated at 63.5%), an ongoing effort led by the National Vaccine Advisory Committee is examining approaches to meet Health People 2020 goals of achieving 90% coverage of health care workers annually with seasonal influenza vaccine.

Recovery and disposal of vaccine

Recovery and disposal of vaccine was not an initial focus area during the design of the vaccine distribution program, and should be considered earlier during design of future disposal efforts. However, BARDA and CDC developed and implemented a successful vaccine recovery program that took into account varying state-level regulations. In the future, these final steps of a vaccine distribution program should be considered early in the design phase.

Chapter 6 Summary

Vaccine Development and Production

Successes

1. Once the virus causing the initial pandemic was known, development of a vaccine candidate virus and its distribution to manufacturers progressed rapidly, both domestically and internationally.
2. HHS' large investments in pandemic preparedness, including existing contracts and ongoing relationships with vaccine manufacturers, enabled manufacturers to develop and establish the safety and immunogenicity of the 2009 H1N1 vaccine in fewer than six months, and in quantities sufficient for the U.S. population—the stated goal of pandemic planning.
3. HHS quickly established and used a stepwise process to create and then implement a centralized program to distribute vaccine. The process was flexible and was adjusted as the situation evolved.
4. HHS used a rigorous decision-making process and made well-informed decisions as it pertained to first stockpiling adjuvant, ultimately deciding not to use adjuvant in the vaccine.
5. NIH and BARDA-supported vaccine manufacturers rapidly conducted clinical studies as soon as vaccine was available, providing valuable information needed to approximate required doses before the vaccination program began, as well as insights into the vaccine's safety profile.
6. The 2009 H1N1 vaccine was safe. Under the auspices of NVAC, federal public health officials created the H1N1 Vaccine Safety Risk Assessment Working Group and implemented a multifaceted, rigorous, and transparent program that included frequent public communications of its findings.
7. FDA rapidly approved monovalent 2009 H1N1 vaccine as a "strain change" under the established regulatory framework for licensure of influenza vaccines.
8. As recommended by senior public health leaders following the 1976 swine flu episode, many public advisory boards (including the National Biodefense Science Board, NVAC, Advisory Committee for Immunization Practices, and Vaccines and Related Biological Products Advisory Committee) were utilized successfully during the 2009 H1N1 pandemic for consultation on numerous vaccination policy and logistics issues.

Opportunities for Improvement

1. The U.S. has depended on egg-based technology that has been in use since the 1950s for the production of influenza vaccines. Although generally reliable, due to unpredictable virus growth this technology may not produce timely vaccine for influenza pandemics. In addition, completing the manufacture and distribution of 2009 – 2010 seasonal influenza vaccine contributed to delays in production and delivery of 2009 H1N1 pandemic vaccine. As a result, even though the six-month

goals for initial vaccine delivery were met, most of the vaccine arrived too late to vaccinate much of the public before the pandemic peaked. High vaccine production yields, more modern vaccine design, potency testing and production technologies (such as cell-based vaccines and recombinant vaccines) are essential to accelerate the speed of production and increase the vaccine yield. The speed and reliability of vaccine production is an important consideration for the future; this is especially important when novel strains occur. Improvements—which will take several years to accomplish and were underway but not yet completed when the pandemic occurred—have been mandated by the Pandemic and All Hazards Preparedness Act (2006) and by other legislation and Executive Branch directives.

2. Early projections from BARDA regarding timing of vaccine supply changed frequently and were inaccurate. This led to public confusion and temporary erosion of confidence in the federal government, and created challenges for the planning and execution of local vaccine administration efforts. However, as the just in time system began to function better, later BARDA's projections, which were based on information supplied weekly from the vaccine manufacturers themselves, increased in accuracy.
3. Vaccinators had to work with multiple formulations of vaccine, as well as with different age and risk group indications. In addition, vaccines with different age and risk group indications arrived at different times. While this was an unavoidable by-product of the effort to use all existing manufacturing seasonal influenza vaccine platforms, available fill/finish lines, and approved indications and make as much vaccine available as quickly as possible, it resulted in confusion and challenges in planning a mass vaccination program.

Vaccine Allocation, Distribution, Administration, and Monitoring

Successes

1. Building on the existing VFC Program vaccine distribution process, CDC implemented a federally financed and controlled distribution process that was scalable and used procedures and systems already familiar to many providers. Over 126 million doses of monovalent 2009 H1N1 vaccine were delivered to nearly 70,000 locations, over 330,000 total shipments, with 95 percent of orders received within 48 hours of ordering. The number of providers enrolled to offer vaccine, greater than 120,000, was nearly triple the number enrolled in the VFC Program.
2. The decision for the USG to purchase all 2009 H1N1 vaccine for the American public provided greater control over vaccine distribution.
3. The vaccine safety monitoring system was strengthened to provide more robust monitoring of the safety of 2009 H1N1 vaccine than had previously been possible. Status reports on vaccine safety were regularly reported to the public through the NVAC review process. The resulting safety monitoring and reporting system was effective and benefited from strong collaboration across agencies.

4. State and local health departments used approaches to vaccine delivery that had been piloted and used effectively during previous influenza seasons, including the use of school-located clinics and retail pharmacies. The pandemic response resulted in valuable new information about opportunities and challenges in this type of interface between public health and other public and private organizations.
5. There were higher immunization coverage rates among children and pregnant women—two critical priority groups—than during past seasonal influenza epidemics. ACIP-recommended 2009 H1N1 vaccine priority groups, which were supported by high quality data, remained in place for the duration of the pandemic, and were well-received by the public. The ACIP also provided a sub-prioritization plan that could be adapted to local circumstances.

Opportunities for Improvement

1. Because vaccine supply was initially limited, local health departments needed to make decisions about sub-prioritization of groups based upon ACIP guidance regarding these groups. As a result, there was considerable local variation regarding eligibility for vaccine, creating confusion among the public.
2. Information collected during and after the pandemic response indicated that racial and ethnic minorities were vaccinated at comparatively lower rates than other groups—a serious, ongoing issue for seasonal influenza vaccination, especially for adults. Because of its impact on morbidity and mortality, this disparity merits continued evaluation and action by federal, state, tribal, local, and territorial authorities.
3. As one method of estimating coverage, telephone surveys were used to produce periodic national estimates of vaccine coverage. However, due to limited sample sizes these estimates did not provide information at the state level until late in the vaccination program. State level estimates by age and risk subgroups were provided to CDC leadership and states in January 2010. New analysis techniques are now available to provide earlier release of more reliable state level estimates in future outbreaks.
4. During the pandemic, health care workers had relatively low rates of vaccination. This is consistent with historic data collected on health care workers during seasonal influenza. While there have been gradual improvements, this remains an area in need of continued action and evaluation.
5. During the pandemic, real-time information on the population that had actually received 2009 H1N1 vaccine was limited to weekly national estimates of the proportion of children, adults, and persons in ACIP target groups versus other groups; estimates by race and ethnicity were available in October 2009. Additionally, state level data were available monthly based on the BRFSS sampling design.
6. A policy and plan for recovery, donation, and if necessary disposal of unused pandemic vaccine had not been developed in advance of the 2009 H1N1 pandemic.

7. Although the federal government considered using the SNS POD model for vaccine distribution, it decided to build upon the Vaccine for Children program. Local and state health officials expressed concerns that the public health care infrastructure would be unable to support the vaccination campaign without substantial participation from the private sector.
8. The HHS Pandemic Influenza Plan did not formally address drug delivery devices such as needles and syringes as critical components of a vaccination campaign. As a consequence, there were no existing requirements for ancillary supplies until after the pandemic had begun.

CHAPTER 7: COMMUNICATION AND EDUCATION

In the early stages of the 2009 H1N1 outbreak, it became clear that it was an incident requiring public health and clinical staff to connect and exchange information on a frequent basis between federal agencies, states, private partners, and the general public. Daily and clear communications about epidemiological, safety, and clinical issues were a critical component of the 2009 H1N1 response.

The White House, HHS, and other response partners placed substantial emphasis on developing integrated and coordinated communications and education for the general public and for populations of special interest. Toward this end, the White House hosted weekly interagency calls to coordinate communications and a nation-wide public messaging campaign to ensure that the messages were integrated, consistent, and targeting all of the relevant groups. Also, HHS, DHS, and ED hosted an Influenza Summit for state and local public health, emergency response, and education officials. In addition, 2009 H1N1 Communication Packets were distributed to state and local officials to help them educate their constituents about preventing the spread of the flu. The Administration also sought to communicate with the broader public about 2009 H1N1 via the news media, providing unprecedented media access to key officials and issuing a call to action to prepare for 2009 H1N1. Information was disseminated through a wide array of media venues, including websites (HHS's flu.gov being the primary example), webcasts, podcasts, texting, news briefings, brochures, flyers, and other media outlets.

Given the overlap between the Communications and Education pillar and other pillars described in this report, this chapter focuses on communications with the general public and other participants. Communication related to specific issues may be found in previous chapters of this report, including vaccine availability (Ch. 6 Vaccine), guidance for and communication with health professionals (Ch. 3 Mitigation: Addressing Medical Needs), public health messaging around prevention and school closures (Ch. 4 Mitigation: Community Mitigation), and communications between federal agencies (Ch. 8 Cross-cutting Issues).

Information sharing and messaging

Communication with the public was one of the more successful aspects of the 2009 H1N1 response. Individuals tasked with developing communications actively sought subject matter expert input and rapidly shared that information. The communications campaign drew upon multiple communications channels to educate and inform the public and specific participants. Constant internal communication and inclusion of communications experts in key activities and meetings helped ensure unified, effective messaging.

Reports were perceived as measured and balanced, and the willingness to change the message over time to "get it right" suggested transparency in the federal government's response. As Dr. Richard Besser, acting director of CDC, noted in a press briefing on April 24, 2009, "I want to acknowledge the importance of uncertainty. At the early stages

of a pandemic, there's much uncertainty, and probably more than everyone would like. Our guidelines and advice are likely to be interim and fluid, subject to change as we learn more. We're moving quickly to learn as much as possible and working with many local, state and international partners to do so. Our recommendations, advice, approaches will likely change as we learn more about the virus and we learn more about its transmission. Because things are changing, because influenza viruses are unpredictable, and because there will be local adaptation, it's likely that at any given moment there will be confusing or maybe conflicting information available (CDC 2009f)." CDC's early acknowledgement that information and recommendations were necessarily in flux helped to minimize criticism when the changes occurred. However, messaging to the public about the number and locations of cases, populations at higher risk, guidance for seeking care, and how to prevent the spread of influenza were seen as successful overall.

