
CHAPTER 6 — PROTECTING HUMAN HEALTH

Introduction

Protecting human health is the crux of pandemic preparedness, and the goals and pillars of the *National Strategy for Pandemic Influenza (Strategy)* reflect this. If we fail to protect human health, we are likely to fail in our secondary goals of preserving societal function and mitigating the social and economic consequences of a pandemic. Consequently, the components of the Strategy, the elements of this Implementation Plan (Plan), and the projected allocation of resources to preparedness, surveillance, and response activities all reflect the overarching imperative to reduce the morbidity and mortality caused by a pandemic. In order to achieve this objective, we must leverage all instruments of national power and ensure coordinated action by all segments of government and society, while maintaining constitutional government, law and order, and other basic societal functions.

The emergence of an easily transmissible novel strain of influenza into a human population anywhere poses a threat to societies everywhere. Influenza does not respect geographic or political boundaries. When pandemic strains emerge they sweep through communities and nations with frightening velocity. The three pandemics of the 20th century each encircled the globe, sparing few if any communities, within months of their emergence into human populations. The cumulative and concentrated mortality of a pandemic can be appalling. The 1918 pandemic, for example, killed more people in 6 months than acquired immunodeficiency syndrome (AIDS) has killed in the last 25 years and more than were killed in all of World War I. The primary strategy for protecting human health, therefore, must be prevention of emergence of a pandemic strain from animal reservoirs, if possible, or rapid containment of a human outbreak at the source, if emergence does occur. Federal Government efforts to prepare for and to support prevention and containment strategies are described throughout this document.

Protecting human health in the setting of a pandemic will require: (1) effective domestic and international surveillance for, and prompt response to, influenza outbreaks in both humans and animals; (2) improved diagnostic tests; (3) the rapid development, production, and distribution of definitive medical countermeasures (i.e., vaccines); (4) the targeted and effective use of antiviral medications and other potentially scarce medical resources to treat symptomatic individuals; (5) the judicious application of community infection control measures; (6) effective communication of risk reduction strategies to the private sector and to individuals; and (7) the full collaboration of the public and the private sector. A dynamic and resourceful public health and medical response has the potential to save lives by delaying the occurrence of outbreaks, decreasing the proportion of the population who develop influenza or become critically ill, and reducing the burden on critical health care facilities. For such a response to occur, Federal, State, local, and tribal officials must ensure that all stakeholders understand their responsibilities and are adequately prepared to play their part, they must prioritize the use of scarce resources, and they must ensure the continuity of essential government, emergency, and medical services.

Fortunately, we live in an era of great medical and scientific progress. Today we have a better understanding of the influenza virus and the illness that it causes than ever before. Vaccinology is making rapid strides and we are learning more about the use of adjuvants and other dose-sparing strategies. Two new and effective antiviral medications (oseltamivir and zanamivir) have received Food and Drug Administration (FDA) approval in the last 7 years. We understand much more about the transmission dynamics and epidemiology of influenza than we did at the time of the last pandemic, in 1968. We have better international and domestic disease surveillance systems and we have developed a national network

of diagnostic laboratories incorporating standardized reagents and protocols. Since September 11, 2001, we have made significant investments in all aspects of public health emergency preparedness. We are, in short, better prepared than ever to meet the immense challenge posed by a pandemic.

But the challenge will be formidable. We do not understand why some influenza viruses are efficiently transmitted and some are not. In the event of a pandemic, we will have to overcome severe shortfalls in surge capacity in our health care facilities. Our current vaccine production capabilities cannot keep pace with an evolving pandemic. We lack adequate stockpiles of antiviral medications and plans to distribute the supplies we have. Most surveillance systems do not operate in real time. We cannot quantify the value of many infection control strategies and do not know the optimal timing for or sequencing of those that would affect entire communities. Finally, and perhaps most importantly, members of the public may not appreciate the importance of the care they will provide to ill family members, the degree to which they can modify their risk of becoming ill, nor the extent to which their collective actions will shape the course of a pandemic.

Key Considerations

The overarching strategic goals of the *Strategy* are to: (1) stop, slow, or limit the spread of disease; (2) mitigate disease, suffering, and death; and (3) sustain infrastructure and mitigate impact to the economy and the functioning of society. These goals are not sequential but mutually supportive. The objective of the *Strategy* is to accomplish all three goals, to whatever extent possible, at all times during a pandemic.

Epidemiology

The transmission of a communicable agent between individuals is a chance event, the probability of which varies according to the nature and intimacy of their interactions. Epidemics occur when, on average, an infected individual transmits infection to more than one other person (R_0 , or reproductive rate, >1). Conversely, and critically, outbreaks of infectious disease will diminish and ultimately terminate when, on average, an infected individual transmits infection to less than one other person (reproductive rate less than one). *The key to stopping an epidemic is to bring the reproductive rate below 1 and keep it there through whatever means, or combination of means, feasible.* These means can include the administration of effective vaccines or antiviral prophylaxis, the identification and isolation of infected individuals and quarantine of their contacts, and the implementation of appropriate infection control and social distancing measures.

The velocity of an epidemic — the speed with which an epidemic spreads through a community — is a function of the basic reproductive rate for the disease in question and how long it takes for infected individuals to infect others (generation time, or T_g). Influenza is moderately infectious but has a very short generation time. Recent estimates have suggested that while the reproductive rate for most strains of influenza is less than 2, the generation time may be as little as 2.6 days. These parameters predict that in the absence of disease containment measures the number of cases of epidemic influenza will double about every 3 days. It is important to note that the magnitude of the reproductive rate determines the intensity of measures required to halt transmission, while the components of the generation time — that is, the duration of the latent and infectious periods — determine how and when these measures must be applied.

Patients with influenza typically become infectious after about 1 to 1.5 days and prior to becoming symptomatic. At about 2 days, most infected persons will develop symptoms of illness, the spectrum and severity of which may vary considerably. Understanding the natural history of influenza makes it possible

to assess potential response measures and determine the factors critical for their success. Given that 2 days will elapse between infection and illness in most cases, for example, a significant percentage of infected persons who travel internationally to the United States and are asymptomatic when boarding a flight will still be well upon arrival and will not be detected by screening at the border.

Pivotal Importance of Initial Conditions

While we cannot predict the severity of a pandemic before it begins, the initial analysis of the characteristics of the virus and its epidemiology will tell us much about the way in which the pandemic will unfold. The cardinal determinants of the public health response to a pandemic will be its severity, as defined by the ability of the pandemic virus to cause severe morbidity and mortality, especially in otherwise low-risk populations, and the availability and effectiveness of vaccine and antiviral medications.¹⁵ Decisions about the prioritization and distribution of medical countermeasures; the content of risk communication campaigns; the application of community infection control measures; and whether and when to make adjustments in the delivery of care commensurate with available resources are interrelated and all fundamentally determined by these factors, which will be known from the beginning of an outbreak. These are the critical triggers that will dictate the actions of public health authorities.

Severe pandemics, for example, pose the greatest threat to critical infrastructure and national security. Groups receiving priority access to medical countermeasures during a severe pandemic will reflect the need to maintain infrastructure and security functions. When vaccine and antiviral drug supplies are very limited, targeting necessarily will be narrower and the importance of community infection control measures will be greater. An inadequate supply of countermeasures in the setting of a severe pandemic would also be an indication to authorities to expand surge capacity and prepare to alter standards of care by expanding staff, extending the defined roles of providers, and establishing infirmaries. Public messaging to health care professionals, other stakeholders, and the general public would seek to prepare them for a severe pandemic and the shortage of medical countermeasures. It would not be necessary to wait for numbers of cases to rise exponentially.

Greater vaccine and antiviral drug supply, on the other hand, would permit more flexibility in the strategies and objectives for the use of medical countermeasures. Preservation of critical infrastructure and security functions would still be crucial, but consideration might also be given to efforts to decrease transmission of infection in communities through the early immunization of children or by providing post-exposure prophylaxis to household contacts of ill persons. Anticipating a pandemic caused by a highly pathogenic virus, authorities would still move to expand surge capacity and prepare to change the way care is delivered by expanding staff, extending the defined roles of providers, and establishing infirmaries. Public messaging would be tailored accordingly.

In a less severe pandemic, where infrastructure and security concerns are not as significant, efforts could be focused on protecting those at high risk for severe disease and death from the beginning, especially if supplies of medical countermeasures are inadequate. Public health authorities might recommend home care, with or without isolation, for the great majority of patients and the costs and benefits of community infection control measures would be calculated differently.

¹⁵ It is important to emphasize that the severity of a pandemic is a function not of the attack rate or transmissibility of the virus, both of which appear to be relatively constant between pandemics, but of its ability to produce severe illness or death. The severity of illness caused by a strain of influenza with pandemic potential will be quickly apparent, although continued monitoring and analysis will be necessary to refine initial assessments.

The value of a decision framework based on pandemic severity and the supply of vaccines and antiviral medications is that such a framework facilitates decisive and concrete pre-pandemic planning and allows the construction, in advance, of response algorithms and decision trees. It is important to caveat these observations by noting that since antiviral resistance can develop over time and the virulence of circulating strains may change as the virus adapts to its human hosts, ongoing monitoring for antiviral resistance and geographically circumscribed or more global changes in vaccine effectiveness or viral pathogenicity during a pandemic will be essential. Strategies for use of vaccine and antiviral medications that are in short supply may shift in response to such observations or as the supply of countermeasures changes over time.

Maintaining Situational Awareness

Surveillance

The goal of influenza surveillance is to track novel influenza subtypes and detect clusters of severe human infection heralding the emergence of strains with pandemic potential, so as to facilitate early and aggressive attempts at containment. International surveillance programs and goals are described in Chapter 4 - International Efforts. Domestic surveillance goals include detection of initial U.S. cases if the pandemic begins abroad, defining its spread, elucidating health impacts and high-risk groups, and monitoring characteristics of the virus, including antigenic and genetic changes, and changes in antiviral resistance patterns.

The Federal Government collects outpatient, hospital, and mortality surveillance data through a variety of systems and networks, and in recent years has improved its capability to aggregate and analyze data in real time. Unfortunately, current systems do not provide sufficient depth and coverage to guide all elements of the national response, and a great deal of analysis and time is required to assess the consequences of seasonal influenza outbreaks and the effectiveness of the annual vaccine. To remedy this shortcoming, and to enhance their own situational awareness, State and local public health departments should make it a priority to establish or enhance influenza surveillance systems within their jurisdictions. To improve national surveillance capabilities, the National Biosurveillance Integration System (NBIS) has been established to provide an all-source biosurveillance common operating picture to improve early-warning capabilities and facilitate national response activities through better situational awareness.

