



# IDS

Infectious Diseases Society of America

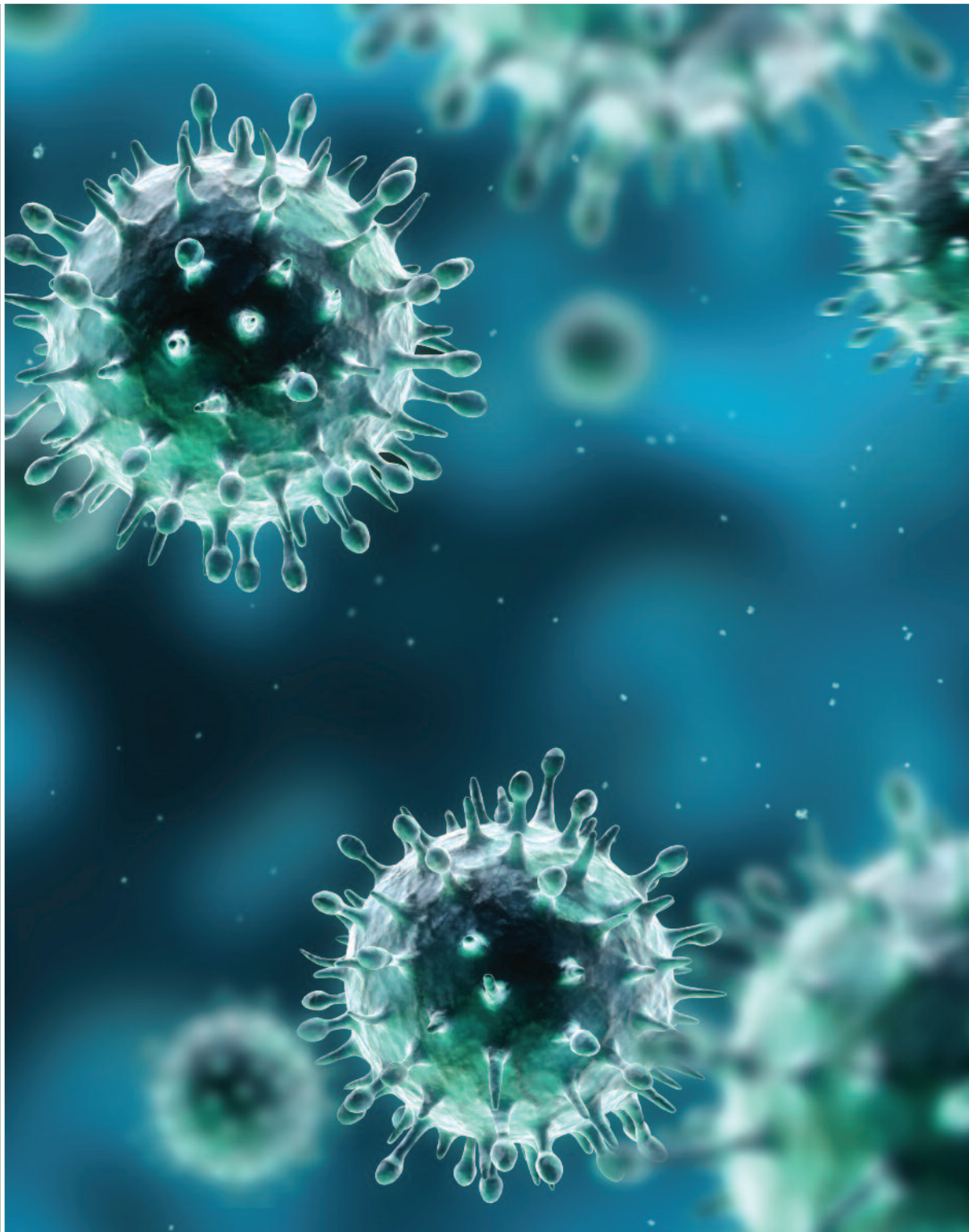
## Pandemic and Seasonal Influenza Principles for United States Action

SEPTEMBER 2012

The Infectious Diseases Society of America is an organization of physicians, scientists, and other health care professionals dedicated to promoting human health through excellence in infectious diseases research, education, prevention, and patient care.

The Society, which has nearly 10,000 members, was founded in 1963 and is headquartered in Arlington, Virginia.

For more information, visit [www.idsociety.org](http://www.idsociety.org).



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# Influenza Preparedness— Why We Should Care

The Infectious Diseases Society of America (IDSA) first issued a set of Pandemic and Seasonal Influenza Principles for U.S. Action in January 2007. Our intent—then and now—was to inform and educate the United States government and policymakers on how to best prepare for and respond to seasonal and pandemic influenza.

We did not know the timeliness of our principles document until the first report of the discovery of a novel strain of influenza A H1N1 virus in 2009 (technically referred to as A(H1N1)pdm09). The 2009 H1N1 influenza pandemic illustrates the unpredictable nature of pandemics and demonstrates the importance of being well prepared. The emergence of the 2009 H1N1 virus showed dramatically that a novel virus with human-to-human transmissibility was capable of traversing the globe within 6-8 weeks, attaining pandemic status, and demonstrating that an influenza pandemic might not reflect our experience or expectations. Such events convincingly demonstrate to the modern world that, in addition to severe illness and death, the spread of new influenza strains can cause significant societal and economic disruption and anxiety, and, in extreme cases, may threaten economic and national security. These events also demonstrate our continued vulnerability to emerging infectious diseases.

The 2009 H1N1 pandemic disproportionately affected younger, otherwise healthy persons, as well as pregnant women. In the U.S. alone, approximately 60.8 million cases, 274,000 hospitalizations, and 12,500 deaths occurred. Although the number of deaths was less than in some previous influenza pandemics, 87 percent of those deaths occurred in people under the age of 65, a significant departure from the pattern usually seen with seasonal influenza and many pandemics.

Just as the world must be prepared for pandemic influenza, so must we prepare for seasonal influenza, which remains a serious public health concern. According to the Centers for Disease Control and Prevention (CDC), seasonal influenza is associated with 3,000 to 50,000 deaths in the U.S. each year, depending on the severity of the virus strain. Preparedness for influenza pandemics is inextricably tied to our efforts related to seasonal influenza, and the occurrence of seasonal influenza provides us with an annual opportunity to strengthen our preparedness and response capabilities.

U.S. government agencies and Congress have key roles to play to ensure the essential tools necessary to prepare for seasonal and pandemic influenza both domestically and globally (see Box 1) are available, including creating incentives for the development of medical countermeasures and ensuring their availability; strengthening public health infrastructure to effectively manage surveillance and communication needs; and harmonizing domestic and global activities. There were a number of notable successes in the response to the 2009 H1N1 influenza pandemic, but the pandemic exposed deficiencies in the ability of governments in the U.S. and abroad to develop, manufacture, deliver, and administer billions of doses of vaccine in the time necessary to mitigate the impact of the virus' spread. Evaluating where we succeeded and where we failed will better prepare us for future pandemics, seasonal influenza, and other outbreaks of novel infectious diseases.