CDC played a central communication role and was cited as effective in maintaining consistent messaging across agencies. Federal-state partnerships were important in maintaining a unified voice down to the local level, although coordinating federal messaging with that of state and local public health officials was challenging. Drs. Richard Besser and Anne Schuchat, Rear Admiral, USPHS from CDC served as two consistent spokespeople who built confidence and trust with the public and helped to maintain a unified voice.

Despite these successes, the response to the pandemic confronted several challenges to its efforts to communicate with the public about the vaccination program. The pandemic vaccines were initially reserved for populations at the highest risk. Anti-vaccine groups expressed and gained a certain amount of traction (as well as a number of prominent spokespersons) for their views; communicating effectively about uncertainties on these issues was challenging. In retrospect, public officials should have been more cautious in their messaging about the time of initiation of the vaccination program. Also, an opportunity for improvement exists in the better coordination of media campaign activities within HHS communications units as to avoid redundancies.

Flu.gov was an excellent centralized resource

In the summer of 2009, HHS transformed the former pandemic influenza planning website, www.pandemicflu.gov, into a new website, www.flu.gov, designed to be a one-stop information clearinghouse that brought together flu-related information from across HHS and other federal departments and agencies. The new website incorporated information about the novel 2009 H1N1 influenza as well as seasonal influenza. During the period when 2009 H1N1 was a concern, more than 13.5 million people visited flu.gov.

CDC and other HHS agencies and offices collaborated to develop syndication technology, which allowed flu.gov to import content produced by CDC and initially posted on the CDC website. This ensured that flu.gov would have the most current information and significantly reduced the resources necessary to build and maintain flu.gov. The website continually provided updated information on the origins and spread of the flu, the efforts to develop and later produce and distribute an H1N1 vaccine, and a broad range of information for public and private sectors about dealing with known and potential

scenarios. The website was a platform for all CDC and other news conferences, briefings, and updates.

Flu.gov was consistently cited as an excellent centralized resource that contained a wealth of information. For example, flu.gov posted communication toolkits for businesses, employers, childcare groups, and institutions of higher education. Flu.gov was also a repository for a range of educational materials and Public Service Announcements (PSAs), including several for children. These PSAs, featuring characters from Sesame Street and Sid the Science Kid, taught kids healthy habits, such as hand washing and sneezing into their elbow, and explained why it is good to get a flu shot. In October, HHS also launched the H1N1 Flu Self-Evaluation on flu.gov to help individuals understand symptoms of influenza and make decisions regarding their health. Other available materials included fact sheets, additional PSAs, and materials for priority groups such as pregnant women.

Overall, flu.gov was very well received. The entire flu.gov website was translated continuously into Spanish. Relevant sections were also translated into both Chinese and Vietnamese. Web translation made use of a proprietary service which provides near real-time translation, ensuring that time sensitive content was available to audiences nearly simultaneously. In addition, many of the toolkit materials noted above were translated into Spanish. This issue is discussed in more detail below.

As vaccine became available and began moving into the marketplace, the Department benefited from a strong collaboration with Google, the American Lung Association, and ASTHO, which resulted in the creation of a web-based flu clinic locator application, whereby people could enter a zip code and be directed to local flu vaccine clinics. The application provided information about the availability of vaccine (both 2009 H1N1 and seasonal), clinic hours, directions, and special information including the availability of vaccine for children. HHS turned the locator into a widget, which was picked up on hundreds of state, local, and nonprofit websites. Google provided the flu vaccine locator as the first return for searches on a multitude of flu and vaccine-related search terms. On HHS.gov alone, the clinic locator was accessed 4.9 million times.

It was recognized early in the 2009 H1N1 pandemic that the media was extremely important—indeed critical—to successful communications with the public. For the most part, the news media had open access to experts at the CDC, and media were able to regularly interact with them through interviews and media briefings. Another component of media relations included monitoring news sources and social media sites to identify information gaps, clarify misunderstandings, and dispel rumors.

Media tours may be used to address the gaps identified through media monitoring. CDC conducted a multi-day event with the media in August, and in early September 2009, HHS held a training session for 40 members of the national press. Multiple table-top exercises were conducted with the media to help them understand how decisions were made and to educate the media in science and health. These efforts were viewed as successful. However, several challenges remained, including the need to educate the media about how to interpret and report limitations of data, particularly raw data as compared to data that has

been cleaned and analyzed; ongoing training with foreign journalists and international media; and ongoing training on pandemic concepts and science with foreign journalists and international media."

Social media tools were used to disseminate 2009 H1N1 messaging to broad audiences

CDC utilized a range of social media such as widgets, RSS (Really Simple Syndication) feeds, podcasts, YouTube videos, Twitter, text and mobile updates, and other social networking sites, including Facebook and MySpace, to disseminate information to the public and other participants. The pandemic demonstrated how useful social media can be in reaching populations, in gaining their understanding, and in impacting their behavior. Formal evaluation of the use and impact of social media is an important consideration

The social media tools used by HHS during the 2009 H1N1 pandemic response included:

- *YouTube:* HHS conducted an enormously successful video PSA contest via YouTube. The widely promoted contest invited people to submit public service announcements, with the best PSA winning a $250 cash prize. There were more than 400 entries. These entries were narrowed to the top 10 and then people were invited to vote on their favorite (tapping the viral nature of social media). The PSAs on YouTube were downloaded more than 420,000 times. The contest received national media attention—further spreading the prevention message. The winning PSA featured a singing hip-hop doctor and was featured on national television. Every PSA campaign, all CDC briefings, and all flu webinars were also made available on YouTube. CDC's YouTube channel continues to grow in popularity and had nearly 3.4 million views and 77 videos during 2009. By May 31, 2009, CDC's "Symptoms of H1N1 (Swine Flu)" video, initially launched on April 28, had attracted more than 1 million views. Its popularity remained high throughout the year; it was the second most viewed video on YouTube.com in the News and Politics category in 2009.
- *RSS feeds:* Individuals subscribe to RSS feeds, which provide updated news headlines, blog posts, or selected website content. The "2009 H1N1 Flu (Swine Flu) Health Messages254" RSS feed was CDC's most popular; it had received over 10.5 million views as of December 31, 2009. CDC podcasts were also widely accessed; the most popular, entitled "Swine Flu," was downloaded over 246,000 times during 2009. The Flu.gov RSS feeds provided timely information on the latest H1N1 news and allowed individuals to automatically receive updates via their preferred content consumption tool.
- *Widgets:* Widgets placed on a website displayed and automatically updated specific content. Flu.gov developed a wide range of widgets and badges that allowed third-party sites, including those for federal, state, and local government agencies, to easily direct citizens to Flu.gov as the central resource for the federal response to H1N1. The Flu.gov New Widget allowed for others, particularly state/local health departments and news outlets, to provide automatically updated information to their audiences. As of January, 2010, three of CDC's top five widgets were related to 2009 H1N1: the Flu RSS Reader Widget, the FluIQ Widget, and the H1N1 Flu Widget. Widgets were useful to small health

departments and other agencies that did not necessarily have the resources to monitor and continually update their website content related to 2009 H1N1. As mentioned above, the flu vaccine locator widget directed thousands of people on hundreds of sites to local clinic information.

- *Blog:* The Flu.gov blog provided an effective channel to respond in a timely manner to emerging issues as well as provide information and highlight resources in a much more user-friendly manner than formal guidance or standard news releases would allow.
- *eCards:* Flu.gov Electronic Cards (or eCards) allowed individuals to personalize critical health messages and share them easily with friends, family and colleagues.
- *Twitter:* Twitter was used to provide information, commentary, and descriptions of events and to highlight certain audio and video content that the user could access by a click-through to content on the CDC.gov website. The Flu.gov team posted frequently on the @Flugov Twitter account on both the latest situational news as well as on the release of new guidance or resources from across the Federal Government. The National Center for Health Marketing's Division of eHealth Marketing (DeHM) managed three Twitter profiles as of January 2010. In April and May 2009, all three twitter accounts led to over 380,000 click-throughs to CDC.gov content. During the remainder of 2009, however, the tweets averaged between 10,000-20,000 click-throughs per month.
- *Social Networking:* CDC also had a presence on social networking sites such as Facebook. These pages contained content on a wide range of health topics including H1N1. Although the site could be accessed by anyone, at the end of 2009, it had more than 53,000 friends who received notification when information was added or updated (CDC 2009g).

Social media tools seem promising; however, further evaluation could be productive as there is little empirical evidence regarding the reach, effectiveness, and overall value of social media.

There were frequent and open lines of communication related to various aspects of the 2009 H1N1 pandemic among a wide range of participants

In addition to the resources described above through flu.gov and social networking sites, HHS maintained frequent and open lines of communication with state and local health departments, physicians, community organizations, and Congress during the pandemic. Regular conference calls were scheduled between the CDC, ASPR, ASTHO, NACCHO, and the NPHIC. A range of topics was discussed including case counts, development and production of vaccines, timing and distribution of vaccines and medical countermeasures, communications strategies, and funding. ASPR led regular coordination and information dissemination calls with the interagency through the Secretary's Operations Center (SOC). In early July, the Secretaries of HHS, DHS, and ED hosted the H1N1 Influenza Preparedness Summit for delegations from 54 states, tribes, and territories. During the one-day summit, administration officials laid out specific ways that states and local governments could start their planning and preparation efforts and announced new

programs and resources to help state and local governments prepare for the fall influenza season.

The Joint Information Center within the CDC also held more than 30 Clinician Outreach and Communication Activity calls for organizations representing physicians, nurses, emergency medical technicians, lab technicians, and veterinarians. The organizations, in turn, pushed the information out to their group members. The calls were transcribed, archived, and posted on the CDC website for those who wished to access the specific content. Each of the calls included subject matter experts from CDC who briefed on the current state of the 2009 H1N1 pandemic and updated any recommendations for medical countermeasures or treatment. These calls were also an opportunity to ask questions and receive clarification on certain issues. CMS also conducted outreach to providers through a variety of mechanisms including conference calls, web conferences, and Question and Answer documents.

However, the communication mechanisms used by CDC and CMS posed challenges. For example, the agencies could not monitor how much information was being pushed out through partners, and did not know whether there were pockets of physicians who were not regularly receiving updates. One solution employed to increase the number of physicians receiving updates was to reformat messages so they could be accessed on physicians' mobile devices.

In special cases, CDC did more extensive outreach to insurance companies and pharmacies to disseminate guidelines for antiviral medication. The CDC contacted insurance companies and asked them to speak with their providers about the proper guidelines for medical care. CDC also worked with pharmacies, asking them to post information about antiviral medications so they could educate and speak with their customers and with physicians about proper antiviral medication use.