In the event of a pandemic, States should be prepared to increase diagnostic testing for influenza as well as the frequency of reporting to the Centers for Disease Control and Prevention (CDC). Early detection of pandemic virus at a local level requires the collection and testing of appropriate specimens as recommended. The most intense testing will be necessary during the early stages of a pandemic, when detecting the introduction of the virus into a State or community is the primary goal.

Response

Maintaining situational awareness during a pandemic will be extremely difficult. In addition to the surveillance and disease reporting activities described above, Federal, State, and local authorities will also be called upon to collect, analyze, integrate, and report information about the status of their hospitals and health care systems, critical infrastructure, and materiel requirements, and they will be called upon to supply such information at a time when their capabilities may be eroded by significant absenteeism.

Hospital and health care resource tracking can and should be performed in real time. The identification of stress points and focal insufficiencies in real time will permit the burden of patient care to be distrib-

uted across health care systems more equitably, preserving core functionalities despite significant and even extreme surges in demand. Additionally, the early recognition of increased systemic loads could serve as a trigger to public health officials to implement or promote more stringent disease containment measures and to make adjustments in the delivery of care commensurate with available resources.

Implementing disease containment and infection control measures is likely to impose significant costs on affected communities. Determining the optimal timing and thresholds for interventions with significant associated costs will be difficult in the absence of quantitative data about their effectiveness and the benefits they will confer. Insights into the biology and patterns of transmission of pandemic influenza, as well as the efficacy of various disease containment strategies, will evolve in real time and should be tractable to analysis and modeling.

Role of Rapid and Reliable Diagnostic Tests

During periods of heightened surveillance for the emergence of novel influenza strains and early in a pandemic, when disease is localized in one or several countries, both clinical and epidemiological (e.g., exposure) characteristics are important for surveillance and case detection. As the pandemic begins to spread, rapid diagnostic tests may be widely used to distinguish influenza A from other respiratory illnesses. Once pandemic disease is widespread, cases will be identified primarily by clinical presentation. Historically, most patients with pandemic influenza have presented with signs and symptoms similar to those of seasonal influenza, although in some the presentation is more fulminant and progresses very rapidly.

Rapid diagnostic tests for influenza are screening tests for influenza virus infection that provide results within 60 minutes and can be used for individuals or groups. Diagnostic tests will be most critical in the early phases of a pandemic, when identification of the first cases in a locality is important, and they may also be useful as the epidemic declines and pandemic disease becomes less prevalent. Depending on their sensitivity and specificity, such tests might also facilitate screening of travelers at ports of entry or prior to boarding inbound flights. At present, widely available rapid diagnostic tests and testing protocols do not distinguish between specific subtypes and strains of influenza and, because of their suboptimal sensitivity and specificity, cannot even definitively distinguish between influenza and other causes of similar illness. Because the available diagnostic tests have differing sensitivities, specificities, and technical requirements, they may find use in different settings and for different purposes during a pandemic.

New technologies and new approaches are driving down costs and improving the specificity and sensitivity of rapid diagnostic tests to the point that subtype- and strain-specific tests may be available for large-scale screening within the next couple of years. If these tests can be packaged in a way that facilitates their use in non-clinical settings, their potential to facilitate disease containment efforts will be even greater, by allowing more effective screening of travelers (and thus the more targeted application of movement restrictions) or even by identifying patients before they become symptomatic or infectious. The Federal Government will continue to support research in this area, in an effort to promote such advances.

In the interim, existing diagnostic technologies must be used to greatest effect to rapidly screen individuals infected with pandemic influenza. To this end, the Department of Health and Human Services (HHS), the Department of Agriculture (USDA), the Department of Energy (DOE), the Environmental Protection Agency (EPA), the Department of Defense (DOD), the Federal Bureau of Investigation (FBI), and the Department of Homeland Security (DHS) participate, with State and local public health laboratories, in the Laboratory Response Network (LRN), the member laboratories of which have adopted

uniform diagnostic standards, protocols, and reagents, and can perform subtype- and strain-specific confirmation testing for influenza. HHS and the private sector have also developed high-throughput rapid diagnostic kits that will undergo field testing by U.S. and Southeast Asian scientists and public health officials to ascertain the utility and robustness of these products.

Countermeasure Production, Prioritization, Distribution, and Security

The optimal way to control the spread of a pandemic and reduce its associated morbidity and mortality is through the use of vaccines. Broadly speaking, vaccines may be divided into those that are developed against strains of animal influenza viruses that have caused isolated infections in humans, which may be regarded as “pre-pandemic” vaccines, and those that are developed against strains that have evolved the capacity for sustained and efficient human-to-human transmission (“pandemic” vaccines). Because emergence in human populations necessarily reflects genetic changes within the pandemic virus, pre-pandemic vaccines may be a good or poor match for — and offer greater or lesser protection against — the pandemic strain that ultimately emerges.

Current FDA-licensed inactivated influenza vaccines are based on technologies developed more than 30 years ago. Scientists first select the three virus strains that they expect to circulate in the United States during the following season. These strains are then adapted to grow in fertilized chicken eggs and manufacturers inject each adapted virus strain separately into millions of eggs, which are subsequently incubated to produce influenza virus. Large batches of these eggs are harvested and the viral particles that are obtained are inactivated, chemically disrupted, and blended into a single vaccine product that includes all three influenza virus strains. A single dose of the trivalent vaccine contains 15 ug of hemagglutinin for each of the three antigenic components. The total dose (45 ug) is approximately the amount of purified virus obtained from the allantoic fluid of one egg. Current manufacturing processes thus require manufacturers to procure one fertilized chicken egg for every dose of vaccine produced and are dependent on the timely availability of vaccine seed strains.

Antiviral medications can be used for treatment or prophylaxis of people exposed to influenza. Currently only two classes of medication — the neuraminidase inhibitors and the adamantanes — demonstrate efficacy against circulating influenza viruses. Both classes of medication are most effective if administered in the earliest stages of infection. Adamantane resistance emerges fairly quickly (adamantane-resistant H5N1 influenza already circulates, for example) and does not appear to affect viral fitness, in terms of the transmissibility of the virus or its ability to produce illness. Resistance to oseltamivir, the oral neuraminidase inhibitor, emerges more slowly but has been associated with treatment failure in patients with H5N1 influenza. Resistance to zanamivir, the inhaled neuraminidase inhibitor, has not been documented in immunocompetent hosts, but its efficacy in treating patients with H5N1 or other subtypes and strains with pandemic potential requires further assessment.

Production

The Federal Government has established two primary vaccine goals: (1) establishment and maintenance of stockpiles of pre-pandemic vaccine adequate to immunize 20 million persons against influenza strains that present a pandemic threat; and (2) expansion of domestic influenza vaccine manufacturing surge capacity for the production of pandemic vaccines for the entire domestic population within 6 months of a pandemic declaration.

While progress can be made toward the first goal with current egg-based manufacturing methods, the existing domestic influenza vaccine manufacturing base lacks sufficient surge capacity to meet the

second. Moreover, since populations have no baseline immunity to strains of influenza with pandemic potential, it is highly probable that more vaccine antigen will be required per person to induce protective immunity. The amount of vaccine antigen that is currently manufactured is matched to the usual requirements for seasonal influenza vaccine, and not the requirements for a pandemic vaccine, which may require significantly more hemagglutinin per person than a seasonal vaccine to induce an effective immune response. Furthermore, in the event of a pandemic it is likely that bulk influenza vaccine manufactured outside the United States (and accounting for about 40 percent of annual domestic supply) will be unavailable. Thus, the measures taken by the Federal Government over the past several years to ensure a secure egg supply and support the expansion and diversification of influenza vaccine manufacturing capacity will require significant enhancement and acceleration.

The Federal Government has adopted a three-pronged strategy to secure the required surge capacity for pre-pandemic and pandemic vaccines. Current initiatives fall broadly under the categories of advanced vaccine development, establishment, and expansion of new U.S. vaccine manufacturing facilities, and vaccine acquisition. In keeping with our goal of developing a rapid response vaccine manufacturing capability, we will support the advanced development of cell-based influenza vaccine candidates. The Federal Government will also support the renovation of existing U.S. manufacturing facilities that produce other FDA-licensed cell-based vaccines or biologics as well as the establishment of new domestic cell-based influenza vaccine manufacturing facilities.¹⁶ To accommodate pre-pandemic vaccine needs without disturbing seasonal influenza vaccine manufacturing campaigns, the Federal Government will continue through 2008 to procure H5N1 vaccine from manufacturers of U.S.-licensed influenza vaccines. With these and other initiatives, the pandemic vaccine capacity goal for the United States may be within reach by the end of 2010.

Improvements in vaccine technology may alleviate some vaccine capacity concerns. Dose-sparing strategies for influenza vaccines that are currently under evaluation may reduce the requirement for vaccine antigen per dose and/or allow for effective immunization with a single shot. In the future, broad-spectrum influenza vaccines may supplement seasonal and pandemic influenza vaccines to provide broader virus specificity and longer persistence of enhanced immunity, especially in the populations most vulnerable to influenza — children, the elderly, and the chronically ill.

The Federal Government has established two primary goals for stockpiling existing antiviral medications: (1) establishment and maintenance of stockpiles adequate to treat 75 million persons, divided between Federal and State stockpiles; and (2) establishment and maintenance of a Federal stockpile of 6 million treatment courses reserved for containment efforts. In an effort to expand the medical armamentarium, the Federal Government is also supporting research projects to optimize dosing strategies for existing antiviral medications, identify novel drug targets, and develop compounds that inhibit viral entry, replication, and maturation.

¹⁶ Cell-based manufacturing methods use mammalian cells to grow the influenza viruses used in the vaccine and offer a number of advantages. Vaccine manufacturers can bypass the step needed to adapt the virus strains to grow in eggs. Cells may be frozen in advance and large volumes grown quickly. U.S. licensure and manufacture of influenza vaccines produced in cell culture also will provide security against risks associated with egg-based production, such as shortages and the potential for egg supplies to be contaminated by various poultry-based diseases. Finally, the new cell-based influenza vaccines will provide an option for people who are allergic to eggs and therefore unable to receive the currently

licensed vaccines. It should be noted that certain issues must be addressed by extensive testing and characterization prior to the banking and use of mammalian cells for vaccine production. For example, such cells may be at risk of contamination with various disease-causing organisms affecting the animals from which the cells or cell-growth media components were derived, and there may be tumorigenicity concerns with cells that may be useful for high-yield manufacturing.

Prioritization

The Federal Government is developing guidelines to assist State and local governments and the private sector in defining groups that should receive priority access to scarce medical countermeasures. Priority recommendations will reflect the pandemic response goals of limiting mortality and severe morbidity; maintaining critical infrastructure and societal function; diminishing economic impacts; and maintaining national security. Limiting transmission also may be an objective. Antiviral prophylaxis of household contacts of infected individuals and vaccination of children may decrease disease spread in affected communities but would require large quantities of drug and vaccine. If supplies and public health resources were sufficient, these strategies might be pursued in certain settings.