## **BOX 1** **ESSENTIAL TOOLS**

- Vaccines
- Antimicrobial Drugs
- Diagnostic Tools
- Effective Communication Skills and Strategies
- Surveillance Capacities
- Community Mitigation Strategies
- Public Health Systems
- Medical Care Systems with Surge Capacity
- A Dedicated and Protected Health Care Workforce
- Well-Coordinated Global Approach
- Sufficient and Sustained Funding



# Executive Summary

IDSAs updated principles rely upon the experience of the 2009 H1N1 influenza pandemic and are intended to assist the U.S. Department of Health and Human Services' (HHS) Assistant Secretary for Preparedness and Response (ASPR) and other agency officials as they establish priorities for implementation of the reauthorized Pandemic and All-Hazards Preparedness Act (PAHPA). We also trust that this document will be helpful to congressional appropriators as they consider future funding needs in this critical area. IDSA's principles continue to stress that seasonal influenza and pandemic influenza preparedness efforts are closely related, and neither can be ignored nor treated in isolation.

In May of 2012, HHS released its 2009 H1N1 Influenza Improvement Plan<sup>1</sup> that details key priorities for improving preparedness. We are pleased to see that many of HHS's priorities parallel our own recommendations, and we urge HHS to work with stakeholders to implement key priorities and Congress to fund them. We also highlight three themes that are not readily apparent in the HHS Plan that require additional consideration. First, there is a critical need for coordination between HHS and other U.S. government departments, as well as a need for better coordination within HHS, particularly concerning influenza vaccine efforts. Second, we urge HHS not to simply conduct a one-time or sporadic reassessment of its efforts, but to establish processes for continual review of critical and rapidly evolving components of influenza preparedness, such as the contents of the Strategic National Stockpile (SNS). And, third, HHS should more vigorously support the uptake of the annual influenza vaccine by health care workers including through the adoption of a mandatory approach.

This executive summary provides IDSA's general principles. The full report includes current status assessments and more detailed recommendations for each principle.

## **Principle 1.** **Strengthen Influenza Vaccine Efforts**

Vaccines are considered the first line of defense to protect the population against seasonal and pandemic influenza, as they can prevent infection and control the spread of disease. However, as the 2009 H1N1 influenza pandemic demonstrated, we urgently need to improve influenza vaccine technologies so that manufacturers can develop vaccines faster and in greater supply. A universal influenza vaccine that would elicit protection against a broad range of antigenically diverse influenza viruses including different subtypes, with improved vaccine efficacy and effectiveness, is particularly attractive for pandemic preparedness. But technology alone is not the answer. Even a widely available vaccine would be ineffective if we overlooked research into improving delivery and uptake, as well as monitoring safety and effectiveness in different age groups and populations.

## **Principle 2.** **Enhance Pharmaceutical Availability and Medical Management of Influenza**

Antiviral drugs are the primary therapeutic tools used to minimize severe illness and

death during an influenza outbreak. We need new antiviral drugs that are easy to use, broadly accessible, and effective against emerging drug-resistant influenza variants. Preferred features include simplicity of formulation, simplicity of regimen, breadth of efficacy, and uncomplicated storage requirements. Intravenous formulations are needed for severe disease often seen in patients who are hospitalized with complications of influenza, including pneumonia and extra-pulmonary disease. Special consideration must be given to treatment for the pediatric and obstetric populations. As secondary bacterial infections are known to cause deaths in patients stricken with influenza, the development of antibacterial drugs, particularly those for treating pneumonias due to resistant organisms such as methicillin-resistant *Staphylococcus aureus* (MRSA), also must be priorities. Drugs that modify the potentially harmful immune response of the body to influenza may be effective in preventing complications. We need research to develop and test immune modulating treatments for influenza.

<sup>1</sup> <http://www.phe.gov/Preparedness/mcm/h1n1-retrospective/Documents/2009-h1n1-improvementplan.pdf>

### **Principle 3. Improve Accuracy and Availability of Diagnostic Tools for Influenza**

The lack of accurate, rapid diagnostic tools during the 2009 H1N1 influenza pandemic made clinical response challenging and was an obstacle to surveillance. Rapid, highly sensitive diagnostic tools are needed to quickly and accurately diagnose seasonal and pandemic influenza, to identify influenza A subtypes and novel subtypes, and to detect antiviral resistance in appropriate settings. High quality tests are needed in public health and hospital laboratories, as well as at the point of care.

### **Principle 4. Strengthen Influenza Communication Strategies**

Good communication with the public and medical providers is a fundamental component of any response effort, as successful communication can lay the groundwork for effective dispensing and acceptance of medical countermeasures (e.g., drugs, vaccines, and diagnostic tests). Public concerns about vaccines or distrust of government must be taken into account in advance of a crisis. During any infectious disease emergency, complex policy decisions must be made before complete scientific and epidemiologic information is available. The policies must be flexible and able to adapt as the situation evolves. The current media environment with its 24-hour news cycle creates challenges but also opportunities for more complete and transparent communication regarding seasonal and pandemic influenza.

### **Principle 5. Improve and Better Coordinate Influenza Surveillance**

A strong and robust public and animal health surveillance system is necessary at the global, national, and local levels. Such a system requires ongoing support and funding from policymakers and elected officials. The unexpected emergence of the 2009 H1N1 pandemic in Mexico demonstrated the migration of influenza virus genes across two continents and included genetic recombination of influenza strains from three animal species. H1N1 and the ongoing H5N1 panzootic (i.e., pandemic in animals) serve as important reminders of the global link between human and animal health. Cooperation between

human and animal health experts and adequate resources are critical to the surveillance, diagnosis, treatment, prevention, and control of cross-species transmission and emerging infections. Building upon a common pool of knowledge will enhance integrated surveillance efforts that can translate into faster detection of novel or emerging disease threats.

### **Principle 6. Evaluate and Refine Influenza Community Mitigation Measures**

Influenza prevention and control involves appropriate use of vaccines and antiviral agents to the extent available, but other community mitigation strategies also can potentially slow the spread of disease. Possible strategies include isolation and quarantine; exposure avoidance and social distancing, including school closures; the simple practice of appropriate and frequent hand washing; respiratory etiquette by covering the mouth and nose when coughing or sneezing; and potentially, the use of masks. However, the efficacy, costs, consequences, and optimal use of these strategies must be better understood. Mitigation strategies must be evaluated systematically to inform policy and preventive measures.

### **Principle 7. Build All-Hazard Public Health and Medical Care Systems Capable of Responding to Seasonal and Pandemic Influenza**

**Public Health Systems:** Public health systems are crucial to the response of seasonal influenza outbreaks and influenza pandemics, and cannot be assembled at the time of crisis. As concerns were mounting about the avian influenza virus that was circulating in Asia, the global public health infrastructure was challenged in 2005 to prepare for the next influenza pandemic. This ultimately led to efforts to improve surveillance, mitigation strategies, and the availability of vaccines and antivirals. Challenges remain in all of these domains, but particularly in the readiness to quickly distribute and dispense large quantities of appropriate medical countermeasures. More planning and exercises are needed, as are strategies for optimizing dispensing and administration, especially to at-risk populations in need of special attention before, during, and after an incident.

**Medical Care Systems:** Medical care systems are a critical component of state, regional, and local preparedness and response. Medical care facilities are often first-line responders as patients will seek treatment from their local physician, emergency room, or public health clinic. However, the current health care system has limited surge capacity. As such, strategic planning is necessary to allow for public health systems and medical care systems to leverage resources and coordinate response activities. In advance of an outbreak or pandemic, it is necessary for public health and medical care systems to measure capacity, monitor response times and capabilities, and develop flexible strategies to cope with large surges in the need for medical care.

**Principle 8.**  
**Protect the Health Care Workforce During Seasonal and Pandemic Influenza Outbreaks**

The availability of a dedicated and protected health care workforce is critical to the successful implementation of influenza preparedness and response plans. Beyond vaccination efforts for the general population, health care providers need specific targeted strategies, which may include mandates, to enhance uptake of the influenza vaccine and protect the health of both patients and health care personnel during annual influenza season and during a pandemic. Vaccination strategies must be supplemented by availability of antiviral treatment, personal protective equipment, vaccine injury compensation, and liability protection for health care workers.