ASPR also engaged in communication and education efforts regarding the functional needs of at-risk individuals and mental and behavioral health concerns related to pandemic influenza. These efforts included a listening session and report on at-risk individuals in pandemic influenza and other scenarios that brought together experts and practitioners representing a broad scope of at-risk individuals and included nongovernmental organizations, health care providers, and federal agencies involved in public health preparedness and planning and emergency response. At the request of ASPR, the National Biodefense Science Board, through its Disaster Mental Health Subcommittee, produced a set of recommendations detailing actions that could be taken to address psychological and behavioral health concerns caused or exacerbated by the pandemic.

Regular calls were also held with community and faith-based organizations, although these discussions were less frequently mentioned in interviews. As noted, the 2009 H1N1 Influenza Pandemic had a disproportionate impact on children. ASPR hosted two workshops, in July and October of 2009, to discuss pediatric issues in emergency response with national experts and stakeholders. The workshops focused on enhancing pediatric

medical response capabilities and improving capacity for pediatric-suitable medical countermeasures, with a particular emphasis on H1N1.

HHS did a significant amount of work to keep Congress informed. For example, the Office of the Assistant Secretary for Legislation hosted weekly conference calls for Congressional staffers, which included subject matter experts from throughout HHS. The calls offered an opportunity for staffers to get updates and ask questions. In addition, HHS leaders and subject matter experts provided testimony in at least 17 Congressional committee hearings and fielded hundreds of Congressional inquiries during the pandemic.

In addition to the communications efforts stemming from the federal government, all states held conference calls between their public health and healthcare systems to ensure clear lines of communication existed. Some states not only extended their communications efforts by working with their local government agencies on media inquiries, they also took the initiative to reach out to their neighboring states. For example, South Carolina set up calls with adjoining states to increase interstate communication and collaboration in the region. Other states identified this regional cooperation as being difficult to achieve.

Various states set up hotlines for clinicians to receive information and to report "suspicious" cases. However, as was the case within the federal government, reaching private medical providers proved challenging for those states that did not already have systems in place to do so. Those with established systems often worked with their local hospital and medical associations to reach private medical providers through the CDC's HAN and Epi-X. For the general public, media public service announcements and information hotlines helped to decrease the number of individuals who presented themselves to medical centers but did not require treatment. Those with symptoms were directed to their primary medical provider, which mitigated overcrowding at hospital emergency departments. In addition, H1N1-specific information was placed on state websites, and included links pointing to websites such as the CDC's H1N1 information page.

Most states were able to communicate effectively between DHS, public health authorities, and health care facilities as these entities set up uniform Incident Command Systems (ICSs). These command centers disseminated standardized messages and helped to achieve coordinated emergency responses. In Connecticut, the Department of Public Health communicated with officials from FEMA and the HHS Regional offices to share information from the Principal Federal Official Situational Reports. In one instance, the Los Angeles County Department of Public Health, which manages CDC's Public Health Emergency Preparedness Cooperative Agreement to Los Angeles, took a lead role in the H1N1 response by collaborating with the Department of Health Services, which in turn manages the ASPR Hospital Preparedness Program (HPP) grant. Together, these departments synchronized the public health and health care response for their community. The Department of Health Services coordinated primarily with hospitals and the Clinic Association to explain their roles, as well as deployed a liaison to L.A. County's Incident Command Center.

Communications did not adequately reach all desired minority, disadvantaged, and other hard-to-reach populations

Many felt that 2009 H1N1 communication and education efforts did not succeed in reaching minority, disadvantaged, and other hard-to-reach populations, including AI/AN, migrant workers, and non-English speakers. In a recent study, researchers found that 24 hours after the 2009 H1N1 public health emergency was declared, only nine states had information or a link to information in a language other than English on their home pages (Ringel et al. 2009). Such findings call into question the ability of many state and local health departments to "provide accurate, credible, actionable, and timely information to the public in culturally and linguistically appropriate ways to inform decision making and reduce uncertainty before, during, and after a public health emergency" (CDC 2009i). The lack of Spanish-language material was potentially problematic, given that the 2009 H1N1 pandemic originated in Mexico and there were early concerns about border and immigration issues (Ringel et al. 2009); CDC was, however, translating information into Spanish as soon as the information became available, and posting it on its CDC en Español website. Others felt that the higher rates of hospitalization among minority members suggested a need for improved communications and outreach.

Several states with significant populations of migrant workers from Mexico raised concern about the transmission and treatment of the H1N1 virus. In addition, Alaska had to consider how to identify and address H1N1 cases among cruise ship tourists; as the state had an established relationship with the cruise ship industry, they were able to facilitate this process. South Carolina, in collaboration with the Coast Guard, developed specific plans for how to manage pandemic flu outbreaks in their coastal and tourist areas. However, South Carolina also noted that it would like to focus on more effective ways to reach other special populations, such as their Hispanic residents.

For those states with a significant portion of their population living in rural areas, the spread of a virus may be slower, but resources also tend to be more scarce and difficult to mobilize. In Oklahoma, the Health Department worked in cooperation with Indian Health Services to help serve their American Indian populations. The State of New York developed plans and guidance for pediatric populations and pregnant women, which were helpful during the response.

The H1N1 influenza pandemic was for some states' health departments the first time they had been approached by health care facilities specializing in long term care, veterans affairs, and mental and behavioral health. Recognizing the need to expand state plans to include these special populations, many states are currently working to include these facilities into their emergency and pandemic plans, and are developing community mitigation guidances to accommodate these needs.

Although reaching minority, disadvantaged, and other hard-to-reach populations continued to be a challenge during the H1N1 response, a number of useful practices were identified. For example, activating and building capacity in trusted community and faith-based networks was a promising means of assuring access for vulnerable populations to H1N1 prevention information and services. The Interfaith Health Program at Emory University

partnered with the HHS Center for Faith-Based and Neighborhood Partnerships and CDC to increase 2009 H1N1 influenza vaccination and anti-viral distribution capabilities that assure maximum reach to vulnerable, medically high-risk, and minority populations. Utilizing a competitive RFA process, 9 diverse faith and public health partnership sites were selected across the U.S. H1N1 response capacity was developed across the network of 9 sites and locally with small seed grants, an initial 2-hour training (now a web based video training to use for replication) and follow-up with technical assistance conference calls with CDC. A total of 4606 community and faith-based organizations, health institutions and agencies, and networks across all 9 sites were engaged in outreach efforts. Combined, the 9 sites reached approximately 417,218 individuals with training, educational materials, H1N1 guides, vaccine event information, and prevention "kits." When the partners encountered more mistrust than was expected, primarily in minority communities, the project intensified educational efforts with key religious community leaders, brought in expert guest speakers to clergy meetings, hosted public forums in faith-based and community settings, and activated intermediary structure to facilitate sharing innovations across the nine sites and link regularly to national information resources.

Communications with hard-to-reach populations may be improved by focusing the scope of communication activities. At times, communication activities may have been so broad that it may have diluted the group's ability to focus on a few more targeted, effective strategies, particularly for minority populations.

Many hard-to-reach populations are also not connected to mainstream media or may be suspicious of the government, making communications more difficult. For such populations, targeted messaging about prevention and vaccination—addressing their specific concerns in ways that are logistically feasible and culturally acceptable—may be more effective.

Although communication with hard-to-reach populations was seen on whole as an area for improvement, there were examples of effective communication with such groups. For example, IHS used a range of approaches, including dissemination of information through schools and Native American radio stations. Other work was done by the Embassy of Mexico in Washington, D.C. in partnership with HHS to deliver prevention and mitigation messages to the U.S.-based Mexican population. They developed a special one-page flyer in Spanish for the immigrant population, which addressed fears of undocumented immigrants. This was distributed to the Mexican consulates throughout the U.S.

Another area of improvement may be the quality of communications materials, specifically the level of readability in mainstream media. However, the effectiveness of these messages is largely dependent on whether the individual trusts the messenger and is predisposed to follow instructions, understands enough of the underlying health/science concept to judge the message's importance, and has the means to do what the message is directing. Although CDC does test messages, such testing could be expanded and may have been beneficial before messages were posted or disseminated. Furthermore, messages should be vetted by those with low literacy to ensure that they are not only as

simple and digestible as possible, but also provide enough content to motivate and act upon.

Although frequent updating of 2009 H1N1 information and guidance was viewed as a marker for transparency in the communications process, it was not without its challenges. In addition to the information posted on flu.gov, other agencies, including CDC, the Occupational Safety and Health Administration (OSHA), Federal Emergency Management Agency (FEMA), and Office of Personnel Management (OPM), hosted websites containing 2009 H1N1 information. However, because information was evolving rapidly, these websites often had conflicting information, making it difficult for readers to ascertain which information on these sites, or flu.gov, may have been outdated, or technically incorrect. Other federal agencies often took selected information from these sites and re-posted it to their own websites, but the speed at which things changed meant that unless those agencies syndicated or continually monitored the updates and revised their web pages accordingly, those agencies had outdated and inaccurate information as well.

An opportunity for improvement may be in making better use of CDC's widgets (described above) and content syndication. Content syndication is a technical application that exports content from a CDC.gov page to a partner website, displaying CDC content within the partner's web page. As a result, the content is automatically updated, providing a streamlined process for disseminating current and credible content in real time on other websites. This would seem to be a particularly effective approach to address the challenges of rapidly updating multiple websites individually.

An opportunity for improvement may be developing communications and messaging about a new influenza pandemic where much is still unknown. There is a need to look for better ways to educate people about uncertain situations and talk clearly about the situation in a way that individuals will understand. In addition, there is a need to develop strategies for crisis messaging of complex scientific information and initial conclusions of research studies in ways that will be informative.

Chapter 7 Summary

Successes

1. Communications with the public were regular, balanced, transparent, and unified, which built confidence and trust with much of the public. Flu.gov was an excellent centralized resource for those with access to online services.
2. Communication, information sharing, and coordination across response organizations overall were timely and efficient, but offer opportunities for improved efficiencies.
3. Social media tools were used to disseminate 2009 H1N1 messaging to broad audiences.
4. The simple "wash your hands, cough in your elbow, stay home if sick" flu prevention message was enormously effective in raising awareness about the

importance of hand washing in preventing the spread of germs. Its public acceptance may have, however, limited recognition and compliance with vaccine messages that followed.

5. There were frequent and open lines of communication related to various aspects of the 2009 H1N1 pandemic among a wide range of participants.