Priorities for vaccine and antiviral drug use will vary based on pandemic severity as well as the vaccine and drug supply. In settings of very limited vaccine and drug supply, narrow targeting and efficient use are required. Vaccine may be reserved for critical personnel, while antiviral medications are reserved for symptomatic individuals who are at high risk of serious complications or death. With greater availability, it may be feasible to expand priority groups and implement strategies to limit disease transmission. Recognizing that no single priority list is appropriate for all scenarios, Federal guidance will be developed for multiple contingencies.

The use of pre-pandemic vaccine will be targeted to maintain critical societal functions through the protection of critical infrastructure personnel and to protect those who are at greater risk of early exposure and infection during a pandemic, such as health care providers or first responders. Pre-pandemic vaccination objectives may include primary immunization if the match between the pre-pandemic vaccine and the circulating virus is close, or priming the immune system to respond more rapidly and robustly to an initial dose of pandemic vaccine, when it becomes available, if the match is suboptimal.

Recommendations put forward by the Advisory Committee on Immunization Practices and the National Vaccine Advisory Committee are included in the *HHS Pandemic Influenza Plan* and provide initial guidance to Federal, State, local, and tribal partners regarding many of the potential target groups being considered.

Distribution

When sustained and efficient human-to-human transmission of a potential pandemic influenza strain is documented anywhere in the world, the Federal Government will develop and distribute recommendations on target groups for vaccine and antiviral drugs. These recommendations will reflect data from the pandemic and available supplies of medical countermeasures in light of the considerations outlined above. These recommendations will be provided to Federal health care providers and State, local, and tribal authorities.

A treatment course of oseltamivir for adults and adolescents ages 13 and above is 1 capsule taken twice daily for 5 days, or 10 capsules. A typical prophylaxis course for adults and adolescents is one capsule taken once daily for at least 10 days, although oseltamivir has been shown to be safe and effective when taken for up to 6 weeks. Because prophylaxis requires significantly more medication, results in the administration of a scarce medical resource to people who might not have become sick in any case, and only reduces risk during the period when the medication is being taken, current plans propose using antiviral medication stockpiles only for treatment once a pandemic is underway. Prophylactic use of antiviral medications will be reserved for initial containment efforts and other highly select circumstances.

Given the highly distributed nature of a pandemic, the need to deliver antiviral prophylaxis within 2 days of exposure or to provide therapy to infected patients within 2 days of the onset of symptoms presents significant unresolved logistical challenges. It will be necessary to develop and exercise pandemic influenza countermeasure distribution plans in each of the States and territories and public-private partnerships supporting the seamless, efficient, and timely distribution of these countermeasures may also be required.

Security

It is conceivable that criminal elements may try to take advantage of medical countermeasure scarcity and citizens' fears regarding a pandemic by producing and distributing counterfeit vaccines and antiviral medications. The Federal Government will aggressively monitor efforts to produce and distribute counterfeit drugs, both domestically and internationally, and ensure that existing laws are vigorously enforced in order to deter such conduct, protect the integrity of our drug supply, and maintain public confidence.

Reducing Disease Transmission and Rates of Illness

While preventing a pandemic after person-to-person transmission becomes well established may be impossible, the systematic application of disease containment measures can significantly reduce disease transmission rates with concomitant reductions in the intensity and velocity of any pandemics that do occur. The goals of disease containment after a pandemic is underway are to delay the spread of disease and the occurrence of outbreaks in U.S. communities, to decrease the clinical attack rate in affected communities, and to distribute the number of cases that do occur over a longer interval, so as to minimize social and economic disruption and to minimize, so far as possible, hospitalization and death. Investigation of early local outbreaks of pandemic influenza will provide helpful clinical and epidemiological information and support real-time modeling of pandemic response measures.

The primary strategies for preventing pandemic influenza are the same as those for seasonal influenza: vaccination; early detection and treatment with antiviral medications; and the use of infection control measures to prevent transmission. However, when a pandemic begins, a vaccine might not be widely available, and the supply of antiviral drugs may be limited. The ability to limit transmission and delay the spread of the pandemic will therefore rely primarily on the appropriate and thorough application of infection control measures in health care facilities, the workplace, the community, and for individuals at home. CDC recommendations in this regard are described at length in Supplement 4 of the *HHS Pandemic Influenza Plan*.

In the initial stages of a domestic outbreak, it might be feasible to perform case tracking and contact tracing, with isolation of individuals with known pandemic influenza and voluntary quarantine of their close contacts. Antiviral post-exposure prophylaxis targeted at contacts of the first cases identified in the United States may slow the spread of the pandemic. Quarantine of case contacts has played an important role in the management of outbreaks of other diseases transmitted by large-particle droplets, but its role in containing influenza has not been fully defined.

Depending on the severity of a pandemic and its anticipated effects on health care systems and the functioning of critical infrastructure, communities may recommend or implement general measures to promote social distancing and the disaggregation of disease transmission networks. As a general rule, the value of such measures will be greatest if the interventions are implemented early in the course of a community outbreak and sustained until definitive countermeasures are available. In the case of a pandemic, where it may not be possible to delay the spread of disease indefinitely, the goal of such meas-

ures will be to decrease the clinical attack rate and to distribute the number of cases that do occur over a longer interval, so as to minimize social and economic disruption.

Some social distancing measures, such as the recommendation to maintain one-yard spatial separation between individuals or the recommendation to businesses to conduct meetings by teleconference, will be sustainable indefinitely at comparatively minimal cost, whereas others (e.g., implementation of “snow day” restrictions) are associated with substantial costs and can be sustained only for limited periods. Low-cost or sustainable social distancing measures should be introduced immediately after a community outbreak begins, while the more costly and non-sustainable measures should be reserved for situations in which the need for disease containment is critical. Decisions as to how and when to implement such social distancing measures will be made on a community-by-community basis, with the Federal Government providing technical support and guidance to local officials.

The clinical attack rates for seasonal and pandemic influenza are highest among children. Closure of schools and targeted vaccination of children have demonstrated efficacy in diminishing community influenza rates. Modeling supports school closure as an effective means of reducing overall attack rates within communities and suggests that the value of this intervention is maximized if school closure occurs early in the course of a community outbreak. Cancellation of non-essential public gatherings, restrictions on long-distance travel, and social distancing within the workplace could also potentially decrease rates of influenza transmission, but the real-world effectiveness of these interventions has not been quantified. Measures to be considered within schools and in the workplace are described in Chapter 9.

“Snow day” restrictions — the recommendation or mandate by authorities that individuals and families limit social contacts by remaining within their households — should reduce community transmission rates and would afford protection to households where infection has not yet occurred. How long and how effectively snow day restrictions can be maintained has not been determined and thus the value of such restrictions has not been quantified. For maximum effectiveness and to the extent possible, snow day restrictions should be maintained for at least two incubation periods, as defined by epidemiological analysis of the circulating pandemic strain. In the absence of definitive countermeasures (i.e., an effective vaccine), snow day restrictions will serve to disrupt but not stop community transmission of influenza. The uses of snow day restrictions during a pandemic will vary. They might be employed to decompress health care facilities by temporarily reducing the rate of new infections within an affected community. The optimal timing for the implementation of snow day restrictions has not been determined but should be tractable to modeling. The economic impacts of snow day restrictions could be quite large and should be weighed against the likely health benefits.

Geographic Quarantine (*Cordon Sanitaire*)

Geographic quarantine is the isolation, by force if necessary, of localities with documented disease transmission from localities still free of infection. It has been used intermittently throughout history in efforts to contain serious epidemics and must be differentiated from the quarantine of case contacts, where exposure to an infectious agent but not infection per se has been confirmed. Geographic quarantine results in the detention, within an epidemic zone, of persons who may or may not have been exposed to the pathogen in question. Some nations, notably Australia in the fall of 1918, have imposed reverse geographic quarantines, in an effort to keep epidemic disease out. The value of efforts to impose modified forms of reverse geographic quarantine is discussed at greater length in Chapter 5. In summary, even if such efforts prove unsuccessful, delaying the spread of the disease could provide the Federal Government with valuable time to activate the domestic response.

Once influenza transmission has occurred in multiple discrete locations, and it is clear that containment efforts have failed, the value of conventional geographic quarantine as a disease containment measure in any particular locality will be profoundly limited. Whether geographic quarantine should play a role in efforts to contain an outbreak of influenza with pandemic potential at its source will depend on the area and population affected, whether the implementation of a *cordon sanitaire* is feasible, the likelihood of success of other public health interventions, the ability of authorities to provide for the needs of the quarantined population, and in all likelihood geopolitical considerations that are beyond the scope of this chapter. The implementation of conventional geographic quarantine imposes significant opportunity costs and may result in the diversion of significant resources and assets that might be used to better effect supporting less draconian disease containment measures.

Quarantine at the level of families and individuals is a legitimate public health intervention that figured prominently in the public health response to severe acute respiratory syndrome (SARS). It is important to underscore that the value of individual quarantine as a public health intervention is determined by the biology of the agent against which it is directed. Because influenza infection can be transmitted by persons who are not ill, and because viral shedding occurs prior to the onset of clinical illness, isolation of ill persons or exclusion from work of those who are ill will reduce but not prevent transmission in public settings. Because of influenza's short generation period, isolation and quarantine must be implemented very quickly to have an impact and will not be as effective as for a disease like SARS or smallpox where the generation time is longer and asymptomatic shedding of virus does not appear to be significant. Nevertheless, the value of isolating patients with pandemic influenza and quarantining their contacts is clearly supported by recent modeling efforts.

Expanding Medical Surge Capacity

While a pandemic may strain hundreds of communities simultaneously, each community will experience the pandemic as a local event. In the best of circumstances, patients and health care resources are not easily redistributed; in a pandemic, conditions would make the sharing of resources and burdens even more difficult. The Federal Government will provide medical countermeasures, resources, and personnel, if available, in support of communities experiencing pandemic influenza, but communities should anticipate that in the event of multiple simultaneous outbreaks, the Federal Government may not possess sufficient medical resources or personnel to augment local capabilities. The development of medical and public health mutual aid arrangements through the Emergency Management Assistance Compact (EMAC) and other mechanisms is encouraged, but States and localities should anticipate that all sources of external aid may be compromised during a pandemic.