**Principle 9.**  
**Continue to Strengthen International Collaboration**

A coordinated global approach to influenza surveillance and control is critical, including a more consistent international recognition of the importance of seasonal and pandemic influenza. Influenza does not respect national boundaries. It is critical to apply public health tools across national boundaries, to establish global surveillance systems, to disseminate consistent guidelines worldwide, to ensure equity of access to countermeasures, to rapidly conduct research, and to apply the findings internationally. The effectiveness of the global public health emergency system relies upon routine attention to preparedness, agility in responding to surveillance information and catastrophes, and the resilience that promotes rapid recovery.

**Principle 10.**  
**Allocate Significant and Sustainable Funding for Long-Term Planning and Action**

Adequate seasonal and pandemic influenza preparedness and response efforts require long-term governmental coordination and planning, which must be maintained through sustained and adequate funding. Federal, state, and local funding has decreased in past years, compromising seasonal and pandemic influenza preparedness and response efforts, including disease surveillance. Strong, multi-year funding commitments are critical to protecting public health and saving lives.

**BOX 2**  
**INFLUENZA VIRUSES**

There are three types of influenza viruses, classified as A, B, or C, based on their antigenic composition. Public health experts are most concerned with type A influenza virus. Type A viruses are subdivided into groups based on two surface proteins: hemagglutinin (HA) and neuraminidase (NA), which are represented as H1 through H6 and N1 through N9, respectively. Because Type A viruses can be found in humans and animals, surveillance of influenza A viruses in animals is critical to detecting the emergence of novel viruses with pandemic potential in humans.

Human influenza A and B viruses cause seasonal influenza every year. Because the changes in seasonal influenza viruses are generally incremental and viruses circulating during the Southern Hemisphere winter are similar to those that circulate in the coming winter in the Northern Hemisphere, scientists can predict with moderate accuracy which virus will circulate during the influenza season. Pandemic influenza typically is caused by the emergence of a virulent new strain of influenza A to which most people have no immunity. This allows it to cause a global outbreak of serious illness. Influenza C infections are relatively uncommon, can cause mild respiratory illness, and have never been reported to cause epidemics.

# IDSA's Principles with Specific Recommendations

## 1. Strengthen Influenza Vaccine Efforts

**D**uring the 2009 H1N1 influenza pandemic, an insufficient and untimely supply of vaccine was available nationally and globally, with even more limited or delayed supply and delivery in low- and middle-resource countries. Seasonal influenza programs remain challenged by the need to manufacture new vaccines every year to match the evolving antigenic changes of circulating virus strains; the suboptimal immunogenicity of influenza vaccines in mismatched years and in vulnerable populations; and suboptimal vaccine uptake rates.

However, vaccine manufacturing capacity in the U.S. is at an all-time high, as are the number and types of influenza vaccines available and in development. Inactivated and live attenuated vaccines, a high dose influenza vaccine for persons 65 years and over, and an intradermally administered vaccine for persons 18-64 years are now licensed and marketed in the U.S. Research and development (R&D) continues in many important areas—including cell-based manufacturing, adjuvants, and recombinant technologies—and several companies are testing quadrivalent vaccines with two influenza A and two influenza B strains. From 2005 through March 2011, HHS and the Department of Defense (DoD) awarded \$2.1 billion in contracts and technology investments for advanced development of novel influenza vaccine technologies.

Globally, modest investments have yielded large dividends. The World Health Organization (WHO) has led technology transfer programs to manufacturers in developing countries, which have contributed to an estimated global influenza vaccine capacity of nearly 900 million doses of trivalent vaccine in 2010—a nearly three-fold increase over supplies in 2006. Progress has been made in virus sharing, securing advanced commitments for pandemic vaccine intended for use in low-resource countries, and increasing regulatory support for developing country manufacturers.

### **Principle:**

The widespread use of influenza vaccine should be the central strategy for protecting human health against seasonal and pandemic influenza.

IDSA supports continued U.S. efforts to improve the effectiveness and accelerate the development, manufacturing, and broader use of influenza vaccines. Several federal agencies are involved in achieving this goal through activities that include vaccine discovery, development, regulatory review and approval, acquisition, and field trials. There is room to improve synchronization, priority-setting, interagency coordination, and decision-making along the continuum of activities. These improvements can speed progress and ensure efficient use of government resources.

To address this, IDSA recommends the designation of a specific lead office and director within HHS to facilitate coordination of influenza vaccine efforts.

Currently, discovery research and early-stage development fall under HHS's National Institutes of Health (NIH), delivery falls under HHS's Office of the Assistant Secretary for Health (ASH) through the National Vaccine Program Office (NVPO), while later-stage development and preparedness fall under HHS's Assistant Secretary for Preparedness and Response (ASPR) and its Biomedical Advanced Research and Development Authority (BARDA). CDC directs studies of vaccine effectiveness and also collaborates with partners to develop alternative delivery and manufacturing technologies. There is a need for collaboration with public and private partners to assist the proposed lead office in outlining a comprehensive approach that will systematize, coordinate, and strengthen vaccine R&D, resulting in increased production capacity, accelerated licensure, and monitoring of vaccine



performance and safety. The proposed lead office and each individual agency involved in vaccine efforts must articulate clear short- and long-term goals defined through a coordinated process that is public and transparent, incorporates the input of a broad range of experts (preferably through the creation of an advisory board), and is periodically re-visited. Funding for such efforts must be multi-year (at least five years) and sustainable.

The U.S. should encourage global efforts that emphasize swift and scalable manufacturing, an equitable and affordable vaccine supply, immunogenic and broadly cross-protective vaccines, rigorous safety monitoring, and regulatory harmonization between countries as new vaccines are introduced.

### **Specific Recommendations:**

*To strengthen influenza vaccine efforts, HHS (ideally through the proposed new lead entity) must work in concert with DoD, WHO, vaccine manufacturers, and other public and private partners to:*

- optimize coordination, planning, and decision-making among federal agencies involved in influenza vaccine development and delivery, and ensure the inclusion of a robust external and transparent advisory process;
- support development and testing of novel influenza vaccines, including new adjuvants, with improved immunogenicity, efficacy, and breadth of protection for seasonal and pandemic influenza;
- support research on the immune response to influenza vaccines, including novel vaccines, to identify new correlates of vaccine-induced immune protection, particularly among at-risk groups with suboptimal immune responses (e.g., infants, elderly, immunosuppressed);
- prospectively establish and implement protocols and systems for ongoing evaluation of the impact of influenza vaccines on seasonal and pandemic influenza among high-risk groups and the general population, including maintaining support for ongoing studies at CDC;
- optimize seasonal influenza vaccine seed strain production and release criteria for influenza vaccines to accelerate manufacturing timelines;
- support efforts by WHO, non-governmental organizations, foundations, and other partners to increase international influenza vaccine production



- capacity and annual uptake, and to coordinate and facilitate development, production, licensing, and distribution of a global supply of affordable seasonal influenza vaccines, as well as stockpiling of pandemic influenza vaccine seed stocks;
- strengthen capacity in resource-constrained countries to monitor disease burden, as well as vaccine distribution, performance, and safety;
- maintain and expand ongoing post-marketing surveillance systems for monitoring vaccine effectiveness and safety, including for individual influenza vaccines (e.g., live attenuated influenza vaccine [LAIV] v. trivalent inactivated vaccine [TIV] v. newly licensed vaccines); and
- strengthen global capacity to monitor influenza A viruses among animals, and to rapidly share viruses and virological data for viruses of human pandemic potential for risk assessment and vaccine development.