Opportunities for Improvement

1. Some communications with both the public and participants were too complex and did not use plain language.
2. Communications did not adequately reach all desired minority, disadvantaged, and other hard-to-reach populations.
3. There were ongoing questions about the severity and seriousness of the pandemic that affected public perceptions, especially as the second wave of the pandemic was not as severe as predictions circulating in the media. This led to some public skepticism about the seriousness of the pandemic and the need for vaccination.
4. Rapidly changing information on 2009 H1N1 challenged the federal government's ability to provide consistent public health information and to support clinical practice.
5. Different components of HHS awarded contracts for media campaigns to promote vaccination. The campaigns had different themes but in some cases resulted in duplicated efforts. Consideration should be given to designating one clear lead for media campaign activities in behalf of the Department in the future.
6. State partners need to be informed about federal media campaign plans much earlier and updated regularly on their status, so they can integrate these effectively with their own efforts and access products from the federal campaign more quickly.

CHAPTER 8: CROSS-CUTTING ISSUES

A wide array of activities and issues associated with the response to 2009 H1N1 cannot be neatly associated with a single particular pillar. Rather, they cut across several or all of the pillars. These include, but are not limited to, issues around planning, coordination, funding, staffing, and federal workforce protection. In this chapter, cross-cutting activities are summarized.

Prior pandemic preparedness planning

Since 2001, there has been substantial acceleration in investment of public funds aimed at improving the nation's ability to respond to a public health emergency. This includes pandemic preparedness planning, the PHEP cooperative agreements, the HPP grants, and other work to build capacity of state and local public health departments. In response to the growing threat of H5N1 (avian flu) beginning in late 2003, a significant portion of that funding focused specifically on pandemic preparedness. These investments supported a range of activities, including pandemic planning efforts at the federal, state, territorial, tribal, and local levels, as well as to help develop these capacities internationally. The November 2005 National Strategy for Pandemic Influenza (NSPI) (HSC 2005) and accompanying May 2006 NSPI Implementation Plan (IP) (HSC 2006) issued by the White House outlined a comprehensive federal strategy and literally hundreds of activities, organized by pillars that were different from those in the 2009 H1N1 Framework. The NSPI IP specified lead and supporting federal agencies, an implementation timetable, and performance measures for each activity. According to the NSPI IP, almost all activities were to have been completed within two years (i.e., nearly a full year before 2009 H1N1 emerged in spring 2009) (HSC 2006). Initially, federal agencies reported quarterly to the White House on status/achievement of performance measures. Since this was the official plan in place at the time 2009 H1N1 emerged, it is possible to glean some insights regarding the adequacy of the planning itself as well as the adequacy of the implementation of capabilities called for in the plan.

Although challenges arose in the response to 2009 H1N1associated with the preparedness efforts put in place with this funding, prior planning efforts laid the foundation for an effective response, and relationships built through pandemic planning over the past few years allowed the adaptation of plans as the pandemic unfolded.

There were a number of concrete examples of how the prior investment in pandemic preparedness paid off during the response to 2009 H1N1. Many of these examples are included throughout the report; several are highlighted again here.

First, many people felt that the rapid development of 2009 H1N1 vaccine was attributable, at least in part, to work done in the past several years to increase domestic vaccine manufacturing capacity and streamline the vaccine licensure process. In particular, the clear delineation of the requirements for approving a pandemic vaccine as a strain change, rather than a new vaccine, was thought to be very helpful.

Second, the passage of the Public Readiness and Emergency Preparedness Act (Pub. L. No. 109-148) facilitated the manufacture of the pandemic vaccine by giving the Secretary of HHS the authority "to issue a declaration that provides immunity from tort liability (except for willful misconduct) for claims of loss caused, arising out of, relating to, or resulting from administration or use of medical countermeasures to diseases, threats and conditions determined by the Secretary to constitute a present, or credible risk of a future public health emergency to entities and individuals involved in the development, manufacture, testing, distribution, administration, and use of such medical countermeasures (HHS 2010)." In the 1976 pandemic, manufacturers were unable to obtain commercial liability insurance, which led to granting tort immunity as a prerequisite for vaccine production.

Third, despite some challenges in adapting pre-developed pandemic messages to the specifics of the 2009 H1N1 pandemic, several people noted the benefit of having a set of such messages on which they could build their public communications.

Fourth, the 2006 NSPI IP laid the foundation for advances in rapid diagnostic technologies and their wide use in laboratories throughout the United States and internationally. These enabled the early recognition, characterization, and tracking of the novel influenza virus.

Fifth, going forward, additional operational planning will be useful, especially for the "last mile" of the delivery of public health and medical care, as well as the development of operational plans at the federal, state, and local levels.

Despite the overall sense that investments in pandemic preparedness planning were instrumental in the success of the response to 2009 H1N1, several deficiencies were noted. In particular, there was a general sense that the existing plans, including the federal NSPI IP, were not as nimble as they should have been. 2009 H1N1 differed in several important ways from the pandemic scenarios for which the plans had been developed, including where it would originate and how severe the disease would be. It was challenging to adapt the plans based on the specifics of 2009 H1N1.

In this regard, the benefits of learning from history were apparent, whether it was from study of the 1918 pandemic, or the 1976 swine flu incident. Early in the 2009 H1N1 pandemic, the White House convened a meeting of HHS officials and public health and medical leaders who had been involved with the 1976 pandemic. The benefits of this meeting suggest that when possible, such historical perspectives should be routinely examined. It also led HHS to put in place a history project that attempted to document events and decisions as they were occurring.

Difficulty with adaptation appears to have been most problematic in several key areas. First, it raised problems around community mitigation measures, where many of the triggers for action were defined by the measures of disease severity and the case fatality ratio, measures that could not be ascertained in the early phase of the pandemic. Second, nearly all planning called for "containment measures" before a full-blown pandemic emerged, with weeks to months expected for this evolution to occur. However, by the time

the novel influenza virus was recognized in April 2009, it had already spread widely in human populations. Third, because the pandemic was less severe than anticipated, the existing plans did not adequately address a process for states' to request federal public health and medical assistance in the absence of a Stafford Act declaration (Li et al. 2010). As a result, early in the response, state requests for federal public health and medical assistance were sent to multiple federal departments. It took time and effort for these requests to make their way to HHS so that appropriate assistance could be provided (Li et al. 2010). In addition, an appropriation from Congress was needed to obtain additional funding for response activities. Congressional notification requirements associated with the funding, as well as the decision making process for allocating the funding, were challenging to the distribution of funding to State and local governments for response efforts.

Interestingly, although the 2005 HHS Pandemic Preparedness Plan actually did include scenarios with a range of severity, mirroring the variability of severity of the three influenza pandemics in the 20th century (two of which were relatively "mild" in terms of fatalities), subsequent preparedness planning focused largely on the worst-case scenario There should be an ongoing focus in the process for adapting the response to be flexible to meet the actual scenario.

Finally, the existing plans did not clearly delineate roles and responsibilities across federal agencies, including agencies across HHS (most notably CDC and ASPR) and the respective responsibilities of HHS and DHS. A report to the White House on preparations for the response to 2009 H1N1 developed by the President's Council of Advisors on Science and Technology (PCAST) noted that, "While the National Strategy for Pandemic Influenza Implementation Plan provides a comprehensive list of assignments for a multitude of offices, agencies, and departments involved in federal planning processes, the large number of tasks and responsible units poses challenges with respect to delineating roles and responsibilities of similar and potentially overlapping tasks." (PCAST 2009)

Communication and information sharing across response organizations

One of the major takeaways from the 2009 H1N1 experience is that federal, state, local, tribal and territorial governments, community organizations and the non-profit and private sectors all play critical and interdependent roles in a pandemic influenza response, and therefore play a crucial role in pandemic influenza planning. Communicating to these entities HHS' strategic path forward in the post-2009 H1N1 era will inform and begin to align the ongoing planning efforts of these and other emergency planners to help ensure a successful, coordinated response to the next, possibly more severe, pandemic.

Good communication and information sharing were key factors in the success of the response. The communication occurred on many different levels. Daily calls organized and led by various HHS agencies with the Department's senior leadership brought people together to work through issues on a day-to-day basis. This practice accelerated decision making and allowed for coordinated planning, as well as provided an opportunity to reach consensus on how to proceed.

The use of liaisons was another factor that facilitated information sharing within HHS. Having people from different offices embedded with them (e.g., CDC representatives working in FDA offices [or vice versa] and state health officials working at CDC) opened lines of communication between offices and sectors and promoted information sharing. For example, an HHS liaison to DOS was valuable in coordinating international aspects of the H1N1 response. It may be desirable to have liaisons designated, in place, and familiar with the other agency before an event and included in all relevant discussions; however, having liaisons in place can be problematic if that person is called upon, but does not have the authority, to speak or make decisions for the liaison's home office.

Federal advisory committees, such as the National Vaccine Advisory Committee, which provided relevant and objective subject matter expertise, were engaged and provided key assistance in specific areas key to the pandemic response.

Similarly, communication between HHS and the private sector was ongoing. The Homeland Security Information Network (HSIN), a secure web-based information system, was an effective way to communicate with private sector partners (e.g., critical infrastructure). During the H1N1 response, HHS provided a number of resources, such as situation reports and mapping products, through the secure web portal. Moreover, the portal allowed a two-way exchange of information letting private sector partners share documents as well. How this system works for state and local health departments could be the focus of future dialog.

At the federal level, the calls offered an efficient way to push information out about guidance, recommendations, and policies, but also to gather important information from the field on what was going on, what was working well, and what challenges people were facing. For state, territorial, tribal, and local officials, the calls offered the opportunity to gather information, ask questions, raise issues, and share ideas and strategies with other jurisdictions. In addition, CDC engaged representatives from NACCHO, NPHIC and ASTHO in their response efforts, at points including them in the CDC Emergency Operations Center. These efforts helped in addressing concerns and getting participating organizations on the same page.

Additional efforts can be made to ensure that information is shared widely across all organizations to maximize the abilities of staff to carry out their response activities.

Structure for a response to the pandemic

In many ways, the response was not handled like other previous responses to an incident and did not make use of existing emergency response structures, and this presented challenges and opportunities. There was no NIMS or NIMS-like structure.[6] The lack of a

[6] NIMS is the acronym for the National Incident Management System. As described by the NIMS Resource Center (http://www.fema.gov/emergency/nims/AboutNIMS.shtm), NIMS provides the template for the management of incidents (including the Incident Command System [ICS] which itself includes a Unified Command option in which multiple agencies/individuals co-lead an incident response), while the National Response Framework provides the structure and mechanisms for national-level policy for incident management.

unified command structure may have impeded interagency communication, created some confusion regarding roles and responsibilities, and resulted in some duplication of efforts. In particular, because there was no single person leading the response, such as an incident commander, coordination and communication across responders was more difficult. In addition, ICS structure may not be well suited to policy development. CDC implemented an ICS structure that had been refined through multiple exercises in the years prior to the 2009 H1N1 pandemic. The nature of the 2009 H1N1 pandemic—a prolonged health event (compared to a shorter term and/or more geographically circumscribed natural disaster) — may not necessarily lend itself to a "standard" ICS structure within an organization.