Personnel

During a pandemic, the number of persons seeking medical care is expected to increase significantly and overcrowding may lead hospital and other health care institutions to adjust clinical care algorithms in order to optimize the allocation of scarce resources. Since most health professionals are already geographically dispersed, local and State governments are in a position to take primary responsibility for identifying, registering, and coordinating volunteer medical and health care personnel within their jurisdictions to respond to any surge in demand for health care. HHS has partnered with States and localities through the Medical Reserve Corps and the Emergency System for the Advanced Registration of Volunteer Health Professionals (ESAR-VHP) Programs to develop locally sponsored emergency response teams and state-based volunteer registries to recruit, credential, and mobilize health care personnel in the event of a large scale medical emergency.

Medical Standards of Care

If a pandemic overwhelms the health and medical capacity of a community, it will be impossible to provide the level of medical care that would be expected under pre-pandemic circumstances. It may be necessary because of hospital overcrowding to establish pre-hospital facilities and alternate-care sites to provide supplemental capacity. In some circumstances, it may be necessary to apply triage principles in the hospital to regulate which patients gain access to intensive care units (ICUs) and ventilators, and it is likely that vaccine, pharmaceuticals, and other medical materiel will also be rationed. Non-clinical personnel and family members may be asked to assist with administrative and environmental tasks, while qualified clinicians may be asked to perform unfamiliar functions such as staffing temporary medical care facilities, visiting patients in their homes, or providing medical advice via on-line or hot-line connections.

The terms 'altered' and 'degraded' standards of care have often been applied to such situations in both government documents and the medical literature. The legal and ethical 'standard of care,' however, is what is reasonably expected of medical systems and providers and is determined by extant circumstances. Relevant conditions include the availability of hospital, ICU, or specialty care beds; medical equipment and materiel; and personnel who are trained and qualified to provide care. As in all situations involving the allocation of scarce medical resources, the standard of care will be met if resources are fairly distributed and are utilized to achieve the greatest benefit. In a pandemic, hospital and ICU beds, ventilators, and other medical services may be rationed. As in other situations of scarce medical resources, preference will be given to those whose medical condition suggests that they will obtain greatest benefit from them. Such rationing differs from approaches to care in which resources are provided on a first-come, first-served basis or to patients with the most severe illnesses or injuries.

Given the strain that a pandemic would place on a community's medical system, it will be necessary for hospitals, medical providers, and oversight agencies to maximize hospital bed surge capacity, and triage and treat patients in a manner that affords each the best chance of survival and recovery within the limits of available resources. In addition, the public must be informed regarding when, how, and where to obtain medical care. In all cases, the goal should be to provide care and allocate scarce equipment, supplies, and personnel in a way that saves the largest number of lives. Planning should therefore include thresholds for altering triage algorithms and otherwise optimizing the allocation of scarce resources. Where prospective and mature data are available, changes in clinical care algorithms should be evidence-based.

In planning for a prolonged mass casualty event, it must be recognized that persons with unrelated medical conditions will continue to require emergency, acute, and chronic care. It is important to keep the health care system functioning and to deliver the best care possible to preserve as many lives as possible. Planning a health and medical response to a mass casualty event must be comprehensive, community-based, and coordinated at the regional level. In making adjustments in the delivery of care because of constrained resources, individual autonomy, privacy, and dignity should be protected to the extent possible and reasonable under the circumstances. Finally, clear communication with the public is essential before, during, and after a mass casualty event such as a pandemic.

Availability of Medical Materiel

Health care facilities typically maintain limited inventories of supplies on-site and depend on just-in-time restocking programs. Replenishment of critical inventories is thus dependent upon an intact supply chain from manufacturing and distribution to transportation and receiving. During a pandemic there

would be an increased demand for both consumable and durable resources. Examples of critical supplies are listed in Supplement 3 to the *HHS Pandemic Influenza Plan*. Competition for these resources at a time of increased demand could result in critical shortages.

Manufacturers and suppliers are likely to report inventory shortages because of the massive simultaneity of need and supply chains may also be disrupted by the effects of a pandemic on critical personnel. Medical facilities should make provision for these considerations in their planning efforts and consider stockpiling critical medical materiel individually or collaborating with other facilities to develop local or regional stockpiles maintained under vendor managed inventory systems.

Facilities

Health care facilities will face increased demand for isolation wards, intensive care unit beds, and ventilators. Historical comparisons and recent severe seasonal influenza epidemics suggest that U.S. health care facilities would be overwhelmed with influenza patients during a pandemic. Extrapolating from the 1918 pandemic, a severe pandemic could result at its peak in the need for significantly more hospital and intensive care unit beds than the U.S. health care system currently supports.

Because of the intense but transient demand for clinical care areas, and because cohorting of patients with pandemic influenza in common treatment areas is an acceptable response to hospital overcrowding, establishing infirmaries in armories or other facilities of opportunity to supplement existing health care facilities is a reasonable consideration for those not critically ill. Suitable spaces can be identified in the pre-pandemic phase, medical materiel and supplies can be stockpiled prospectively, and actions to stand up the infirmary commenced in the early stages of an outbreak. The Federal Government has assembled a limited number of Federal Medical Stations (FMSs), which are scalable, modular, 250-bed deployable caches that require 40,000 square feet of enclosed space and an enabling environment (i.e., loading docks, electrical power source systems, climate control, communications, information technology support) and are configured to provide basic but essential medical care.¹⁷

Psychosocial Concerns

During a pandemic, psychosocial issues may play significantly contribute to, or hinder, the effectiveness of the response. Public anxiety and subjective perception of risk during the initial phases will impact the degree of medical surge; overall compliance with quarantine, snow days, and other control procedures; and participation of the workforce, including health care workers, in response efforts. In later stages of the epidemic, other psychosocial factors may also emerge. During the 1918-1919 “Spanish flu,” for example, people experienced significant distress due to loss of family members and anxiety about work, food, transportation, and basic infrastructure, while the SARS outbreak in 2003 led to psychological distress for health care workers and the general public because of social isolation, stigmatization of groups perceived to be high risk, and general fears about safety and health. While most people are resilient and will need minimal psychological support to cope with catastrophic events such as an influenza pandemic, it is imperative that planning for behavioral health reactions be undertaken to support affected populations and possibly reduce the occurrence of long-term psychological distress. Such planning should involve efforts to recruit, credential, and mobilize mental health and substance abuse personnel (as part of personnel efforts discussed above), along with the development of materials on psychological self-care and related topics, including a plan for dissemination of such materials.

¹⁷ Staffing for FMS units is not provided automatically but must be drawn from available Federal, State, or local medical personnel.

Emergency Medical Services

Emergency Medical Services (EMS) provide critical pre-hospital care and transportation and the individuals engaged in these services are among the high priority groups considered for vaccination. However, when a pandemic begins, a vaccine may not be widely available, and the supply of antiviral drugs may be limited. Illness and absenteeism may adversely affect these services and local governments and hospitals may need to explore alternative methods of transporting patients.

Pre-hospital EMS transportation capability will play a critical role in responding to requests for assistance, providing treatment, and in triaging patients. 9-1-1 call centers/public safety answering points (PSAPs) will experience a significant surge in calls and will determine how and when EMS units are dispatched. Coordination and communication between public health, PSAPs, EMS, and hospital officials will be necessary to ensure optimal patient care as hospital bed availability and pre-hospital resources are strained. Planners should consider modifying PSAP call-taker and dispatch protocols and developing pandemic-specific pre-hospital triage and treatment protocols. A robust statewide or regional system for monitoring PSAP medical calls, EMS responses and transports, and hospital bed availability will be critical for tracking and responding to a pandemic.

Persons with emergency medical licensure not engaged in transporting patients could potentially provide support to personnel working in hospitals and infirmaries and could, with additional education, training and legal authority, broaden their scopes of practice during the emergency and, for instance, administer vaccinations to the public or other emergency support personnel.

Home-based Care

Given that most persons with pandemic influenza will experience typical influenza symptoms, most persons who seek care can be managed appropriately by outpatient providers using a home-based approach. Appropriate management of outpatient pandemic influenza cases may reduce the risk of progression to severe disease and thereby reduce demand for inpatient care. A system of effective home-based care would decrease the burden on health care providers and hospitals and lessen exposure of uninfected persons to persons with influenza. Telephone call centers should be established or augmented within affected communities to provide advice on whether to stay home or to seek care. Home health care providers and organizations can provide follow-up for those managed at home, decreasing potential exposure of the public to persons who are ill and may transmit infection.

Fatality Management

Given the anticipated increase in the number of deaths associated with an influenza pandemic, hospitals and health care facilities working with State, local, or tribal health officials and medical examiners should assess current capacity for refrigeration of deceased persons, discuss mass fatality plans and identify temporary morgue sites, and determine the scope and volume of supplies needed to handle an increased number of deceased persons.

Risk Communication

Government and public health officials must communicate clearly and continuously with the public prior to and throughout a pandemic. To maintain public confidence and to enlist the support of individuals and families in disease containment efforts, public officials must provide unambiguous and consistent guidance on what individuals can do to protect themselves, how to care for family members at

home, when and where to seek medical care, and how to protect others and minimize the risks of disease transmission.

Individuals will, in general, respond to a pandemic and to public health interventions in ways that they perceive to be congruent with their interests and their instinct for self-preservation, and public health authorities should tailor their risk communication campaigns and interventions accordingly. The public will respond favorably to messages that acknowledge its concerns, allay anxiety and uncertainty, and provide clear incentives for desirable behavior. The information provided by public health officials should therefore be useful, addressing immediate needs, but it should also help private citizens recognize and understand the degree to which their collective actions will shape the course of a pandemic.

Providing regular messages through a single spokesperson with professional credibility is highly desirable. Conveying clinical information requires particular care to ensure that a lay audience can understand it. Distinguishing between political and professional messages is essential. Provisions should be made for communication in languages other than English and for those with disabilities.

Other important objectives for communication campaigns include providing information to the public about the status of the response; providing anticipatory guidance and dispelling unrealistic expectations regarding the delivery of health and medical care; providing guidance on how to obtain information about the status of missing persons; and providing information related to influenza complications, including where to seek help if people are having significant difficulties in coping with personal losses or fears about the pandemic.

Regulatory / Financial / Legal Matters

More than one in four Americans receive health care coverage through Medicare, Medicaid, the State Children's Health Insurance Program (SCHIP), the Veterans Health Administration, TRICARE, or other Federal programs. Ensuring access to, and timely payment for, covered services during a pandemic will be critical to maintaining a functional health care infrastructure. It may also be necessary to extend certain waivers or develop incident-specific initiatives or coverage to facilitate access to care. Pandemic influenza response activities may exceed the budgetary resources of responding Federal and State government agencies, requiring compensatory legislative action.