*HHS should designate a specific lead office to coordinate influenza vaccine efforts.*



## 2. Enhance Pharmaceutical Availability and Medical Management of Influenza

The dearth of novel antiviral and antibacterial drugs in development should be of tremendous concern to the U.S. public and policymakers. Microbes are increasingly developing resistance to current drugs that target influenza viruses and the bacteria that commonly cause secondary pneumonia. Oseltamivir resistance is a major emerging threat, and there are very few agents in development that could be used for the treatment of infections caused by oseltamivir-resistant, adamantane-resistant viruses. Clinical research on antivirals for influenza has focused primarily on development of alternative neuraminidase inhibitors (NAIs), reducing or managing antiviral resistance, and on treatment studies in otherwise healthy persons. Inadequate research has been done on therapy in children, seriously ill patients, or those with high-risk conditions, and there are regulatory challenges to studies in these groups. Research is needed on disease pathogenesis in various influenza-related syndromes, the genomics of susceptibility and host responses to influenza, prevention of complications, and treatment of secondary bacterial infections. Certain high risk conditions associated with poor outcomes in patients with influenza require more intensive study, including young age (e.g., infants), compromised immune systems, asthma or chronic obstructive pulmonary disease (COPD), pregnancy, and obesity. Stockpiling antiviral and antibacterial drugs is also a challenge. In 2006, HHS added NAIs to the Strategic National Stockpile (SNS) and implemented a subsidy program to assist the states in developing regional stockpiles. However, the current stockpiles will expire between 2013 and 2016 and, while an active shelf-life extension program is being examined for feasibility at the federal level (but not the state level), in the event of greater need, the manufacturing and supply chains of NAIs are not secure in the U.S.

### Principle:

Influenza antiviral drugs are medical countermeasures that can save lives when an influenza vaccine is ineffective, medically contraindicated, or unavailable. As such, strengthened R&D of new influenza antiviral drugs must be treated as a critical priority for government action. Similarly, strengthened U.S. efforts are needed to advance antibacterial drug R&D, particularly for antibiotics to treat pneumonias caused by resistant organisms such as MRSA and *Streptococcus pneumoniae*. Research to better understand disease pathogenesis, genetic determinants of host susceptibility, and the possible role of immune modulating or anti-inflammatory therapies — including their targets, potency, and timing of use — is essential. Also greatly needed is improved utilization of antiviral agents that encompass earlier initiation of therapy, increased dissemination of expert guidance, implementation of better diagnostics including those for antiviral and antibacterial resistance, and strengthening the evidence base for therapies and optimizing dosing regimens in high-risk and seriously ill adults and children. It also is imperative that the SNS be continually reviewed to ensure that it contains adequate and appropriate antiviral and antibacterial drugs.

### Specific Recommendations:

To enhance pharmaceutical availability and medical management of influenza, HHS agencies must work in concert with federal partners to:

- continue supporting development of novel antiviral, anti-inflammatory, and antibacterial therapies for influenza and its complications, and for linked pathogenesis and therapeutic research in priority patient populations;
- support R&D of novel antivirals and antibacterials that target resistance;

*The dearth of novel antiviral and antibacterial drugs in development should be of tremendous concern to the U.S. public and policymakers.*

explore combination antiviral and antiviral/antibacterial therapies; and incorporate anti-inflammatories into investigational therapeutic regimens based on robust evidence;

- ensure focused research on pathogenesis and therapy of severe influenza, particularly viral pneumonia and acute lung injury, and its complications (e.g., bacterial superinfections) in high-risk groups;
- support research on non-pharmaceutical critical care management strategies for the sickest patients with respiratory failure, including ventilator management and the role of extracorporeal membrane oxygenation (ECMO);
- increase investments in domestic and international hospital-based clinical research networks that can both conduct prospective, multi-center studies of important pathogenesis and management issues related to seasonal influenza, and rapidly mount research responses to outbreaks of severe acute respiratory infections due to novel pathogens;
- encourage effective linkage between civilian and military networks;
- streamline anti-infective regulatory guidance and approval processes, including developing feasible regulatory requirements based on relevant clinical and/or microbiologic endpoints that can aid the development of treatments for severely ill patients;
- develop guidelines and mechanisms for rapidly collecting and analyzing key clinical data in urgent use settings (i.e., Emergency Use Authorizations [EUA] or emergency Investigational New Drug applications [eIND]); and
- develop processes for conducting ongoing assessments of the supplies of influenza antiviral and antibacterial drugs in the SNS and other public and private stockpiles. These assessments should maintain adequate levels, evaluate expirations, and diversify the supply by accommodating newly licensed agents with specific advantages, such as antibacterials for drug-resistant organisms and influenza antivirals for intravenous use or oseltamivir-resistant variants.

### 3. Improve Accuracy and Availability of Diagnostic Tools for Influenza

CDC investments in developing new diagnostic tools for pandemic preparedness and seasonal influenza surveillance were extremely valuable during the 2009 H1N1 influenza pandemic. In response to the pandemic, the U.S. Food and Drug Administration (FDA) approved the 2009 H1N1 reverse transcription polymerase chain reaction (RT-PCR) assay and subsequent modifications under an EUA for use in pre-qualified laboratories on very specific instruments. However, public health laboratories could not meet clinical demands, and the availability of RT-PCR assays for influenza in clinical laboratories continues to be limited. Currently available rapid influenza point-of-care tests have suboptimal sensitivity that limits their clinical utility, especially for detection of novel influenza A viruses. Since 2006, CDC and BARDA have invested \$96 million toward the development of diagnostic tests. From 2009 to 2010, the National Institute of Allergy and Infectious Diseases (NIAID) committed \$24 million to support research projects focused on developing rapid tests suitable for screening patients and helping researchers develop influenza therapeutics. However, these investments have yet to lead to the wide availability of advanced influenza diagnostics for clinicians. The 2010 HHS/ASPR Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) Review found that regulatory science and guidance at FDA need to evolve to facilitate the development and approval of RT-PCR-based tests, multiplex tests that can simultaneously screen for multiple infections, and other tests based on advanced technology.

#### Principle:

Rapid, sensitive, and highly accurate diagnostic tools are needed to quickly and accurately diagnose seasonal and pandemic influenza, identify and distinguish between influenza A virus subtypes and novel subtypes, detect antiviral resistance, and evaluate respiratory outbreaks of unknown etiology. Diagnostics that can simultaneously test for multiple respiratory pathogens could improve surveillance for respiratory disease, improve clinical care, and enhance clinical trials. Highly accurate tests are needed in public health and hospital laboratories, as well as at the point-of-care. Tests should be suitable and available not only

to medical facilities with sophisticated laboratories, but also to any inpatient or outpatient health center, including those in remote areas or with limited resources. Therefore, these diagnostic tools must be simple to use, inexpensive, and not require special storage conditions. To improve surveillance data, testing for influenza viruses in the clinical setting should be linked to public health surveillance systems.