Neither the November 2005 NSPI nor the May 2006 NSPI IP provided clear guidance on the relative roles and responsibilities of DHS and HHS during major incidents where national security is not at risk or that do not elicit an emergency or disaster declaration. Moreover, these plans do not lay out specific triggers for a Stafford Act declaration. Communications activities could be challenging also because some offices within HHS are not accustomed to working with DHS.

There is an opportunity to comprehensively assess the key documents outlining roles and responsibilities (e.g., HSPD-5, the National Response Framework (NRF), in particular ESF-8) to identify and address any conflicts or ambiguities, and for representatives from across HHS (ASPR and CDC, in particular) and DHS to come together to discuss the advantages and disadvantages of various models of coordination and response management. Coming to a consensus about how best to structure a public health response and providing a clear delineation and understanding of the relative roles and responsibilities of each organization would significantly enhance the effectiveness and efficiency of any subsequent response to a pandemic or any other complex event. Conveying the decision widely throughout both departments would be helpful.

Coordination across response organizations

Having mechanisms for collaborating with and informing partners in advance of response events was important. These relationships were forged during prior pandemic planning efforts and served as a solid foundation to the 2009 H1N1 pandemic. Partners in these prior efforts included, at all levels of government, emergency management and response agencies, private sector entities, and the medical and public health community. These collaborations and coalitions worked to foster effective coordination and integration between these partners, with each entity understanding their interdependent and integrated roles in a coordinated response effort. Coordination between HHS and Education was extensive and ongoing throughout the response. There was also substantial dialog between CDC and the Department of Transportation (DOT) about air travel-related guidance and with the Air Transport Association (ATA) on guidance to airline cabin crews.

There were opportunities for coordination between HHS and the Department of Labor (DOL) over recommendations regarding respirators for prevention of 2009 H1N1 transmission. This issue is discussed again later in the chapter in the context of federal workforce protection.

There were frequent calls and updates by federal agencies (especially CDC) with state and local governments and with other non-government participants, but there were opportunities for improvement in federal agency coordination with states. There were also opportunities for improvement in the development of recommendations and the timing of their release, especially for those with major state/local implications, such as for mitigation measures that are operationalized at the local level (e.g., vaccine dispensing and school closures). Updates need to include a better system to inform users in real time and to enumerate what specifically was updated.

DHS/FEMA and HHS have different regional structures and different lines of communication to state and local participants. Better coordination of messaging and federal activities is an opportunity for improvement.

The pillar structure

The organizational structure used by the White House to lead the overall response was organized around four substantive topic areas of focus, or pillars, instead of a more standard NIMS structure, which is organized around response functions rather than by topical/thematic lines. As described in the introductory chapter, the pillars were introduced in the National Framework for 2009 H1N1 Influenza Preparedness and Response, which was released in July 2009 by the National Security Staff at the White House. The pillars include surveillance, mitigation measures, vaccines, and communication and education.

There were a number of concerns raised regarding the pillar structure. First, it was noted that the four pillars included in the Framework did not match the pillars included in prior planning documents, such as the NSPI IP, released in 2006. This created some confusion and made it more difficult to take advantage of prior planning and effectively use the existing documents. Second, the pillar structure was too rigid and did not support cross-cutting issues well, making lines of responsibility unclear. Even more problematic were issues that cannot be associated with any of the pillars because they have no natural home and are thus more likely to go unaddressed. Another criticism of the pillar structure is that it created information and decision silos of vertical communication rather than fostering an integrated approach to the response. However, the silo effects were mitigated to some extent by the coordination and information sharing that occurred within HHS, such as the daily calls among HHS senior leadership. At the state and local operational level, in some ways the pillar structure was more helpful, because it provided a common way to organize, talk about, and track progress.

CDC started out using a NIMS-compliant ICS structure to organize its response efforts, but after several months, the original ICS model was not performing as needed and pre-existing teams were then reorganized into task forces in a strategy that combined the ICS framework with the White House pillar structure.

Pandemic Response Funding for Federal, State, and Local Response

Prior planning did not adequately address how to proceed in the absence of Stafford Act funding. Without Stafford Act funding and its associated processes, Congressional approval was needed to obtain funding. The federal government was able to mobilize

significant new emergency appropriations to respond to the pandemic, but there are opportunities to shorten the process for obtaining funding, particularly funding for distribution to state and local governments. The initial request to Congress for $1.5 billion to respond to H1N1 occurred on April 30, 2009, just two days after the HHS Secretary declared a public health emergency. A second request for an additional $2 billion was sent on June 2, 2009. On June 24, 2009, nearly two months after the declaration of a public health emergency, the supplemental appropriations for 2009 H1N1 (P.L. 111-32) was signed into law, which included $7.65 billion to fund the pandemic response. HHS allocated the funding for a range of activities to prepare for and respond to the 2009 H1N1 pandemic, including developing, purchasing, and distributing 2009 H1N1 vaccine; enhancing influenza surveillance; and assisting state and local health departments with mass vaccination plans and 2009 H1N1 response.

In addition to the challenges associated with estimating the funding needs for response activities, there were additional challenges regarding distribution of funding for state and local response. In particular, the notification process governing the use of the contingent supplemental funds delayed H1N1 response activities at the state and local level. Use of the contingent funds required notification by the President to Congress that the funds were needed, as well as Congressional notification by the Secretary on how the funds would be used, followed by a 15-day waiting period. Prior to Congressional notification, the process for allocating funding also required time due to the novelty of the H1N1 pandemic. While there is a need for accountability, the time required to access the funding limited the ability of state and local governments to respond in real time.

Because the majority of the response to 2009 H1N1—indeed, to any incident—takes place at the state and local level, it is critical that the federal government be able to disperse funds quickly to supplement local resources and support local response activities. The Public Health Emergency Response (PHER) grant program was established to allocate the funds to the state and local level during the 2009 H1N1 response. Supplemental funding for H1N1 response was also provided through the ASPR Hospital Preparedness Program.

PHER funding was allocated in four phases; accessing funds in each phase required submitting a proposal. The grant announcement for the first phase of funding was issued on July 9, 2009, shortly after the allocation of funds from Congress, with a closing date of July 24, 2009. Funding from the first two phases, totaling $508 million, was made available in the late summer of 2009. It supported planning and preparation activities. For example, these funds could be used to assess current capabilities, address identified gaps, and conduct mass vaccination planning. The third phase of funding, totaling $846 million, focused on implementation of a mass vaccination campaign. That funding became available in late September 2009, just before the initial supply of vaccine was delivered. The final phase provided additional funds as needed to continue the 2009 H1N1 vaccination campaign.

Through Phase III, the grant program was supporting 62 awardees, including 50 states, 8 territories and freely associated states, and 4 localities (CDC 2009c). Phase IV funds were provided to 15 states and cities exclusively to continue the H1N1 vaccination campaign

focusing on underserved and vulnerable populations, ACIP priority groups, racial and ethnic minorities, population groups with consistently lower than average seasonal influenza vaccination rates, and population groups disproportionately affected by 2009 H1N1. These PHER Phase IV funds were also used to continue the vaccination of the general public through collaboration with employers, retail businesses, and pharmacies to assure the private sector's capacity for vaccinating the general public. In addition, $90 million was allocated through the HPP, an existing grant program administered by ASPR, to enhance the ability of hospitals and health care systems to prepare for and respond to 2009 H1N1. In particular, awardees could use the money to purchase personal protective equipment, such as N95 respirators, as well as for other preparedness and response activities.

PHER funding was a successful element of the 2009 H1N1 response, but it also offered areas for dialogue and future improvements. The most commonly cited problems with the PHER funding were the following:

- *The process was too slow*. There was a general sense that the process of getting funding out to the states took too long. There was a need for processes to be in place to ensure accountability, as well as a need to better balance accountability and ensure timely access to funding. In addition, it took time for states, once they had the grant funding, to distribute funds to the local level. Moreover, the amount of time varied substantially across states, depending in large part on the state's contracting and procurement processes.
- *The proposal process was cumbersome.* Having to develop and submit a series of proposals during the response to get PHER funding was seen by many as problematic. In particular, writing proposals took precious time and resources that many felt could have been more effectively used in other activities that would have directly impacted the response. This process placed a huge burden on states as well as on CDC, which was responsible for reviewing, awarding, and administering the PHER funding. The grant mechanism, like that used to fund preparedness activities, is not the most appropriate for funding an emergency response. Going forward, the advantages and disadvantages of other potential funding mechanisms should be considered.
- *Policies and processes around the use of funds were too rigid.* Policies were somewhat too restrictive in terms of what the money could be used for, when it could be used, and what would happen to money that was not spent. Policies not allowing carryover of funds were incentives to use the money regardless of need. Moreover, it punished those states that used the funding most efficiently in that they were not able to keep any unused funds.

What worked best in the response were systems that were already in place for routine use. However, when states do not have the capacity to use the funds effectively, rapidly disseminating new financial resources to states may not be an efficient way to fund response activities. In this regard, there was an uneven capacity in states to distribute and use the PHER funds. States have individual mechanisms for moving funds to the local level, and they may find it of importance to evaluate their processes for rapidly distributing

and spending supplemental emergency funds. When states do not have the capacity to use the funds effectively, rapidly disseminating new financial resources to states may not be an efficient way to fund response activities.

Decisions regarding the appropriate levels of funding were challenging, especially considering how uncertain the ultimate impact of the H1N1 pandemic would be. There was a particular challenge in making these decisions in that these funding decisions had to be made in the first days and weeks of the pandemic. At the outset, a consensus emerged that a vigorous, federally funded response was needed. As the pandemic unfolded through the summer and fall of 2009 and the epidemiology of infection with the 2009 H1N1 virus became clear—high attack rates in children and much lower virulence than pandemic planning scenarios had expected—that the uncertain risk of mutation of the H1N1 virus to a more virulent form remained. With hindsight, some have questioned whether the pandemic response was too robust, forgetting that current science had limited capability to foretell the final course of the pandemic. Better communication about the uncertainty in how emergencies will evolve might help reduce this type of retrospective assessment. Moving forward, planning should include a framework for the types of resources that may be needed and a range of estimated costs.