Depending on the severity of a pandemic, certain requirements may be waived or revised to facilitate efficient delivery of health care services. For example, certain Emergency Medical Treatment and Active Labor Act (EMTALA), Medicare, Medicaid, SCHIP, and Health Insurance Portability and Accountability Act (HIPAA) requirements may be waived following a declaration of a public health emergency by the Secretary of HHS and a Presidential declaration of a major disaster or emergency. The authority to waive or amend legal requirements during a pandemic corresponds with the level of government that issues the requirements, whether Federal, State, or local. Statutes and rules may provide flexibility without waiver or revision. For example, HIPAA regulations allow covered entities to disclose patient information in circumstances that could arise during a pandemic, including disclosures: to provide treatment; to public health authorities for disease prevention and control and public health surveillance, investigations, and interventions; to lessen an imminent threat to health and safety; and to contact family members, guardians, or caretakers. In all cases, it will be important to make providers and institutions aware of the established legal framework, so that it is clear which authorities and regulations do or do not apply in a given situation.

Prior to the declaration of a public health emergency, State and local planners should examine existing State public health and medical licensing laws, interstate emergency management compacts and mutual aid agreements, and other legal and regulatory arrangements to determine the extent to which they meet potential new threats. Waivers granted at any level are likely to be targeted to an affected area for a temporary and specified period of time. In the case of an evolving pandemic, it will therefore be important to have the flexibility to extend or expand such waivers as needed.

Roles and Responsibilities

The responsibility for preparing for, detecting, and responding to influenza outbreaks is shared by everyone. This includes private citizens, health care providers, the private sector, State, local, and tribal public health authorities, and the Federal Government. State, local, and tribal governments, the private sector, and the Federal Government all have important and interdependent roles in preparing for, responding to, and recovering from a pandemic. Effective management of the Nation's medical and public health response systems during a pandemic will require coordinated action by all segments of government and society.

State, local, and tribal governments are primarily responsible for detecting and responding to disease outbreaks and implementing measures to minimize the consequences of an outbreak. The Federal Government supports detection and response in many ways, including providing response personnel and expertise, response materiel, diagnostic reference services and testing support, and funding for certain response activities. It is anticipated that the potentially catastrophic nature of a pandemic may overwhelm local, State, and tribal capabilities. Federal agencies will be called upon to provide additional support, but even those resources may be overwhelmed at the peak of a pandemic.

The Federal Government

The Federal Government will use all capabilities within its authority to support the private sector and State, local, and tribal public health authorities in preparedness and response activities. It will increase readiness to sustain essential Federal public health and medical functions during a pandemic and provide public health and medical support services under the *National Response Plan* (NRP). It will be prepared to advise State, local, and tribal governments and the medical and public health communities at large on how to deploy scarce medical resources, use and sequence community infection control measures, and address the medical challenges posed by pandemic influenza. It will perform surveillance for and monitor the progress of a pandemic on a national and international scale, support the development and production of medical countermeasures, and sponsor research on influenza viruses with pandemic potential. It will provide financial support and technical assistance to State, local, and tribal governments as they develop pandemic preparedness plans.

Department of Health and Human Services: HHS's primary responsibilities are those actions required to protect the health of all Americans, including communication of information related to pandemic influenza, leading international and domestic efforts in surveillance and detection of influenza outbreaks, ensuring the provision of essential human services, implementing measures to limit spread, and providing recommendations related to the use, distribution, and allocation of countermeasures and to the provision of care in mass casualty settings. HHS will support rapid containment of localized outbreaks domestically and provide guidance to State, local, and tribal public health authorities on the use, timing, and sequencing of community infection control measures. HHS also supports biomedical research and development of new vaccines and medical countermeasures.

Department of Homeland Security: Pursuant to Homeland Security Presidential Directive 7 (HSPD-7), DHS coordinates overall domestic incident management and Federal response procedures under the NRP and National Incident Management System (NIMS). Under the NRP, DHS is responsible for coordinating the protection of the Nation's critical infrastructure, and within the framework of Emergency Support Function #8 - Public Health and Medical Services (ESF #8) for the deployment of available NDMS medical, mortuary, and veterinary response assets.

Department of Defense: The primary responsibility of DOD is to preserve national security by protecting American forces, maintaining operational readiness, and sustaining critical military missions. DOD's first priority with respect to protecting human health will be to ensure sufficient capability to provide medical care to DOD forces and beneficiaries. DOD can provide medical, public health, transportation, logistical, communications, and other support consistent with existing legal authorities and to the extent that DOD's National Security preparedness is not compromised. Ideally, the human and technical resources of the National Guard should be balanced between support to the Governors of the individual States and the overall needs of national security.

Department of Veterans Affairs: VA provides health care, monetary benefits, and burial benefits to our Nation's veterans. VA's priority with respect to protecting human health is to deliver health care to enrolled veterans and beneficiaries. VA also has a mission to provide medical surge capacity for treatment of casualties arising from DOD operations and can provide other support to the extent that VA's mission to serve veterans is not compromised.

Department of Labor: DOL's primary responsibilities are those actions required to protect the health and safety of workers, including communication of information related to pandemic influenza to workers and employers, and other relevant activities.

State, Local, and Tribal Entities

State, local, and tribal entities should have credible pandemic preparedness plans that address key response issues and outline strategies to mitigate the human, social, and economic consequences of a pandemic. They will initiate the request for the delivery and be primarily responsible for the distribution of medical countermeasures released from national stockpiles. States should be prepared to face challenges in the availability of essential commodities, demands for health care services that exceed existing capacity, and public pressure to enforce infection control measures in ways that may hinder the delivery of emergency services and supplies and exacerbate the economic repercussions of the pandemic. States, localities, and tribal entities should work to improve communication between public health departments and both private sector partners, such as health care facilities, community- and faith-based organizations, and clinical laboratories that are likely to be involved in the response to a pandemic. State, local, and tribal public health departments should coordinate their planning efforts with local Federal health care facilities.

The Private Sector and Critical Infrastructure Entities

The private sector will play an integral role in preparedness before a pandemic begins and should be part of the national response. Businesses and corporations, especially those within sectors constituting the Nation's critical infrastructure, should develop continuity of operations plans that provide for workforce health protection and ensure that essential functions and vital services can be performed in the setting of significant absenteeism. Businesses and corporations should be prepared for public health interventions and recommendations that may increase absenteeism. Elements of the private sector concerned with

health care should be prepared to support local, State, national, and international efforts to contain or mitigate a pandemic.

Individuals and Families

Private citizens must recognize and understand the degree to which their personal actions will govern the course of a pandemic. The success or failure of infection control measures is ultimately dependent upon the acts of individuals, and the collective response of 300 million Americans will significantly influence the shape of the pandemic and its medical, social, and economic outcomes (see *Individual, Family, and Community Response to Pandemic Influenza* between Chapters 5 and 6). Individuals will, in general, respond to a pandemic and to public health interventions in ways that they perceive to be congruent with their interests and their instinct for self-preservation, and public health authorities should tailor their risk communication campaigns and interventions accordingly. Institutions in danger of becoming overwhelmed will rely on the voluntarism and sense of civic and humanitarian duty of ordinary Americans. The talents and skills of individuals will prove crucial in our Nation's response to a pandemic.

Actions and Expectations

6.1. Pillar One: Preparedness and Communication

Preparedness and transparency are critical elements of the Strategy and the foundation of efforts to detect, contain, limit, delay, and mitigate a pandemic. Activities that should be undertaken before a pandemic to ensure preparedness and to communicate expectations and responsibilities to all levels of government and society are described below.

a. Planning for a Pandemic

6.1.1. Continue to work with States, localities, and tribal entities to establish and exercise pandemic response plans.

- 6.1.1.1. The Federal Government shall, and State, local, and tribal governments should, define and test actions and priorities required to prepare for and respond to a pandemic, within 6 months. Measure of performance: completion and communication of national, departmental, State, local, and tribal pandemic influenza response plans; actions and priorities defined and tested.
- 6.1.1.2. HHS, in coordination with DHS, shall review and approve State Pandemic Influenza plans to supplement and support DHS State Homeland Security Strategies to ensure that Federal homeland security grants, training, exercises, technical, and other forms of assistance are applied to a common set of priorities, capabilities, and performance benchmarks, in conformance with the National Preparedness Goal, within 12 months. Measure of performance: definition of priorities, capabilities, and performance benchmarks; percentage of States with plans that address priorities, identify capabilities, and meet benchmarks.
- 6.1.1.3. DHS, in coordination with HHS, DOJ, DOT, and DOD, shall be prepared to provide emergency response element training (e.g., incident management, triage, security, and communications) and exercise assistance upon request of State,

local, and tribal communities and public health entities within 6 months.
 Measure of performance: percentage of requests for training and assistance fulfilled.

6.1.2. Build upon existing domestic mechanisms to develop medical and veterinary surge capacity within or across jurisdictions to match medical requirements with capabilities.

- 6.1.2.1. All health care facilities should develop and test infectious disease surge capacity plans that address challenges including: increased demand for services, staff shortages, infectious disease isolation protocols, supply shortages, and security.
- 6.1.2.2. HHS, in coordination with DHS, DOD, and VA, shall develop a joint strategy defining the objectives, conditions, and mechanisms for deployment under which NDMS assets, U.S. Public Health Service (PHS) Commissioned Corps, Epidemic Intelligence Service (EIS) officers, and DOD/VA health care personnel and public health officers would be deployed during a pandemic, within 9 months. Measure of performance: interagency strategy completed and tested for the deployment of Federal medical personnel during a pandemic.
- 6.1.2.3. HHS, in coordination with DHS, DOT, DOD, and VA, shall work with State, local, and tribal governments and leverage Emergency Management Assistance Compact agreements to develop protocols for distribution of critical medical materiel (e.g., ventilators) in times of medical emergency within 6 months. Measure of performance: critical medical material distribution protocols completed and tested.
- 6.1.2.4. HHS, in coordination with DOD and VA, in collaboration with medical professional and specialty societies, within their domains of expertise, shall develop guidance for allocating scarce health and medical resources during a pandemic, within 6 months. Measure of performance: guidance developed and disseminated.
- 6.1.2.5. HHS shall package and offer to the States and Territories the core operating components of an ESAR-VHP system within 6 months and encourage all States and tribal entities to implement the ESAR-VHP program by providing technical assistance and orientations at State and territory request to implement and operate Federal guideline (ESAR-VHP) compliant systems within 12 months. Measure of performance: guidance and technical assistance, as requested, provided to States to implement ESAR-VHP capability, compliant with Federal guidelines, in all States and U.S. territories.
- 6.1.2.6. HHS, in coordination with the USA Freedom Corps and Citizen Corps programs, shall continue to work with States and local communities to expand the Medical Reserve Corps program by 20 percent within 12 months. Measure of performance: increase number of Medical Reserve Corps units by 20 percent, from 350 to 420 units.