### Specific Recommendations:

*To improve the accuracy and availability of diagnostic tools for influenza, HHS agencies must work to:*

- support the development and wide availability of highly accurate influenza tests for hospitalized patients, (including tests that detect other respiratory pathogens) as well as inexpensive, highly sensitive and specific, simple and accurate point-of-care tests that can provide timely results to guide clinical management and public health responses. Such tests should detect and distinguish between infections with different influenza virus types and influenza A virus subtypes, including novel influenza A viruses. The reagents, supplies, and tests ideally should be stable at room temperature and able to be easily deployed in diverse national and international settings and retain high diagnostic accuracy;
- support the development and availability of influenza tests for clinicians that can identify infection with influenza viruses resistant to available antiviral medications;
- enhance timeliness of electronic laboratory reporting of influenza testing data using hospital laboratories and linking to critical indicators of severity such as

*Diagnostics that can simultaneously test for multiple respiratory pathogens could improve surveillance for respiratory disease, improve clinical care, and enhance clinical trials.*

hospitalization, intensive care unit admission, and death;

- ensure surge capacity for critical items and supplies to diagnose influenza and its potential bacterial complications;
- fund research demonstrating the clinical and public health impact of influenza diagnostics and develop evidence-based recommendations for health care providers on the use of influenza diagnostic tests;
- collaborate with professional societies and other stakeholders to implement best practices including patient selection, specimen collection, test selection, interpretation of results, and implications for clinical management of influenza patients; and
- ensure reimbursement of appropriate diagnostic testing for influenza.





## 4. Strengthen Influenza Communication Strategies

CDCC is to be commended for the overall quality and breadth of its communications efforts during the 2009 H1N1 pandemic, but there were challenges regarding information flow from the various federal agencies to the state and local health departments. Specifically, inconsistencies in recommendations on school closures and health care workers' use of personal protective equipment (PPE) fostered early uncertainty about the U.S. government's response. Providers often did not understand or adopt guidance on the use of diagnostic tests or antivirals in a timely manner. Inadequate communication resulted in a widely held, but erroneous, belief that the 2009 pandemic was mild and of little consequence.

### Principle:

Effective communication is a fundamental element of public health emergency planning and response. Timely, transparent, and clear messages provided by trusted public health leaders are critical components of a successful seasonal or pandemic influenza response strategy. Officials at the national, state, and local levels must be trained in risk communication and must regularly practice these skills, not just in times of crisis.

An optimal communication strategy for seasonal or pandemic influenza is one that provides for the availability of information to the public and to providers through multiple venues.

Underserved and vulnerable populations present special challenges, and efforts must be made to ensure medically literate and culturally competent communication. Potential communication barriers should be recognized in advance of an event and community partnerships made in order to effectively reach people and assess risks.

A successful communication strategy during times of seasonal or pandemic influenza also must include consistent messaging to primary care providers, so they understand the antivirals, vaccines, diagnostics, isolation practices, and clinical management most appropriate to the specific influenza strain or pandemic situation. Efforts must be made to reach health care providers and their professional societies across the continuum of care as well as establish mechanisms for two-way communication to help ensure that all necessary information is provided.

*Timely, transparent, and clear messages provided by trusted public health leaders are critical to success.*

### Specific Recommendations:

*To strengthen influenza communication strategies, HHS agencies must work in concert with state and local health officials to:*

- develop and periodically revise an influenza response communications strategy to ensure that all communications are coordinated, intact, and functional—this effort must include high-level decision makers who will need authority to issue public statements during pandemics without an unwieldy approval process;
- ensure that messages during a seasonal or pandemic influenza response effort are accurate, timely, transparent, and consistently delivered by designated communicators who are experienced, well-trained, and well-versed in risk communication principles and in influenza biology;
- ensure frequent, accurate, timely, and bi-directional communication between national, state, and local public health agencies, as well as between public health agencies, clinicians, and other partners such as professional medical societies;
- identify underserved and vulnerable populations and assist states and local governments in doing the same; target communications efforts to each population; and evaluate the effectiveness of these methods during preparedness drills and annually during seasonal influenza;
- use traditional and nontraditional forms of communication (such as social media) in advance of an event, such as annually during seasonal influenza; and
- ensure that preparedness and response plans include hotlines and social media forums to answer questions from the public and clinicians in a timely and transparent manner; and develop and implement appropriate training for individuals who staff these forums.



CDC's Anne Schuchat, MD, FIDSA, communicates with reporters during the 2009-2010 H1N1 influenza pandemic.

## 5. Improve and Better Coordinate Influenza Surveillance

The U.S. federal government, the WHO, and other international bodies have greatly enhanced surveillance efforts at all levels, but limited federal funding threatens the ability to sustain these efforts. Domestically, upgraded surveillance efforts carried out by state and local health, agriculture, and wildlife agencies; hospitals; and clinicians were instrumental in detecting the first four U.S. cases of the 2009 H1N1 pandemic influenza virus. Current U.S. influenza surveillance systems include syndromic, clinical, and virologic systems that are capable of reporting:

- ◆ influenza-like illness from a national network of sentinel providers;
- ◆ outbreaks from institutional settings;
- ◆ nationally notifiable conditions including human infection with a novel influenza A virus, and influenza-associated pediatric mortality;
- ◆ pneumonia and influenza mortality from vital registrars in 122 U.S. cities;
- ◆ influenza-associated hospitalization in 16 states; and
- ◆ testing of U.S. specimens from the WHO Global Influenza Surveillance Network (GISN) to monitor virus circulation, antigenic changes, and antiviral susceptibility patterns.

Global efforts have begun to improve local and international surveillance, which will be greatly enhanced by further harmonization and integration of local and international laboratory and clinical surveillance systems.

### Principle:

Influenza surveillance systems are critical to estimate disease burden; determine appropriate intervention and control activities; monitor seasonal influenza viruses for antiviral resistance and for antigenic changes that impact vaccine development; and detect the emergence of novel influenza viruses with pandemic potential. Sustained funding is essential to maintain and enhance epidemiologic and virologic surveillance systems at the international, national, state, and local levels. A critical role of surveillance systems is the early detection of an emerging infectious threat that enables officials to respond rapidly to contain and reduce the threat of transmission, morbidity, and mortality. Lessons learned from the 2009 H1N1 influenza pandemic dictate a “One Health” approach that includes stronger collaborations in human, animal, and environmental sectors, both domestically and internationally. Sustained funding is necessary to enhance and strengthen traditional influenza surveillance systems to directly link epidemiological and clinical data with laboratory reports. Systems for syndromic surveillance

that utilize electronic health data could improve how we measure disease burden and risk factors for severe disease. Pandemic and seasonal response efforts depend upon timely collection and analysis of high quality surveillance data, and future preparedness efforts can be enhanced by further refinement of mathematical and epidemiologic models of disease transmission.



### **Specific Recommendations:**

*To improve and better coordinate influenza surveillance, HHS agencies must work in concert with U.S. and global partners to:*

- develop, assess, and integrate new technologies for data collection, including less resource-intensive methods such as electronic data capture and Internet and social-media applications;
- enhance the ability of public health officials to conduct rapid field investigations when a novel influenza virus emerges;
- increase collection of respiratory specimens from influenza patients coupled with patient clinical and demographic data across the continuum of care to monitor for antiviral resistance, changes in circulating influenza virus strains, and mutations that may be associated with increased severity of disease; and ensure submission of influenza viruses to the CDC to support surveillance for virologic changes;
- endorse the 2011 WHO framework for global sharing of influenza viruses, strengthening of laboratory-based influenza virus surveillance, and access to global influenza diagnostic testing;
- use data from surveillance systems to model the burden and spread of influenza virus infections globally;
- routinely evaluate the U.S. influenza surveillance system network and enhance

*We need a “One Health” approach with strong collaborations in human, animal, and environmental sectors, both domestically and internationally.*

influenza epidemiologic and virologic surveillance systems based upon changing patterns of disease, technological advances, and migration of human and animal populations;

- facilitate cooperation and collaboration between the animal and public health sectors and the commercial swine, poultry, and live bird industries, to facilitate expanded comprehensive and sustained surveillance of avian and swine influenza viruses among animals and persons working in the agricultural sectors;
- establish mechanism for regular and timely data sharing among public health and animal health officials that includes epidemiologic and virologic data and influenza viruses identified and isolated from animals and from humans in the U.S. and globally;
- ensure collaboration with domestic and global veterinary and wildlife partners to monitor for the emergence of a novel influenza virus from avian or mammalian



- hosts, including reassortant viruses among poultry, pigs, and aquatic birds; and
- support the expansion of sustained human and animal influenza virus surveillance

abroad, including building and strengthening laboratory-based influenza surveillance capacity in Africa, Asia, and other tropical and subtropical regions.