Federal workforce protection

Protection of the federal workforce involves the full range of federal departments and agencies. There were many federal entities involved in USG-workforce protection efforts, including the White House NSS, OSHA, OPM, DHS, and HHS (including Federal Occupational Health [FOH], FDA, CDC and NIH, as well as NIH's National Institute of Occupational Safety and Health [NIOSH]). The various roles they played included developing policy and guidance around issues such as seasonal influenza and 2009 H1N1 vaccines, antiviral medications, measures to reduce employee exposures, appropriate use of respirators, and human resources flexibilities (including leave and telework options). Furthermore, each federal department was responsible for developing and implementing department-specific plans to protect its workforce. With so many organizations involved, coordination and a clear delineation of roles and responsibilities was challenging. Further complicating matters was the fact that many federal agencies (e.g., other than HHS, VA, and DOD) do not have their own occupational medicine experts, which made it more difficult for them to plan for and respond to the 2009 H1N1 pandemic with regard to protecting their workforce.

The Emerging Issues Workgroup of the Federal Advisory Council on Occupational Safety and Health (FACOSH) noted significant differences in the protective actions taken by different agencies during the initial response in the spring of 2009. This was most evident at multi-employer worksites such as federal buildings and airports, where employees of one agency could be seen wearing N95 respirators while others were not wearing any PPE (FACOSH 2009). The FACOSH further noted that guidance from CDC was frequently updated, creating confusion and major challenges for agencies in planning and implementing response actions.

Initial guidance during the pandemic was generated by CDC and OPM without the consultation of OSHA, which created problems (FACOSH 2009). A number of issues regarding the federal workforce arose across multiple federal agencies. One was how to handle non-federal contract employees, especially with regard to vaccination. Another was the large number of federal employees based overseas, again problematic from the perspective of vaccine allocation and delivery. Yet another issue regarded guidelines for diagnosing and reporting illness to employers and provision of guidance for how long to stay home after becoming ill. Such issues arose in an environment in which it was unclear who was responsible for developing and communicating recommendations regarding federal workforce protection."

Federal workforce protection was a key area for improvement. Better planning and a clear delineation of roles and responsibilities across relevant agencies (i.e., OSHA, HHS, OPM, and DHS) are desirable.

Workforce staffing issues

The response to 2009 H1N1 began in late April, continued through the fall of 2009, and carried over into the winter of 2010. In fact, some aspects of the response, such as the recovery of unused 2009 H1N1 vaccine, were still underway over a year after initial detection of the 2009 H1N1 virus. This extended response is in stark contrast to typical emergencies. It was challenging to maintain staffing to sustain such a lengthy response.

Coordination with international partners

As described in earlier chapters, many aspects of the government's response to the international dimension of the 2009 H1N1 pandemic were quite successful—for example, collaboration with GHSI partner countries (which include Canada, Mexico, Japan, Germany, Italy, France, and the United Kingdom, as well as the European Commission); the International Partnership for Avian and Pandemic Influenza (IPAPI) Core Group; and with the WHO and WHO Regional Offices with regard to situational awareness, distribution of laboratory diagnostics, and the provision of international assistance, including antiviral medications and 2009 H1N1 influenza vaccine. These successes were largely attributed to relationships and processes that already existed prior to the pandemic, as well as the flexibility of ASPR, OGHA, and CDC staff. Overall, coordination with other donor countries regarding provision of and response to requests for international assistance could be improved.

In addition, within ten days of CDC first detecting 2009 H1N1, HHS notified H1N1 to the World Health Organization (WHO) as potential public health event of international concern (PHEIC) per the International Health Regulations (2005). The WHO Director General later declared the 2009 H1N1 pandemic as the first PHEIC under the IHR (2005). Throughout the course of the pandemic, HHS remained in close contact with WHO and the WHO Regional offices, sharing information and coordinated on issues such as international vaccine deployment.

At the same time, experiences during the pandemic uncovered opportunities to further facilitate international collaboration in future global pandemics and on the need to better

coordinate communications and issuing of recommendations across countries, again particularly with Mexico and Canada. HHS is currently leading collaborations with Canada and Mexico to strengthen our continent's preparedness by revising the North American Plan for Animal and Pandemic Influenza (NAPAPI), with particular attention paid to collaboration on communications at all stages of an influenza pandemic. This includes sharing of communication strategies and activities to minimize the possibility of conflicting information or contradictory messages.

Several HHS investments in global health security led to advantages and new opportunities for coordination during the 2009 H1N1 response:

- CDC provided multi-year technical and financial support for development and implementation of the 2005 IHR, which were tested for the first time during the H1N1 pandemic. By May 29, 2009, WHO had received reports of cases of H1N1 from the IHR focal points of 48 countries, which collectively reported more than 13,000 cases in all five WHO regions. For the first time in history, public health authorities were able to monitor a worldwide outbreak of contagious disease in almost real-time, providing information on geographical spread, clinical severity, and disease risk factors.

- The Global Outbreak Alert and Response Network (GOARN) received intensive U.S. investments during its first five years from CDC and ASPR. Through CDC's cooperative agreement with WHO, ASPR provided WHO with funds for early warning, surveillance, and response that supported the development of logistics and communications tools for GOARN, as well as helped nations strengthen IHR-mandated core capacities. GOARN played a major response role during the H1N1 pandemic, fulfilling requests for technical assistance from 27 countries in Asia, Africa, Europe, and the Americas.

- For more than 15 years, the CDC Influenza Laboratory has provided technical support to the WHO Global Influenza Surveillance Network, which tracks emerging influenza viruses for use in vaccines and identifies influenza viruses with pandemic potential. During the H1N1 pandemic, CDC worked with the WHO Network to monitor genetic changes and drug-susceptibility in H1N1 isolates collected from countries throughout the world.

The HHS investment in the WHO Global Influenza Surveillance Network will pay off for years to come as an essential component of global preparedness to future influenza pandemics. The HHS investments in IHR and GOARN are likely to provide even greater benefits by enhancing global preparedness for responding to all types of public health emergencies.

Policies and principles to guide provision of international assistance prior to and during the 2009 H1N1 pandemic

Principles and strategic frameworks regarding the provision of international assistance and response to requests for assistance during a pandemic were not in place prior to the 2009

H1N1 pandemic. This proved problematic when, during the course of the 2009 H1N1 influenza pandemic, the USG received international requests for 2009 H1N1 influenza vaccine, antiviral medications, RT-PCR diagnostic kits and other public health and medical assets (including PPE such as masks, gloves and aprons), medical supplies (such as alcohol gels, disinfectants, thermometers, syringes, soap, mobile hospitals, and pharmaceuticals other than antivirals/vaccines, etc.), thermal scanners, PCR machines, computers/office equipment, financial assistance and 2009 H1N1 influenza virus and candidate vaccine seed strains.

These international requests for assistance (RFA) were received by multiple federal departments and agencies, and had to be established after the pandemic had already begun. A review of federal after action reports revealed that multiple federal departments and agencies received international RFAs, but the federal government lacked a centralized, well-coordinated process to receive and respond to RFAs from foreign partners. In addition, here was insufficient pre-pandemic HHS activity to develop personnel rosters, standard operating procedures, information systems, tracking mechanisms, contact information, telecommunications support, etc., for HHS to manage and respond to international requests for assistance. There were also insufficient HHS staff identified before the pandemic and too few staff assigned after the pandemic to receive, manage, implement, and track requests and responses for international assistance.

In response to received and anticipated requests for international assistance during the 2009 H1N1 influenza pandemic, the ASPR and OGHA, in coordination with the HSC, developed and drafted the Strategic Decision Framework for Responding to International Requests for Pandemic Support under the HSC sub-Interagency Policy Committee on Supporting H1N1 International Requests and Engagement (SHIRE). The SHIRE Framework provided principles and criteria as well as the decision-making process to respond to these requests for international assistance and was approved by the Domestic Resilience Group Interagency Policy Committee (DRG) in July 2009. It was used to guide subsequent international deployment of antivirals, PPE and RT-PCR diagnostic kits. Specifically, HHS deployed 420,000 treatment courses of antivirals to the Pan American Health Organization that were distributed to 11 countries in Latin America and the Caribbean under the SHIRE Framework. This was in addition to the 400,000 treatment courses of antivirals deployed to Mexico in the early stages of the pandemic. The 2009 H1N1 influenza vaccine was not yet available at the point in time when the framework was approved. Decisions regarding international deployments of 2009 H1N1 influenza vaccine were made at a later date. Overall, HHS deployed H1N1 RT-PCR Kits and other testing kits to 147 countries, 820,000 courses of antiviral medications to countries in Latin America and the Caribbean, and nearly 17 million doses of H1N1 vaccine to the World Health Organization. This provision of international assistance was complicated by a variety of legal, export, regulatory, logistical, geopolitical, and funding issues.

Policies and operational mechanisms for the provision of international assistance need to be reviewed and refined in advance of future emergency situations. The USG needs better coordination among its departments and agencies that receive requests to provide assistance internationally during public health emergencies. Policy and deployment plans

for medical response assets (including medical countermeasures and personnel) are two critical areas that need to be explored. There is also a need to develop clearer policy and operational guidelines on if, when, and how USG assets would be provided to other countries. Triggers for key international actions for the departments involved (DOS, USAID/OFDA, DOD, and HHS) need to be clarified, agreed upon, and then fully communicated to all relevant parties.

The USG needs to work with its departments, agencies and international partners to identify and address barriers to the provision and acceptance of international assistance during a pandemic, including addressing legal, regulatory, logistical, and funding issues. HHS is formalizing a policy and operational framework to allow for the coordinated and efficient interagency response to international requests for health and medical assistance during an influenza pandemic within existing legal and regulatory frameworks, and that is achievable with current operational capabilities. HHS is also working with federal and international partners to determine how the USG could accept international assistance in the form of medical products or personnel during a public health emergency, should it be required.

International deployment of 2009 H1N1 influenza vaccine

Beginning in May 2009, the USG received 17 bilateral requests for influenza vaccine assistance. At the same time, the WHO Director General emphasized that "an influenza pandemic is a global event that calls for global solidarity." In an attempt to provide assistance with H1N1 vaccine to developing countries with little or no access to it, the USG started an interagency process to explore options to support developing countries in their response to 2009 H1N1 influenza pandemic. The decision to deploy 2009 H1N1 influenza vaccine to the WHO was coordinated by the White House National Security Staff (NSS) International H1N1 Vaccine Assistance (IHVA) Working Group and reached through extensive USG interagency policy discussions.