- 6.1.2.7. HHS, in coordination with DHS, DOD, VA and the USA Freedom Corps and Citizen Corps programs, shall prepare guidance for local Medical Reserve Corps coordinators describing the role of the Medical Reserve Corps during a pandemic, within 3 months. Measure of performance: guidance materials developed and published on Medical Reserve Corps website (www.medicalreservecorps.gov).
- 6.1.2.8. DHS, in coordination with the USA Freedom Corps, shall direct other Citizen Corps programs to prepare guidance detailing appropriate pandemic preparedness activities for each program, within 3 months. Measure of performance: guidance materials developed and published on Citizen Corps website and component program websites.

b. Communicating Expectations and Responsibilities

6.1.3. Work to ensure clear, effective, and coordinated risk communication, domestically and internationally, before and during a pandemic. This includes identifying credible spokespersons at all levels of government to effectively coordinate and communicate helpful, informative messages in a timely manner.

- 6.1.3.1. HHS, in coordination with DHS, DOS, DOD, VA, and other Federal partners, shall develop, test, and implement a Federal Government public health emergency communications plan (describing the government's strategy for responding to a pandemic, outlining U.S. international commitments and intentions, and reviewing containment measures that the government believes will be effective as well as those it regards as likely to be ineffective, excessively costly, or harmful) within 6 months. Measure of performance: containment strategy and emergency response materials completed and published on www.pandemicflu.gov; communications plan implemented.
- 6.1.3.2. HHS, in coordination with DHS, shall develop, test, update and implement (if necessary) a multilingual and multimedia public engagement and risk communications strategy within 6 months. Measure of performance: risk communication material completed and published on www.pandemicflu.gov and other venues; State summit meetings held.
- 6.1.3.3. HHS, in coordination with DHS, DOD, and the VA, and in collaboration with State, local, and tribal health agencies and the academic community, shall select and retain opinion leaders and medical experts to serve as credible spokespersons to coordinate and effectively communicate important and informative messages to the public, within 6 months. Measure of performance: national spokespersons engaged in communications campaign.

6.1.4. Provide guidance to the private sector and critical infrastructure entities on their role in the pandemic response, and considerations necessary to maintain essential services and operations despite significant and sustained worker absenteeism.

- 6.1.4.1. State, local, and tribal public health and health care authorities, in collaboration with DHS, HHS, and the Department of Labor (DOL), should coordinate emer-

gency communication protocols with print and broadcast media, private industry, academic, and nonprofit partners within 6 months. Measure of performance: coordinated messages from communities identified above.

- 6.1.4.2. DOT, in cooperation with HHS, DHS, and DOC, shall develop model protocols for 9-1-1 call centers and public safety answering points that address the provision of information to the public, facilitate caller screening, and assist with priority dispatch of limited emergency medical services, within 12 months. Measure of performance: model protocols developed and disseminated to 9-1-1 call centers and public safety answering points.

c. Producing and Stockpiling Vaccines, Antiviral Medications, and Medical Material

6.1.5. Encourage and subsidize the development of State-based antiviral stockpiles to support response activities.

- 6.1.5.1. HHS shall encourage and subsidize the development of State, territorial, and tribal antiviral stockpiles to support response activities within 18 months. Measure of performance: State, territorial, and tribal stockpiles established and antiviral medication purchases made toward goal of aggregate 31 million treatment courses.

6.1.6. Ensure that our national stockpile and stockpiles based in States and communities are properly configured to respond to the diversity of medical requirements presented by a pandemic, including personal protective equipment, antibiotics, and general supplies.

- 6.1.6.1. HHS, in coordination with DOD, VA, and State, local, and tribal partners, shall define the mix of antiviral medications to include in the Strategic National Stockpile (SNS) and State stockpiles and develop recommendations for how the different agents are to be used, within 6 months. Measure of performance: development of policy concerning the selection, relative proportions, and use of antiviral medications in SNS and State stockpiles.
- 6.1.6.2. HHS, in coordination with DOD, VA, and State, local, and tribal partners, shall define critical medical material requirements for stockpiling by the SNS and States to respond to the diversity of needs presented by a pandemic, within 9 months. Measure of performance: requirements defined and guidance provided on stockpiling.
- 6.1.6.3. DOD, as part of its departmental implementation plan, shall conduct a medical materiel requirements gap analysis and procure necessary materiel to enhance Military Health System surge capacity, within 18 months. Measure of performance: gap analysis completed and necessary materiel procured.
- 6.1.6.4. HHS, DOD, VA and the States shall maintain antiviral and vaccine stockpiles in a manner consistent with the requirements of FDA's Shelf Life Extension Program (SLEP) and explore the possibility of broadening SLEP to include equivalently maintained State stockpiles, within 6 months. Measure of performance:

compliance with SLEP requirements documented; decision made on broadening SLEP to State stockpiles.

6.1.7. Establish domestic production capacity and stockpiles of countermeasures to ensure sufficient antiviral medications and vaccine for front-line personnel and at-risk populations, including military personnel.

6.1.7.1. HHS, in coordination with DHS, DOJ, VA, and in collaboration with State, local, and tribal partners, shall determine the national medical countermeasure requirements to ensure the sustained functioning of medical, emergency response, and other front-line organizations, within 12 months. Measure of performance: more specific definition of sectors and personnel for priority access to medical countermeasures and quantities needed to protect those groups; guidance provided to State, local, and tribal governments and to infrastructure sectors for various scenarios of pandemic severity and medical countermeasure supply.

6.1.7.2. HHS shall establish and maintain stockpiles of pre-pandemic vaccines adequate to immunize 20 million persons against influenza strains that present a pandemic threat, as soon as possible within the constraints of industrial capacity. Measure of performance: procurement of 20 million courses of pre-pandemic vaccine against influenza strains presenting a pandemic threat.

6.1.7.3. HHS in collaboration with State/local partners shall procure and allocate sufficient stockpiles of countermeasures to ensure continuity of critical medical and emergency response operations, within 18 months, within the constraints of industrial capacity. Measure of performance: sufficient quantities of antiviral medications and other countermeasures procured and distributed between SNS and State stockpiles.

6.1.7.4. DOD shall establish stockpiles of vaccine against H5N1 and other influenza subtypes determined to represent a pandemic threat adequate to immunize approximately 1.35 million persons for military use within 18 months of availability. Measure of performance: sufficient vaccine against each influenza virus determined to represent a pandemic threat in DOD stockpile to vaccinate 1.35 million persons.

6.1.8. Establish domestic production capacity and stockpiles of countermeasures to ensure sufficient vaccine to vaccinate the entire U.S. population within 6 months of the emergence of a virus with pandemic potential.

6.1.8.1. HHS shall work with the pharmaceutical industry toward the goal of developing, within 60 months, domestic vaccine production capacity sufficient to provide vaccine for the entire U.S. population within 6 months after the development of a vaccine reference strain. Measure of performance: domestic vaccine manufacturing capacity in place to produce 300 million courses of vaccine within 6 months of development of a vaccine reference strain during a pandemic.

6.1.9. Establish domestic production capacity and stockpiles of countermeasures to ensure antiviral treatment for those who contract a pandemic strain of influenza.

- 6.1.9.1. HHS shall, to the extent feasible, work with antiviral drug manufacturers and large distributors to develop agreements supporting the Federal procurement of available stocks of antiviral drugs both during the pre-pandemic and pandemic periods, within 12 months. Measure of performance: new antiviral medications procured by SNS, within the constraints of industrial capacity; Federal contracts in place with antiviral drug manufacturers and distributors.
- 6.1.9.2. HHS, in collaboration with the States, shall purchase sufficient quantities of antiviral drugs to treat 25 percent of the U.S. population, with reserve of 6 million treatment courses for outbreak containment within 18 months, within the constraints of industrial capacity. Measure of performance: 50 million treatment courses of antiviral drugs procured by SNS; States and tribes make stockpile purchases toward aggregate 31 million treatment course goal.
- 6.1.9.3. DOD shall procure 2.4 million treatment courses of antiviral medications and position them at locations worldwide within 18 months. Measure of performance: aggregate 2.4 million treatment courses of antiviral medications in DOD stockpiles.

6.1.10. Facilitate appropriate coordination of efforts across the vaccine manufacturing sector.

- 6.1.10.1. HHS, in coordination with the private sector, shall assess the ability of U.S.-based pharmaceutical manufacturing facilities to contribute surge capacity and to retrofit existing facilities for pandemic vaccine production. This assessment will be completed within 6 months and should inform efforts to expand vaccine capacity. Measure of performance: completed assessment.
- 6.1.10.2. HHS, in coordination with DHS, DOD, VA, DOC, DOJ, and Treasury, shall assess within whether use of the Defense Production Act or other authorities would provide sustained advantages in procuring medical countermeasures, within 6 months. Measure of performance: analytical report completed on the advantages/disadvantages of invoking the Defense Production Act to facilitate medical countermeasure production and procurement.

6.1.11. Address regulatory and other legal issues to the expansion of our domestic vaccine production capacity.

- 6.1.11.1. HHS shall assess its existing authorities and develop a plan of action to address any regulatory or other legal issues related to the expansion of domestic vaccine production capacity within 12 months. Measure of performance: regulatory and legal issues identified in assessment.
- 6.1.11.2. HHS shall develop a protocol and decision tools to implement liability protections and compensation, as authorized by the Public Readiness and Emergency Preparedness Act (Pub. L. 109-148), within 6 months. Measure of performance: publication of protocol and decision tools.

6.1.12. Expand the public health recommendations for domestic seasonal influenza vaccination and encourage the same practice internationally.

- 6.1.12.1. HHS shall collaborate with health care providers, industry partners, and State, local, and tribal public health authorities to develop public information campaigns and other mechanisms to stimulate increased seasonal influenza vaccination, within 12 months. Measure of performance: domestic vaccine use increased relative to historical norms.

d. Establishing Distribution Plans for Medical Countermeasures, Including Vaccines and Antiviral Medications

6.1.13. Develop credible countermeasure distribution mechanisms for vaccine and antiviral agents prior to and during a pandemic.