## 6. Evaluate and Refine Influenza Community Mitigation Measures

In 2007, national interim guidance on “Community Strategy for Pandemic Influenza Mitigation” was released, which lays out a detailed response framework and identifies barriers to planning and research needs. However, many key issues remain unresolved, including better understanding of the efficacy and consequences of community mitigation measures.

### Principle:

National guidance on community pandemic mitigation measures—such as social distancing, school closures, and infection control steps including respiratory protection and isolation—should be evaluated and refined in collaboration with key stakeholders and technical experts. Guidance should articulate a standardized, scientifically rigorous, and locally adaptable approach to community containment that corresponds to pandemic severity. The current scientific basis used to identify optimal measures to interrupt transmission of influenza in the community is inadequate and must be strengthened. Measures relevant to mitigation of seasonal influenza outbreaks should be identified and incorporated into routine seasonal influenza response activities. Community mitigation measures for seasonal and pandemic influenza should include the identification of appropriate triggers for implementation and termination, the limitations and assumptions of recommended strategies, the minimization of social and economic consequences of mitigation measures on local communities (such as the impact on employment or the effect of alternate gathering places for children), and an evaluation of the practical implications of recommended strategies that could facilitate or hamper successful implementation.

### Specific Recommendations:

*To evaluate and refine influenza community mitigation measures, HHS agencies must work in concert with their partners to:*

- support research that will provide the scientific basis for developing optimal community mitigation strategies;
- develop optimal methods to rapidly assess pandemic severity and inform the public and those responsible for implementation of the appropriate community mitigation measures;
- ensure ongoing critical review of the limitations, assumptions, and feasibility of the conclusions of mathematical models used in developing community mitigation strategies, as new data become available, while also identifying ways to validate and strengthen key assumptions through testing and reformulation of the models;
- identify potential efficacy and benefits and the adverse social and economic consequences of community mitigation strategies and the implications for successful policy implementation;
- ensure that necessary actions to minimize or prevent adverse consequences of

community mitigation measures are identified along with corresponding resources;

- include diverse stakeholders in guidance development and evaluation processes, including federal, state, and local public health agencies; business leaders; medical professionals; educators; professional societies; and state and local elected officials;
- educate the public and stakeholders regarding community mitigation guidance, its scientific rationale, remaining uncertainties, limitations, and costs of implementation; and
- ensure periodic evaluation, review, and revision of community mitigation guidance as new information becomes available.

*The current scientific basis used to identify optimal measures to interrupt transmission of influenza in the community is inadequate and must be strengthened.*

## 7. Build All-Hazard Public Health and Medical Care Systems Capable of Responding to Seasonal and Pandemic Influenza

Numerous federal plans and policies have called for improving community-level public health emergency preparedness, including the 2005 HHS Pandemic Influenza Plan, the 2006 Pandemic and All-Hazards Preparedness Act, the 2009 National Health Security Strategy, the 2011 Presidential Policy Directive (PPD)-8, and the CDC's 2011 Public Health Preparedness Capabilities and National Strategic Plan for Public Health Preparedness and Response. However, many of the capabilities described in these documents cannot be achieved with the limitations of the current public health systems. Significant deficiencies remain in the ability of public health systems across the country to respond to large-scale health emergencies. It is critical to ensure that medical care systems are prepared and able to fully integrate and coordinate with state and local public health systems during times of seasonal influenza epidemics and pandemic influenza. Although hospital and health care system preparedness was enhanced by previous grants from the U.S. Health Resources and Services Administration (HRSA), in the absence of ongoing funding, health care facilities have not been able to sustain these efforts. Likewise, gaps in preparedness at the public health system level have been exacerbated by recent reductions in funding. Without long-term investments in public health and medical care systems, as well as in coordination of the two, previously developed capacity and future progress will be seriously jeopardized.

### Principle:

#### A. Public Health Systems

Sustainable and robust public health systems, particularly at the state and local level, that are capable of detecting, responding to, and recovering from seasonal and pandemic

*Sustainable and robust public health systems, particularly at the state and local levels, that are capable of detecting, responding to, and recovering from seasonal and pandemic influenza outbreaks are critical.*

influenza outbreaks are critical. Such systems must be based on a sustainable core, local public health infrastructure, and must include:

- ◆ the capacity for prompt disease detection and response, including robust public health laboratory response;
  - ◆ the ability to ensure community resilience;
  - ◆ distribution and tracking of medical countermeasures and implementation of community non-pharmaceutical interventions;
- ◆ development and coordination of regional health care coalitions for large-scale health emergency responses;
  - ◆ use of incident management systems, and the use of rapid and reliable data and information exchange systems;
  - ◆ public engagement activities, effective public messaging, and risk communications systems; and
  - ◆ public health surge capacity. Planning assumptions must be periodically evaluated and revised, as appropriate, and funding must be adequate and sustained.

#### B. Medical Care Systems

It takes coordinated, local planning with input from public and private partners to build a medical care system that is capable of responding to and recovering from seasonal and pandemic influenza outbreaks. Emergency preparedness begins at the local level, with each facility developing a plan, but the overall response has to be driven by the needs of the larger community in which each of these hospitals, clinics, long-term care facilities, home health care providers, and other health care institutions operates. Local health care facilities and systems must collaborate closely with local and/or state public health agencies

on planning and response to large-scale public health emergencies. To be successful, such robust collaboration requires adequate and sustained funding.

*Emergency preparedness begins at the local level, with each facility developing a plan, but the overall response has to be driven by the needs of the larger community in which each of these hospitals, clinics, long-term care facilities, home health care providers, and other health care institutions operates.*

### **Specific Recommendations:**

*To build all-hazard public health systems capable of responding to seasonal and pandemic influenza, HHS agencies must work in concert with federal, state, and local partners to:*

- facilitate creation and implementation of national guidance for crisis standards of care based on the 2009 Institute of Medicine (IOM) *Guidance for Establishing Crisis Standards of Care for Use in Disaster Situations: A Letter Report* and related guidance;
- align and coordinate the various federal agency funding mechanisms to ensure development of preparedness and response capabilities with measurable

outcomes that are proportionate to the risk, size, and complexity of the community, and consistent with the most current CDC Public Health Preparedness Capabilities, including adequate epidemiological and laboratory capacities, and preparedness in health systems;

- develop methods to rapidly collect clinical information from health care facilities during health emergencies, including real-time research on clinical illness and effectiveness of treatments and countermeasures, as well as prompt communication of the results to clinicians and public health professionals; and
- facilitate the creation of systems that allow for rapid implementation of standardized community-based triage methods, possibly including nurse triage lines, self-triage, etc., and corresponding risk communication for the public regarding when to seek medical care.