Final recommendations were made based on vaccine supplies and availability for international deployment, taking into consideration domestic need and demand, requests from the WHO and/or bilateral requests from other partners, legal authority for procuring and deploying the vaccines, available funding and other relevant factors. The decision making process also included considerations about the quantity and source of ancillary supplies needed and options for financing the costs of deployment and transportation. Based on the NSS/IHVA Working Group recommendations, the President made a decision and a public announcement of the deployment on September 17, 2009.

ASPR and OGHA, in close collaboration with DOS, coordinated the USG interagency planning and execution of internationally deployed vaccines from the USG, including provision of a portion of the transportation costs. This interagency collaboration also created an application and permit process that facilitated the shipping of medical supplies to countries lacking full diplomatic relations with the United States.

USAID and BARDA coordinated the provision of ancillary items and funding for the transportation of some of the USG vaccine deployment to WHO. USAID also provided direct assistance in selected countries to support development of in-country vaccine deployment plans as well as actual influenza vaccine distribution and immunization. The deployment of 2009 H1N1 influenza vaccine to the WHO was facilitated through frequent logistics and coordination calls between the HHS vaccine deployment team, the WHO, and other relevant entities to include vaccine manufacturers, the United Nations Office for Project Services (UNOPS), and the designated freight forwarder for each shipment. WHO served as the overall coordinator of the H1N1 vaccine deployment initiative, but did not have pre-determined procedures and processes in place to support large-scale deployments of influenza vaccine in place pre-pandemic. Challenges faced by the WHO that impacted deployment of USG vaccines included liability issues, vaccine registration requirements, and ensuring that recipient countries had in place funding and approved Vaccine Deployment and Vaccination Plans to support distribution of the vaccine.

HHS and USAID also remained in close contact in order to coordinate the deployment of vaccine, transport of vaccine and the deployment of ancillary items, though ultimate decisions on the recipient countries were made by the WHO based on their allocation procedures—thus, these decisions were not necessarily aligned. The USG deployed 16,860,100 doses of pandemic influenza vaccine to nine countries under the direction of WHO deployment efforts. Decision making processes and operational mechanisms in support of this international deployment proved challenging as there were no pre-established policies and mechanisms in place pre-pandemic for a large scale international deployment of influenza vaccine. In addition, decisions on international donations of H1N1 vaccine did not include provisions for providing vaccine to key international partners, including border countries, and did not address requests from middle-income countries. Moving forward, HHS needs to consider how to address requests for vaccine from developing as well as developed countries.

HHS has since documented the steps taken to distribute USG-deployed vaccine directed by WHO during the 2009 H1N1 influenza pandemic to serve as a guide for potential future international deployments to the WHO and WHO Regional Offices. In addition, HHS is working with the WHO to address issues encountered during the 2009 H1N1 influenza vaccine deployment and exploring options to increase vaccine production capacity in order to decrease future dependence on vaccine deployments during a pandemic.

It is important to note that while H1N1 vaccine became generally available in the U.S., this was not the case on a global scale. Many countries did not have access to pandemic vaccine or were dependent on deployments from the WHO, developed countries, or manufacturers. While pandemic vaccine deployment can aid in developing a country's response to an influenza pandemic, it is unlikely to satisfy the international demand for pandemic vaccine for several reasons. First, deployment can be a lengthy process and does not guarantee sufficient resources to vaccinate significant populations. Also, deployment alone ensures recipient countries remain reliant on WHO and other donors. In addition, it remains to be seen if vaccine would be deployed on a large scale during a more severe influenza pandemic than 2009 H1N1. HHS should work with the USG interagency

including DOS, USAID, and others, as well as with international partners to develop sustainable methods to increase global access to vaccine, especially in developing areas of the world, particularly through continued support of the "WHO Global Pandemic Influenza Action Plan to Increase Vaccine Supply II."

Chapter 8 Summary

Successes

1. Prior pandemic preparedness planning, including the Public Health Emergency Preparedness (PHEP) cooperative agreement and other work to build capacity of state and local public health departments laid the foundation for an effective response to the 2009 H1N1 pandemic at federal, state, territorial, tribal, and local levels.
2. Overall, communication, information sharing, and coordination across response organizations was very good but offers opportunities for improved efficiencies.
3. The pillar structure used to organize the response functioned effectively at the operational level and helped avoid information and decision silos.
4. Utilization of pre-established relationships with international partners was instrumental in sharing information and coordinating international aspects of the response to the 2009 H1N1 pandemic.
5. HHS was able to rapidly notify WHO of the 2009 H1N1 virus as a potential PHEIC under the IHR (2005).
6. From the beginning of the pandemic, HHS communication with WHO was effective and enabled coordination on issues such as international vaccine deployment.
7. Early in the pandemic, ASPR, OGHA, and HSC recognized problems associated with not having policies in place to guide international deployment of medical supplies and equipment, and cooperated to rapidly develop the SHIRE Framework that provided principles, criteria, and a decision-making process for international deployments.
8. HHS successfully deployed nearly 17 million doses of H1N1 vaccine to the WHO to assist in the international response to 2009 H1N1.

Opportunities for Improvement

1. While there was extensive planning for many areas of the pandemic, one area that requires additional planning is the operational aspects of vaccine administration, as opposed to simple dissemination to communities. Going forward, such planning, which must be done in partnership with state, local, tribal and territorial partners, will be critical.
2. Federal and state mechanisms for obtaining and distributing public health emergency funds to state and local governments were burdensome. In particular, the requirement of multiple separate applications with separate guidelines for each state to obtain Public Health Emergency Response (PHER) grants, and the time

required for federal approval of the applications, affected states' capacity to respond effectively.

3. The many federal entities involved in USG workforce protection efforts experienced challenges in the early stages of the response, which may have generated disparities in protective actions across departments and job types.
4. The extended response placed a heavy burden on the workforces at the tribal, local, state, and federal levels.
5. Although coordination with partners was successful in many ways, the pandemic exposed significant areas for improvement in coordinated planning and communication among federal entities with these international partners.
6. In some cases, coordination across all levels of government, private sector and emergency health response organizations was challenging.
7. Given the uncertainty regarding the severity and the ultimate impact of the 2009 H1N1 pandemic, decisions regarding the appropriate level of funding were challenging, particularly given they had to be made in the first days and weeks of the pandemic. At the outset, a consensus emerged that a vigorous, federally-funded response was needed. As the pandemic unfolded through the summer and fall of 2009 and the epidemiology of infection with the 2009 H1N1 virus became clear—high attack rates in children and much lower virulence than pandemic planning scenarios—the uncertain risk of mutation of the 2009 H1N1 virus to a more virulent form remained. With hindsight, it is easy to question whether the pandemic response was too costly, but it should be remembered that current science had limited capability to foretell the final course of the pandemic. Better communication about the uncertainty in how emergencies will evolve might help reduce this type of retrospective assessment. Moving forward, planning should include a framework for the types of resources that may be needed and a range of estimated costs.
8. Prior to the start of the pandemic, USG did not have in place policies or staff sufficient to guide its responses for international requests for assistance. Requests for vaccine, antivirals, diagnostic kits, and medical assets and supplies were received by multiple federal departments and agencies, but the USG did not have a centralized process in place to coordinate the requests.
9. The provision of international assistance was complicated by a variety of legal, export, regulatory, and funding issues.
10. HHS received a number of bilateral requests for vaccine from other countries, and HHS did deploy vaccine to the WHO. However, although the U.S. was a global leader in 2009 H1N1 international vaccine deployment, there were few established policies and principles to guide international deployment in advance of the 2009 H1N1 pandemic. Policies and principles are needed to guide international deployment sharing of available medical countermeasures, including pandemic vaccine, and systems for rapid exchanges of safety and efficacy data, during emergency conditions.

11. Policies and principles to guide international deployment of medical countermeasures, including pandemic vaccine, are needed. In addition, strategies to increase international access to pandemic vaccine and decrease dependence on donations need to be further developed and implemented.

CHAPTER 9: SUMMARY AND CONCLUSIONS

With the response to the 2009 H1N1 influenza pandemic behind us, it is appropriate to step back and examine which aspects of the response worked well and which did not. A retrospective examination can help the nation learn from its experiences and improve its response capabilities before it confronts the next pandemic or other public health emergency. This report describes results of a review of the 2009 H1N1 response to identify key successes, areas for improvement, and the factors (e.g., barriers or facilitators) associated with each. The report is an initial part of an ongoing discussion and consideration for improvement actions.

The review drew on multiple data collection methods (i.e., document review, electronic survey, key informant interviews, and webinars), allowing a wide range of federal and non-federal participants to share their perspectives as subject matter experts with designated roles in the response.

This review gathered information and perceptions from a convenience sample of individuals, often with divergent views. The evaluation team aggregated and summarized these views and identified key themes. The evaluation team did not evaluate, audit, or study the activities discussed. The report is intended as a hypothesis-generating activity for further review, not as an enumeration of 'facts' about what happened.

By design, the report provides broad commentary from a wide array of participants and is intended as a springboard for future dialog leading to enhancements in all-hazards response. It identifies and describes, at a relatively high level, some key issues across the spectrum of the response**.** This overarching retrospective offers a complementary perspective to more detailed agency-specific, office-specific, and interagency after action reviews that have been or are being generated around 2009 H1N1.

On the whole, the response to the 2009 H1N1 influenza pandemic was successful. Notable successes included the rapid identification and characterization of the 2009 H1N1 pandemic virus; the development and production of a 2009 H1N1 vaccine in record time; the efficient distribution of antiviral medications from the SNS to the states; the use of EUAs to increase the availability of antiviral medications and speed the availability of diagnostics; the development and rapid updating of clinical guidance on the treatment of 2009 H1N1; and the effective communication with the public regarding methods to prevent transmission of the influenza virus. Although all of these activities were viewed in a very positive light, none was viewed as a pure success. Challenges and opportunities for improvement were identified in a wide range of areas for which additional efforts and dialog are needed to ensure the nation's ability to prepare for, respond to, and recover from a future pandemic or other public health emergency. Key examples are the traditional methods of producing influenza vaccine; projections of and communication around vaccine supply and availability; research on the effectiveness of personal protective equipment; coordination and implementation of actions to protect the federal workforce; and the mechanism for obtaining, disbursing, and ensuring the accountability of funds to support

the response at the state, territorial, tribal, and local level, and to support key international activities.