- 6.1.13.1. HHS, in coordination with DHS, DOD, VA, and DOJ, and in collaboration with State, local, and tribal partners and the private sector, shall ensure that States, localities, and tribal entities have developed and exercised pandemic influenza countermeasure distribution plans, and can enact security protocols if necessary, according to pre-determined priorities (see below) within 12 months. Measures of performance: ability to activate, deploy, and begin distributing contents of medical stockpiles in localities as needed established and validated through exercises.
- 6.1.13.2. HHS, in coordination with DOD, VA, States, and other public sector entities with antiviral drug stockpiles, shall coordinate use of assets maintained by different organizations, within 12 months. Measure of performance: plans developed for coordinated use of antiviral stockpiles.
- 6.1.13.3. HHS, in collaboration with State, territorial, tribal, and local health care delivery partners, shall develop and execute strategies to effectively implement target group recommendations described below, within 12 months. Measure of performance: guidance on strategies to implement target group recommendations developed and disseminated to State, local, and tribal authorities for inclusion in pandemic response plans.
- 6.1.13.4. HHS, in coordination with DOD, VA, and in collaboration with State, local, and tribal governments and private sector partners, shall assist in the development of distribution plans for medical countermeasure stockpiles to ensure that delivery and distribution algorithms have been planned for each locality for antiviral distribution. Goal is to be able to distribute antiviral medications to infected patients within 48 hours of the onset of symptoms within 12 months. Measure of performance: distribution plans developed.
- 6.1.13.5. HHS, in coordination with DHS, DOS, DOD, DOL, VA, and in collaboration with State, local, and tribal governments and private sector partners, shall develop plans for the allocation, distribution, and administration of pre-pandemic vaccine, within 9 months. Measure of performance: department plans developed and guidance disseminated to State, local, and tribal authorities

to facilitate development of pandemic response plans.

- 6.1.13.6. DOT, in coordination with HHS, DHS, State, local, and tribal officials and other EMS stakeholders, shall develop suggested EMS pandemic influenza guidelines for statewide adoption that address: clinical standards, education, treatment protocols, decontamination procedures, medical direction, scope of practice, legal parameters, and other issues, within 12 months. Measure of performance: EMS pandemic influenza guidelines completed.
- 6.1.13.7. HHS, in coordination with DHS, DOT, DOD, and VA, shall work with State, local, and tribal governments and private sector partners to develop and test plans to allocate and distribute critical medical materiel (e.g., ventilators with accessories, resuscitator bags, gloves, face masks, gowns) in a health emergency, within 6 months. Measure of performance: plans developed, tested, and incorporated into department plan, and disseminated to States and tribes for incorporation into their pandemic response plans.
- 6.1.13.8. DOD shall supply military units and posts, installations, bases, and stations with vaccine and antiviral medications according to the schedule of priorities listed in the DOD pandemic influenza policy and planning guidance, within 18 months. Measure of performance: vaccine and antiviral medications procured; DOD policy guidance developed on use and release of vaccine and antiviral medications; and worldwide distribution drill completed.
- 6.1.13.9. HHS, in coordination with DOD, VA, and in collaboration with State, territorial, tribal, and local partners, shall develop/refine mechanisms to: (1) track adverse events following vaccine and antiviral administration; (2) ensure that individuals obtain additional doses of vaccine, if necessary; and (3) define protocols for conducting vaccine- and antiviral-effectiveness studies during a pandemic, within 18 months. Measure of performance: mechanism(s) to track vaccine and antiviral medication coverage and adverse events developed; vaccine- and antiviral-effectiveness study protocols developed.
- 6.1.13.10. DOJ, in coordination with HHS, DHS, DOS, and DOC, shall lead the development of a joint strategic plan to ensure international shipments of counterfeit vaccine and antiviral medications are detected at our borders and that domestic counterfeit drug production and distribution is thwarted through aggressive enforcement efforts. Measure of performance: joint strategic plan developed; international and domestic counterfeit drug shipments prevented or interdicted.
- 6.1.14. Prioritize countermeasure allocation before an outbreak, and update this prioritization immediately after the outbreak begins based on the at-risk populations, available supplies, and the characteristics of the virus.**
- 6.1.14.1. HHS, in coordination with DHS and Sector-Specific Agencies, DOS, DOD, DOJ, DOL, VA, Treasury, and State/local governments, shall develop objectives for the use of, and strategy for allocating, vaccine and antiviral drug stockpiles during pre-pandemic and pandemic periods under varying conditions of countermeasure supply and pandemic severity within 3 months. Measure of performance:

clearly articulated statement of objectives for use of medical countermeasures under varying conditions of supply and pandemic severity.

- 6.1.14.2. HHS, in coordination with DHS and Sector-Specific Agencies, DOS, DOD, DOL, VA, Treasury, and State/local governments, shall identify lists of personnel and high-risk groups who should be considered for priority access to medical countermeasures, under various pandemic scenarios, according to strategy developed in compliance with 6.1.14.1, within 9 months. Measure of performance: provisional recommendations of groups who should receive priority access to vaccine and antiviral drugs established for various scenarios of pandemic severity and medical countermeasure supply.
- 6.1.14.3. HHS, in coordination with DHS and Sector-Specific Agencies, DOS, DOD, DOL, and VA, shall establish a strategy for shifting priorities based on at-risk populations, supplies and efficacy of countermeasures against the circulating pandemic strain, and characteristics of the virus within 9 months. Measure of performance: clearly articulated process in place for evaluating and adjusting pre-pandemic recommendations of groups receiving priority access to medical countermeasures.
- 6.1.14.4. HHS, in coordination with DHS and Sector-Specific Agencies, DOS, DOD, DOL, VA, and Treasury, shall present recommendations on target groups for vaccine and antiviral drugs when sustained and efficient human-to-human transmission of a potential pandemic influenza strain is documented anywhere in the world. These recommendations will reflect data from the pandemic and available supplies of medical countermeasures. Measure of performance: provisional identification of priority groups for various pandemic scenarios through inter-agency process within 2-3 weeks of outbreak.

e. Advancing Scientific Knowledge and Accelerating Development

6.1.15. Ensure that there is maximal sharing of scientific information about influenza viruses between governments, scientific entities, and the private sector.

- 6.1.15.1. HHS shall develop capability, protocols, and procedures to ensure that viral isolates obtained during investigation of human outbreaks of influenza with pandemic potential are sequenced and that sequences are published on GenBank within 1 week of confirmation of diagnosis in index case, within 6 months. Measure of performance: viral isolate sequences from outbreaks published on GenBank within 1 week of confirmation of diagnosis.
- 6.1.15.2. HHS shall increase and accelerate genomic sequencing of known human and avian influenza viruses and shall rapidly make this sequence information publicly available, within 6 months. Measure of performance: increased throughput of genomes sequenced (versus FY 2005 baseline) and decreased time interval between completion of sequencing and publication on GenBank.
- 6.1.15.3. HHS shall develop protocols and procedures to ensure timely reporting to Federal agencies and submission for publication of data from HHS-supported

influenza vaccine, antiviral medication, and diagnostic evaluation studies, within 6 months. Measure of performance: study data shared with Federal agencies within 1 month of analysis and publication of clinical trial data following completion of studies.

6.1.16. Accelerate the development of cell culture technology for influenza vaccine production and establish a domestic production base to support vaccination demands.

6.1.16.1. HHS shall continue to support the advanced development of cell-culture based influenza vaccine candidates. Measure of performance: research grants and/or contracts awarded to develop cell-culture based influenza vaccines against currently circulating influenza strains with pandemic potential within 6 months.

6.1.16.2. HHS shall support the renovation of existing U.S. manufacturing facilities that produce other FDA-licensed cell-based vaccines or biologics and the establishment of new domestic cell-based influenza vaccine manufacturing facilities, within 36 months. Measure of performance: contracts awarded for renovation or establishment of domestic cell-based influenza vaccine manufacturing capacity.

6.1.17. Use novel investment strategies to advance the development of next-generation influenza diagnostics and countermeasures, including new antiviral medications, vaccines, adjuvant technologies, and countermeasures that provide protection across multiple strains and seasons of the influenza virus.

6.1.17.1. HHS shall continue to support the development and clinical evaluation of novel vaccines and vaccination strategies (e.g., adjuvants, alternative delivery systems, common epitope vaccines). Measure of performance: research grants and/or contracts awarded to support the development of influenza vaccines (including polyvalent influenza vaccines), adjuvants and dose-sparing strategies, and more efficient delivery systems within 12 months, leading to initiation of phase I and II clinical trials to evaluate influenza vaccines and vaccination strategies.

6.1.17.2. HHS shall collaborate with the pharmaceutical, medical device, and diagnostics industries to accelerate development, evaluation (including the evaluation of dose-sparing strategies), licensure, and U.S.-based production of new antiviral drugs and diagnostics. Development activities should include design of preclinical and clinical studies to collect safety and efficacy information across multiple strains and seasons of circulating influenza illness, and advance design of protocols to obtain additional updated information to support revisions in product usage during circulation of novel strains and evolution of pandemic spread. Such collaborations should involve early and frequent discussions with the FDA to explore the use of accelerated regulatory pathways towards product approval or licensure. Collaborations concerning diagnostic tests should include CDC to facilitate access to pandemic virus samples for validation testing and ensure that the test is one that can be used to promote and protect the public health during an influenza pandemic. Measure of performance: initiation of clinical trials of new influenza antiviral drugs and diagnostics.

- 6.1.17.3. HHS, in coordination with DHS, shall develop and test new point-of-care and laboratory-based rapid influenza diagnostics for screening and surveillance, within 18 months. Measure of performance: new grants and contracts awarded to researchers to develop and evaluate new diagnostics.
- 6.1.17.4. HHS shall increase access to standardized influenza reagents for use in influenza tests and research, within 6 months. Measure of performance: standardized influenza reagents distributed to domestic and international partners within 3 business days of a request.

6.2. Pillar Two: Surveillance and Detection

The ability to contain or delay the spread of pandemic influenza depends critically upon the early detection of outbreaks. Within the United States, we will work to establish surveillance systems and reporting mechanisms that provide continuous, real-time “situational awareness” to public health authorities at all levels of government. We will also work to enhance laboratory capacity, develop new and improved rapid diagnostic tests, and consolidate real-time analytical and modeling capabilities to support response activities.

a. Ensuring Rapid Reporting of Outbreaks

- 6.2.1. Support the development and sustainment of sufficient U.S. and host nation laboratory capacity and diagnostic reagents in affected regions and domestically, to provide rapid confirmation of cases in animals or humans.**
 - 6.2.1.1. HHS shall provide guidance to public health and clinical laboratories on the different types of diagnostic tests and the case definitions to use for influenza at the time of each pandemic phase. Guidelines for the current pandemic alert phase will be disseminated within 3 months. Measure of performance: dissemination on www.pandemicflu.gov and through other channels of guidance on the use of diagnostic tests for H5N1 and other potential pandemic influenza subtypes.
 - 6.2.1.2. HHS shall ensure that testing by reverse transcriptase-polymerase chain reaction (RT-PCR) for H5N1 and other influenza viruses with pandemic potential is available at LRN laboratories and CDC within 3 months. Measure of performance: RT-PCR for H5N1 and other potential pandemic influenza subtypes and strains in use at CDC and LRN laboratories.
 - 6.2.1.3. HHS, in coordination with DOD, VA, USDA, DHS, EPA, and other partners, in collaboration with its LRN Reference Laboratories, shall be prepared within 6 months to conduct laboratory analyses to detect pandemic subtypes and strains in referred specimens and conduct confirmatory testing, as requested. Measure of performance: initial testing and identification of suspect pandemic influenza specimens completed at LRN Reference and National Laboratories within 24 hours.
 - 6.2.1.4. All Federal, State, local, tribal, and private sector medical facilities should ensure that protocols for transporting influenza specimens to appropriate reference

laboratories are in place within 3 months. Measure of performance: transportation protocols for laboratory specimens detailed in HHS, DOD, VA, State, territorial, tribal, and local pandemic response plans.