*To achieve this goal for medical care, U.S. health systems, hospitals, and other key partners must work in concert with state and local public health agencies to:*

- develop plans that coordinate preparedness and response activities for all types of influenza severity;
- develop regional and local plans to manage medical surge capacity, including





alternative approaches to ease the demand on medical care systems. These may include the use of dedicated community-wide or regional nurse triage lines and alternate sites of care for patients. Hospitals and health care systems should work closely with public health and community stakeholders to establish and identify additional resources (such as Medical Reserve Corps, Community Emergency Response Teams, visiting nurses, etc.) to assist and participate in various types of care;

- periodically evaluate performance measures and standards; conduct exercises to gauge the effectiveness of preparedness efforts; and ensure that epidemiological, laboratory, and other systems can meet surge demands;
- develop workforce guidelines, including staff recruitment and retention with appropriate credentialing and training on influenza infection prevention and control;
- promote, establish, and sustain partnerships with community stakeholders such as businesses, schools, first responders, emergency management,

*Long-term investments in public health and medical care systems, and better coordination of the two, are essential.*

and the faith-based community, to determine community priorities and the needs of vulnerable populations;

- determine the need for and mechanisms to stockpile medical countermeasures, PPE, and other key assets for an adequate and coordinated local and state response. Hospitals and health systems should evaluate needs for their personnel, particularly for PPE, and develop mechanisms to ensure adequate supplies; and
- promote collaboration between public health, health care organizations, pharmacies, and medical supply distributors, to enhance capabilities for distributing, dispensing, and tracking of community-wide medical countermeasures.

## 8. Protect the Health Care Workforce During Seasonal and Pandemic Influenza Outbreaks

In 2007, a federal interagency task force developed guidance documents on the prioritization of pre-pandemic and pandemic influenza vaccine in which health care workers (HCWs) were classified as a high risk group. Some members of Congress have attempted to create an injury compensation fund to specifically protect HCWs who receive pandemic vaccine during a declared public health emergency. The Joint Commission and Centers for Medicare and Medicaid Services (CMS) have made strides in recent years toward requiring certain facilities to offer vaccine and track HCWs' influenza vaccination rates; however, they have not yet called for mandatory influenza vaccination. IDSA and many other organizations in the U.S., including all primary care medical societies, all infectious disease and hospital infection control societies, and several consumer health groups, have advocated for universal immunization of HCWs against influenza. Mandatory vaccination programs are the most effective means for a health care facility to protect patients and preserve the health workforce.

In terms of non-vaccine protective measures, during the 2009 H1N1 influenza pandemic, conflicting guidance came from different federal agencies on the use of N95 respirators, which ultimately created confusion, diverted resources, and undermined trust in the scientific basis of guidance. Supplies of N95 respirators were not adequate to comply with the most stringent guidance, had it in fact been appropriate.

### Principle:

The success of preparedness and response efforts during an outbreak hinges upon the availability of an adequate and skilled health care workforce. The U.S. must preserve medical readiness by ensuring that HCWs, including physicians, nurses, pharmacists, allied health personnel, first responders, and others, are able to perform their duties both during

annual seasonal epidemics and periodic influenza pandemics. Their work can put HCWs at higher risk for contracting and spreading influenza. The U.S. must ensure the availability of influenza vaccinations; antiviral treatment and, if appropriate, prophylaxis; guaranteed, pre-determined injury compensation; and liability protection to eliminate barriers to HCWs' participation during a seasonal or pandemic influenza outbreak. For seasonal influenza protection, the U.S. should require all HCWs to receive annual influenza vaccination through rules, regulations, policies, or laws.

### **Specific Recommendations:**

*To protect the health care workforce during seasonal and pandemic influenza outbreaks:*

*Federal, state, and local agencies must work in concert with stakeholders from professional societies, experts in infection control, and representatives of health care systems to:*

- ensure the availability of pandemic influenza vaccine to all HCWs and other primary responders;
- ensure that HCWs with direct patient contact during a pandemic are in the first tier priority group for receiving vaccines;
- periodically re-evaluate antiviral supply, and consider HCWs for long-term prophylaxis when medically appropriate and as supplies permit;
- support, create, and facilitate local, state, regional, and federal requirements for all HCWs to receive annual and pandemic influenza immunization as a matter of initial and continued employment, except in the case of a valid, documented medical contraindication;
- consider establishing differential reimbursement rates to hospitals and facilities based upon achievement of pre-designated coverage rates and/or the

*The U.S. should require all health care workers to receive annual influenza vaccination.*

presence of a mandatory HCW influenza immunization policy; this would recognize the lower costs of providing care and the lower rates of patient morbidity and mortality when the attending HCWs are immunized; and

- formulate and periodically review guidance for prevention of influenza transmission in health care settings, including use of PPE and engineering, environmental, and administrative measures. Guidance should be based upon the best available science, correspond to the virulence and transmissibility of pandemic and seasonal influenza viruses, and incorporate cost-benefit considerations.

*The U.S. Congress and administration must work together to:*

- establish an injury compensation fund for any HCWs injured by receipt of a pandemic or seasonal influenza vaccine administered as part of their employment; reimbursement should cover medical costs and lost earnings, and could be similar to the compensation fund developed (and proven necessary) to immunize civilian HCWs against smallpox; and
- provide liability protection for clinicians who adhere to local guidance consistent with national recommendations regarding altered standards of care while responding to a declared public health emergency.

## **9. Continue to Strengthen International Collaboration**

U.S. agencies support international research in basic science, vaccine development, translational medicine, epidemiology, diagnostics, therapeutics, and non-pharmaceutical interventions. This occurs through direct interaction between government agencies and host countries, through collaborations with extant networks, or through grants to academic groups working in host countries. Efforts include surveillance and research in animal populations and at the human-animal interface; training of host-country personnel in clinical, epidemiologic, and laboratory science; as well as shorter term training that bridges the current gaps in global capacity. Developing, implementing, and exercising pandemic plans are a high

priority for WHO and partner countries, and are supported by experts from the U.S. and other developed countries. The 2005 International Health Regulations (IHRs) provide the framework for building clinical, laboratory, and epidemiological capacity, with emphasis on preparedness and response capability. For many developing countries, transparency and thus compliance with the IHRs may not be their highest priority, and could result in serious economic ramifications.

There also is the concern that sharing information and samples from disease surveillance activities has not resulted in equitable benefits, such as access to vaccines and medications, commensurate with countries' contributions. This concept of viral sovereignty has created major challenges to trust and transparency and has previously compromised global influenza surveillance efforts and public health security. Recently, diplomatic progress has been made on virus sharing, with a Resolution at the May 2011 World Health Assembly (WHA 64.5) calling for the creation of a Pandemic Influenza Preparedness framework for influenza virus sharing, benefits sharing, and standard material transfer agreements.



### **Principle:**

The 2009 H1N1 influenza pandemic underscored the reality that a novel virus capable of rapidly spreading around the world could arise anywhere. Vulnerability is universal, and international collaboration must be strengthened for the global community to be optimally prepared for the next, potentially more severe pandemic.

### **Specific Recommendations:**

*To continue to strengthen international collaboration:*

*HHS agencies must work with U.S. and global partners to:*

- continue to lead efforts that foster international collaborations related to pandemic influenza preparedness;
- expand support for WHO and its domestic partners through Field Epidemiology and Laboratory Training Programs (FELTP) by contributing

*Efforts include surveillance and research in animal populations and at the human-animal interface; training of host-country personnel in clinical, epidemiologic, and laboratory science; as well as shorter term training that bridges the current gaps in global capacity.*



expertise via the Global Outbreak Alert and Response Network (GOARN), and through bilateral interactions with developing countries; and

- continue to advocate in open forums for equitable benefits such as fair distribution of seasonal and pandemic vaccines.