Key opportunities for further dialogue and improvement

- Greater attention should focus on the needs of children in an emergency.
- Deficiencies were noted in the composition of the SNS and the availability of the pediatric formulation of oseltamivir.
- Development of decision-making protocols and processes are needed that can be used when the evidence base is ambiguous or absent;
- Improved capacity, coordination, and communication of national-level surveillance information, with strengthened international relationships;
- Ongoing development and dissemination of sensitive, specific, and easy-to-use point-of-care diagnostics;
- Increased monitoring of clinical care services at the national level with enhanced surveillance systems;
- Development of a single national IRB for use during public health emergencies;
- Improvements in modeling efforts;
- Improvements and development of self-evaluation tools and algorithms;
- Modernization of vaccine design, potency testing, and production technologies to accelerate the speed of production, and increase the yield and effectiveness of vaccine. This is especially important when novel strains occur, and will be useful in the rapid development of vaccines for other emerging pathogens;
- Development of a national, real-time system to test medical facility stress;
- Development of guidelines for provision of high-quality, safe, rapid medical care in a resource-constrained environment;
- Research and development on community mitigation measures;
- Improvements in systems to track workplace and school absenteeism;
- Improvements in monitoring of antiviral medications after release from the SNS;
- Improvements in research, and adequate preparations for conducting research, to produce interpretable information on safety and efficacy of antiviral medications before and during a pandemic;
- Improved systems and evaluation for monitoring/tracking key resources and medical countermeasures, the distribution methods used, and utilization at the state and local level;
- Improvements in plans and policies for international deployments;
- Clear, consistent, and timely federal guidance on use of masks and respirators in health care and other settings;

- Improvements in use of social media;
- Improvements in communications with minority, disadvantaged, and hard-to-reach populations; and
- Streamlined federal and state mechanisms for obtaining, allocating, distributing, and monitoring use of funds at the state and local level to support pandemic influenza responses, facilitate effective public health actions, and provide accountability for the use of resources.

Return on the planning investment

Prior investment in pandemic preparedness and response and established relationships among key institutional partners were key factors in the success of the response. Since 2003, with the emergence and spread of avian influenza H5N1 in Asia, substantial resources have been allocated across all levels of government to improve pandemic influenza preparedness. Furthermore, another factor that resulted in the investment of resources and expanding the number of companies that provided FDA-approved influenza vaccine was the 2004-05 seasonal influenza vaccine shortage.

There was a general consensus that these investments paid off in a number of concrete ways including helping to strengthen key capacities and capabilities (e.g., improved reference diagnostic tests, broader domestic and international laboratory diagnostic capacity, increased vaccine manufacturing capacity); streamlining processes (e.g., vaccine licensure, EUA issuance, federal reimbursement for local pandemic intervention costs, organization of medical countermeasure allocation and distribution); improving the clarity of public communications; building important relationships within and across organizations; distributing RT-PCR reagents and supplies to public health labs; and releasing sequences for use by developers and other laboratories.

Despite the overall sense that investments in pandemic preparedness planning were instrumental in the success of the 2009 H1N1 response, some elements of the existing plans (including the May 2006 NSPI Implementation Plan) were not sufficiently completed to allow their full value in this response, and others were too dependent on planning assumptions that were not relevant to the H1N1 pandemic, such as the severity of the disease. Examples of *planning not adequately addressed* prior to the pandemic (which consequently needed to be revamped during the response) included plans to vaccinate the federal workforce, the vaccine distribution system, vaccine recovery/disposal, replenishment of stockpile materiel, mechanisms for sharing medical countermeasures with other countries, community interventions during a pandemic (the plan addressed mostly "containment" measures, which WHO defines more as measures to limit evolution into full-blown pandemic), and implications of the limitations of surveillance.

The vast majority of the activities in the May 2006 NSPI Implementation Plan were completed within their assigned timeframes; however, some planned activities had not been fully completed by spring 2009, including activities in each of the four Framework pillars:

- *Surveillance*: real-time clinical surveillance through a nationwide hospital census and mortality tracking system, leveraging of all federal medical capabilities, fully functional integration of surveillance data through the DHS-run National Biosurveillance Integration System, effective monitoring of hospital resources, and modeling to meet all relevant operational decision-making needs;
- *Mitigation measures:* configuration of stockpiles responsive to a diversity of medical requirements;
- *Vaccine:* functional achievement of cell-based vaccine production technologies; and
- *Communications*: multilingual strategy and materials.

It could also be noted that a 24-month time frame for some of these activities, such as functional achievement of cell-based vaccine production, was unrealistic.

Going forward, plans should be more nimble and developed to be relevant across a much broader range of plausible scenarios. Perhaps different kinds of "implementation plans" would be useful, as reflected by the differences between the May 2006 plan (which was very comprehensive and mostly oriented toward preparedness) and the 2009 Framework.

Serendipity played a role

Because the pandemic could have been worse, 2009 H1N1 did not test the nation's response capabilities to its limits. Although 2009 H1N1 did stretch across all U.S. jurisdictions, many small deficiencies in the 2009 H1N1 response would have been major problems had the disease been more severe. These arguments were most often made with regard to addressing the medical needs of patients with 2009 H1N1, including monitoring of clinical disease and critical medical resources. Because the health care system was not seriously stressed during the pandemic, its ability to meet a substantial surge in demand was not fully tested and the difficult issues around allocation of scarce resources and crisis standards of care in an emergency did not have to be confronted. If the health care system had been tested to its limits, serious problems may have emerged because the public health and health care delivery systems are not well prepared to address such issues.

Next steps

Identifying key challenges following the HHS 2009 H1N1 pandemic response is a necessary but not sufficient condition for improving public health preparedness. Unless appropriate dialog occurs and consensus recommendations for the future are implemented, similar problems are likely to emerge during the next public health emergency. This report represents one effort, among others that have been completed, to review the medical and public health efforts during the 2009 H1N1 response. It is intended to stimulate discussion within HHS, the Interagency, and across the relevant organizations (both governmental and non-governmental) about how to build upon the successful elements of the response and concretely address areas needing improvement.

This report has also served as the foundation for the next stage of pandemic planning, which is already underway. This planning includes the development of the 2009 H1N1 Influenza Retrospective Improvement Plan, which identifies priority strategies and activities needed to address identified gaps and shortfalls, and a monthly interdepartmental progress review led by the Assistant Secretary for Preparedness and Response.

It is important to understand that the occurrence of the 2009 H1N1 pandemic has not reduced the risk of a future, severe pandemic or altered the timeframe on which it may occur. For that reason, acting now on lessons learned through this and other reviews of the 2009 H1N1 pandemic experience is imperative.

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APPENDIX: LIST OF ACRONYMS

AARC	American Association for Respiratory Care
ACF	Administration for Children and Families
ACIP	Advisory Committee on Immunization Practices
AI/AN	American Indian/Alaska Native
ARDSNet	Acute Respiratory Distress Syndrome Network
ASPR	Office of the Assistant Secretary for Preparedness and Response
ASTHO	Association of State and Territorial Health Officials
BARDA	Office of the Biomedical Advanced Research and Development Authority
BLA	Biologics License Application
BRFSS	Behavioral Risk Factor Surveillance System
COCA	Clinician Outreach and Communication Activities
CBO	Community-based organization
CCDF	Child Care and Development Fund
CDC	Centers for Disease Control and Prevention
CHIP	Children's Health Insurance Program
CMM	Community mitigation measures
CMS	Centers for Medicare & Medicaid Services
DHS	Department of Homeland Security
DOD	Department of Defense
DOS	Department of State
ED	Department of Education
EHR/EMR	Electronic health record/electronic medical record
EMTALA	Emergency Medical Treatment and Labor Act
EUA	Emergency Use Authorization
FACOSH	Federal Advisory Council on Occupational Safety and Health
FDA	Food and Drug Administration
FOH	Federal Occupational Health
FEMA	Federal Emergency Management Agency
GAO	Government Accountability Office
GBS	Guillain-Barré Syndrome
GHSI	Global Health Security Initiative
GOARN	Global Outbreak and Response Network
HAN	Health Alert Network
HAvBED	National Hospital Available Beds for Emergencies and Disasters
HHS	Department of Health and Human Services
HIPAA	Health Insurance Portability and Accountability Act
HRSA	Health Resources and Services Administration
HSC	Homeland Security Council
ICS	Incident Command Centers
IDE	Investigational Device Exemption
IHR	International Health Regulations
IHS	Indian Health Services
IHVA	International H1N1 Vaccine Assistance Working Group
ILI	Influenza-like illness
IND	Investigational New Drug

IOM	Institute of Medicine
IP	Implementation Plan
IPAPI	International Partnership for Avian and Pandemic Influenza Core Group
IRB	Institutional Review Board
LAIV	Live attenuated influenza vaccine
LDT	Laboratory developed test
MMWR	Morbidity and Mortality Weekly Report
MOU	Memoranda of Understanding
NACCHO	National Association of County and City Health Officials
NAPAPI	North American Plan for Animal and Pandemic Influenza
NHLBI	National Heart, Lung, and Blood Institute
NIH	National Institutes of Health
NIOSH	National Institute of Occupational Safety and Health
NPHIC	National Public Health Information Coalition
NSPI	National Strategy for Pandemic Influenza
NSS	White House National Security Staff
NVAC	National Vaccine Advisory Committee
NVPO	National Vaccine Program Office
OCC	Office of Child Care
OFDA	Office of Foreign Disaster Assistance
OGHA	Office of Global Health Affairs
OPEO	Office of Preparedness and Emergency Operations
OPM	Office of Personnel Management
OSHA	Occupational Safety and Health Administration
PAHO	Pan American Health Organization
PAHPA	Pandemic and All Hazards Preparedness Act
PALISI	Pediatric Acute Lung Injury and Sepsis Investigators
PCAST	President's Council of Advisors on Science and Technology
PCR	Polymerase Chain Reaction
PHEP	Public Health Emergency Preparedness
POD	Points of Dispensing
PPE	Personal protective equipment
PREP Act	Public Readiness and Emergency Preparedness Act
PRISM	Post-Licensure Rapid Immunization Safety Monitoring
PSA	Public Service Announcement
PSI	Pandemic Severity Index
RFAs	Requests for Assistance
RSS	Really Simple Syndication
RT-PCR	Real Time-Polymerase Chain Reaction
SARS	Severe Acute Respiratory Syndrome
SHIRE	Homeland Security Council Sub-Interagency Policy Committee on Supporting H1N1 International Requests and Engagement
SNS	Strategic National Stockpile
SOC	Secretary's Operation Center
TFAH	Trust for America's Health
THAN	Traveler Health Alert Notice

UNOPS	United Nations Office for Project Services
U.S.	United States of America
USAID	United States Agency for International Development
USG	United States Government
VFC	Vaccine for Children Program
VRBPAC	Vaccines and Related Biological Products Advisory Committee
VSRAWG	Vaccine Safety Risk Assessment Working Group
WHO	World Health Organization