**WHO should work with its partners to:**

- continue to provide global leadership in public health preparedness and

coordination of efforts across the international community, including prioritizing virus strain and genetic material sharing within the Global Influenza Surveillance Network (GISN) in all countries; equitable benefits such as fair distribution of seasonal and pandemic influenza vaccines must follow for countries who fairly share viral strains within GISN.

## 10. Allocate Significant and Sustainable Funding for Long-Term Planning and Action

While funding for pandemic preparedness was relatively strong between 2006 and 2009, much of it came in the form of short-term or supplemental (impermanent) funds. Of the \$9 billion that was available domestically for the 2009 H1N1 pandemic response, \$1.4 billion was distributed to states and local governments, while \$1.3 billion was ultimately rescinded under the Fiscal Year (FY) 2011 Continuing Resolution (CR). In the current fiscal climate, significant budget cuts are occurring at all levels of government and in the private sector. Without a renewed financial commitment to long-term pandemic and seasonal influenza preparedness planning, there is the real possibility that the preparedness efforts of the last decade will be eroded as influenza surveillance, vaccine development, and the public health workforce and infrastructure go unfunded or inadequately funded.

### Principle:

Pandemic and seasonal influenza preparedness and response efforts require essential tools (see Box 1) such as public health infrastructure and countermeasures as well as long-term governmental coordination and planning, all of which cannot exist without sustained and sufficient resources and staff. Strong, multi-year funding commitments will have collateral benefits in responding to seasonal influenza outbreaks, influenza pandemics, and other public health and national security threats. In the long term, continuously funded efforts likely will be more cost-effective than periodic emergency funding.

### Specific Recommendations:

*To support long-term planning and action and ultimately to save lives:*

*The administration and U.S. Congress must:*

- ensure adequate and sustained long-term funding for each of the critical activities outlined in this report; and
- align and/or coordinate the various federal agency funding mechanisms to ensure efficient use of funds and adequate development of preparedness and response capabilities at the local, state, and regional levels.

*State and local governments must allocate preparedness funds to:*

- purchase annual influenza vaccine to test mass vaccination protocols; and to the

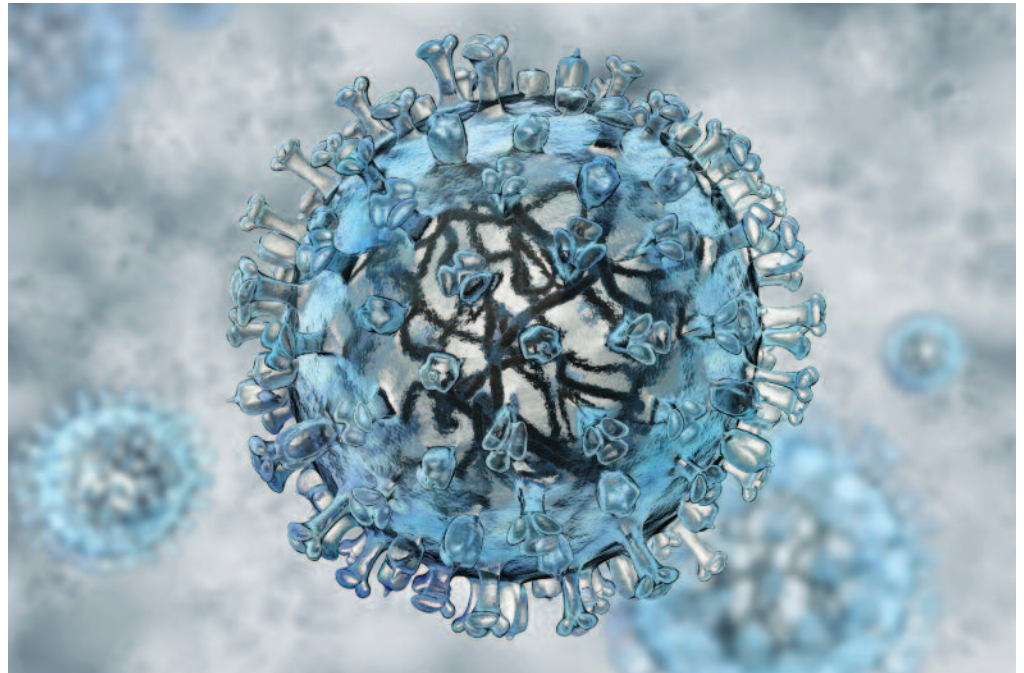
*Strong, multi-year funding commitments will help us respond to seasonal influenza outbreaks, influenza pandemics, and other public health and national security threats. Continuously funded efforts are more cost-effective than periodic emergency funding.*

extent possible, purchase antiviral drugs as well; and

- meet the matching requirement contained in the Pandemic and All Hazards Preparedness Act.

## Conclusion

Influenza remains among the greatest infectious disease threats to our nation and the global community. Despite the investments and progress made in research and preparedness over the past decade, substantial gaps remain. The next influenza pandemic is inevitable, only the timing, severity, and point of origin remain unknown. We cannot be complacent. We cannot afford to be penny-wise and pound-foolish, eroding the progress made and leaving our nation and the world vulnerable. We must be prepared.



# Acronyms

## A

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**ASH** – (HHS) Assistant Secretary for Health  
**ASPR** – (HHS) Assistant Secretary for Preparedness and Response

## B

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**BARDA** – (HHS) Biomedical Advanced Research and Development Authority

## C

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**CDC** – (HHS) Centers for Disease Control and Prevention  
**CMS** – (HHS) Centers for Medicare and Medicaid Services  
**CR** – continuing resolution

## D

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**DoD** – Department of Defense

## E

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**eIND** – emergency Investigational New Drug  
**EUA** – Emergency Use Authorization

## F

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**FDA** – (HHS) Food and Drug Administration  
**FELTP** – Field Epidemiology and Laboratory Training Programs  
**FY** – fiscal year

## G

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**GISN** – Global Influenza Surveillance Network  
**GEIS** – (DoD) Global Emerging Infections Surveillance and Response System  
**GOARN** – (WHO) Global Outbreak Alert and Response Network

## H

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**HCW** – health care worker  
**HA** – hemagglutinin  
**HHS** – Department of Health and Human Services  
**HRSA** – (HHS) Health Resources and Services Administration

## I

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**IDSA** – Infectious Diseases Society of America  
**IHR** – International Health Regulations  
**IOM** – Institute of Medicine

## L

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**LAIV** – live, attenuated influenza vaccine

## M

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**MRSA** – methicillin-resistant *Staphylococcus aureus*

## N

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**NA** – neuraminidase  
**NAI** – neuraminidase inhibitor  
**NIAID** – (NIH) National Institute of Allergy and Infectious Diseases  
**NIH** – (HHS) National Institutes of Health  
**NVPO** – (HHS) National Vaccine Program Office

## P

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**PAHPA** – Pandemic and All Hazards Preparedness Act  
**PCR** – polymerase chain reaction  
**PHEMCE** – (HHS) Public Health Emergency Medical Countermeasures Enterprise  
**PITF** – (IDSA) Pandemic Influenza Task Force  
**PPD** – Presidential Policy Directive  
**PPE** – personal protective equipment

## R

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**R&D** – research and development  
**RT-PCR** – reverse transcription polymerase chain reaction

## S

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**SNS** – Strategic National Stockpile

## T

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**TIV** – trivalent inactivated vaccine

## W

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**WHA** – World Health Assembly  
**WHO** – World Health Organization





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