- 6.2.1.5. State, local, and tribal entities should be prepared, in the event of a pandemic, to increase diagnostic testing for influenza and increase the frequency of reporting to CDC.

6.2.2. Advance mechanisms for “real-time” clinical surveillance in domestic acute care settings such as emergency departments, intensive care units, and laboratories to provide tribal, local, State, and Federal public health officials with continuous awareness of the profile of illness in communities, and leverage all Federal medical capabilities, both domestic and international, in support of this objective.

- 6.2.2.1. HHS shall be prepared to provide ongoing information from the national influenza surveillance system on the pandemic’s impact on health and the health care system, within 6 months. Measure of performance: surveillance data aggregated and disseminated every 7 days, or as often as the situation warrants, to DHS, Sector-Specific Agencies, and State, territorial, tribal, and local partners.
- 6.2.2.2. HHS, in coordination with Federal, State, local, tribal, and private sector partners, shall develop real-time (same-day) tracking capabilities of pneumonia or influenza hospitalizations and influenza deaths to enhance its surveillance capabilities at the onset of and during a pandemic, within 12 months. Measure of performance: real-time (same-day) nationwide hospital census and mortality tracking system is operational for use during a pandemic.
- 6.2.2.3. HHS, in coordination with DOD and VA, shall expand the number of hospitals and cities participating in the BioSenseRT program to improve the Nation’s capabilities for disease detection, monitoring, and situational awareness within 12 months. Measure of performance: number of hospitals (including DOD and VA facilities) participating in the BioSenseRT program increased to 350 hospitals in 42 cities.
- 6.2.2.4. HHS shall reduce the time between reporting of virologic laboratory data from State, local, tribal, and private sector partners and collation, analysis, and reporting to key stakeholders, within 6 months. Measure of performance: time delay between receipt of data and collation, analysis, and reporting of results of 7 days or less.
- 6.2.2.5. HHS shall increase the frequency of reporting and the number and geographic location of reporting health care providers from which outpatient surveillance data are collected through the Sentinel Provider Network (SPN), the Emerging Infections Program (EIP) influenza project, and the New Vaccine Surveillance Network (NVSN), within 6 months. Measure of performance: number of reporting healthcare providers increased to one or more per 250,000 population.
- 6.2.2.6. HHS shall improve the speed at which it performs mortality surveillance through the 122 Cities Mortality Reporting System within 3 months. Measure of

performance: mortality data collected at CDC within 1 week of decedent's demise increased by 25 percent compared with 2005.

- 6.2.2.7. DHS, in collaboration with HHS, DOD, VA, USDA, and other Federal departments and agencies with biosurveillance capabilities and real-time data sources, shall enhance NBIS capabilities to ensure the availability of a comprehensive and all-source biosurveillance common operating picture throughout the Interagency, within 12 months. Measure of performance: NBIS provides integrated surveillance data to DHS, HHS, USDA, DOD, VA, and other interested interagency customers.
- 6.2.2.8. HHS, in coordination with DHS, DOD, and VA, and in collaboration with State, local, and tribal authorities, shall be prepared to collect, analyze, integrate, and report information about the status of hospitals and health care systems, health care critical infrastructure, and medical materiel requirements, within 12 months. Measure of performance: guidance provided to States and tribal entities on the use and modification of the components of the National Hospital Available Beds for Emergencies and Disasters (HAvBED) system for implementation at the local level.
- 6.2.2.9. DOD shall enhance influenza surveillance efforts within 6 months by: (1) ensuring that medical treatment facilities (MTFs) monitor the Electronic Surveillance System for Early Notification of Community-based Epidemics (ESSENCE) and provide additional information on suspected or confirmed cases of pandemic influenza through their Service surveillance activities; (2) ensuring that Public Health Emergency Officers (PHEOs) report all suspected or actual cases through appropriate DOD reporting channels, as well as to CDC, State public health authorities, and host nations; and (3) posting results of aggregated surveillance on the DOD Pandemic Influenza Watchboard; all within 18 months. Measure of performance: number of MTFs performing ESSENCE surveillance greater than 80 percent; DOD reporting policy for public health emergencies, including pandemic influenza completed.
- 6.2.2.10. State, local, and tribal public health departments should develop relationships with hospitals and health care systems within their jurisdictions to facilitate collection of real-time or near real-time clinical surveillance data from domestic acute care settings such as emergency departments, intensive care units, and laboratories.
- 6.2.2.11. State, local, and tribal public health departments should provide weekly reports on the overall level of influenza activity in their States or localities, with assistance from CDC epidemiologists and field officers posted within each State health department in collecting and reporting these data.
- 6.2.3. Develop and deploy rapid diagnostics with greater sensitivity and reproducibility to allow onsite diagnosis of pandemic strains of influenza at home and abroad, in animals and humans, to facilitate early warning, outbreak control, and targeting of antiviral therapy.**

- 6.2.3.1. HHS, in coordination with DHS and DOD, shall work with pharmaceutical and medical device company partners to develop and evaluate rapid diagnostic tests for novel influenza subtypes including H5N1 within 18 months. Measure of performance: new investment in research to develop influenza diagnostics; new rapid diagnostic tests, if found to be useful, are available for influenza testing, including for novel influenza subtypes.
- 6.2.3.2. HHS, in coordination with DHS, DOD, and VA, shall compile an inventory of all research and product development work on rapid diagnostic testing for influenza and shall reach consensus on sets of requirements meeting national needs and a common test methodology to drive further private-sector investment and product development, within 6 months. Measure of performance: inventory developed and requirements paper disseminated.
- 6.2.3.3. HHS, in coordination with DOD, VA, and DHS, shall encourage and expedite private-sector development of rapid subtype- and strain-specific influenza point-of-care tests within 12 months of the publication of requirements. Measure of performance: rapid point-of-care test available in the marketplace within 18 months.
- 6.2.3.4. HHS-, DOD-, and VA-funded hospitals and health facilities shall have access to improved rapid diagnostic tests for influenza A, including influenza with pandemic potential, within 6 months of when tests become available.
- 6.2.3.5. State, local, and tribal public health departments should acquire and deploy rapid diagnostic tests that are specific and sensitive for pandemic influenza strains, as soon as those tests are available. Measure of performance: diagnostic tests, if found to be useful, are accessible to federally funded health facilities.

b. Using Surveillance to Limit Spread

6.2.4. Develop and exercise mechanisms to provide active and passive surveillance during an outbreak, both within and beyond our borders.

- 6.2.4.1. HHS, in coordination with DHS, DOD, VA, USDA, and DOS, shall be prepared, within 12 months, to continuously evaluate surveillance and disease reporting data to determine whether ongoing disease containment and medical countermeasure distribution and allocation strategies need to be altered as a pandemic evolves. Measure of performance: analyses of surveillance data performed at least weekly during an outbreak with timely adjustment of strategic and tactical goals, as required.
- 6.2.4.2. DHS, in coordination with Sector-Specific Agencies, HHS, DOD, DOJ, and VA, and in collaboration with the private sector, shall be prepared to track integrity of critical infrastructure function, including the health care sector, to determine whether ongoing strategies of ensuring workplace safety and operational continuity need to be altered as a pandemic evolves, within 6 months. Measure of performance: tracking system in place to monitor integrity of critical infrastructure function and operational continuity in near real time.

6.2.4.3. DOD and VA shall be prepared to track and provide personnel and beneficiary health statistics and develop enhanced methods to aggregate and analyze data documenting influenza-like illness from its surveillance systems within 12 months. Measure of performance: influenza tracking systems in place and capturing beneficiary clinical encounters.

6.2.5. Develop rapid-response modeling capability to improve decision making during a pandemic.

6.2.5.1. HHS, in coordination with DOD and DHS, shall develop and maintain a real-time epidemic analysis and modeling hub that will explore and characterize response options as a support to policy and decision makers within 6 months. Measure of performance: modeling center with real-time epidemic analysis capabilities established.

6.3. Pillar Three: Response and Containment

In approaching the problem of pandemic influenza, the U.S. Government endorses a layered strategy of response and containment. As outlined in the other chapters of this document, the United States is working with other nations and relevant international organizations to detect and contain outbreaks of animal influenza with pandemic potential with the aim of preventing its spread to humans. In the event of sustained and efficient human-to-human transmission of an influenza virus with pandemic potential, all reasonable actions to contain the epidemic at its source and to delay its introduction to the United States should be attempted. If such efforts fail, all instruments of national power will be directed to limiting or otherwise delaying the spread of disease; minimizing suffering and death; sustaining critical infrastructure and a Constitutional form of government; and reducing the economic and social effects of the pandemic.

a. Containing Outbreaks

6.3.1. Encourage all levels of government, domestically and globally, to take appropriate and lawful action to contain an outbreak within the borders of their community, province, State, or nation.

6.3.1.1. State, local, and tribal pandemic preparedness plans should address the implementation and enforcement of isolation and quarantine, the conduct of mass immunization programs, and provisions for release or exception.

6.3.2. Provide guidance, including decision criteria and tools, to all levels of government on the range of options for infection control and containment, including those circumstances where social distancing measures, limitations on gatherings, or quarantine authority may be an appropriate public health intervention.

6.3.2.1. HHS, in coordination with DHS, DOT, Education, DOC, DOD, and Treasury, shall provide State, local, and tribal entities with guidance on the combination, timing, evaluation, and sequencing of community containment strategies (including travel restrictions, school closings, snow days, self-shielding, and quarantine during a pandemic) based on currently available data, within 6 months, and update this guidance as additional data becomes available. Measure

of performance: guidance provided on community influenza containment measures.

- 6.3.2.2. HHS shall provide guidance on the role and evaluation of the efficacy of geographic quarantine in efforts to contain an outbreak of influenza with pandemic potential at its source, within 3 months. Measure of performance: guidance available within 72 hours of initial outbreak.
- 6.3.2.3. HHS, in coordination with DHS and DOD and in collaboration with mathematical modelers, shall complete research identifying optimal strategies for using voluntary home quarantine, school closure, snow day restrictions, and other community infection control measures, within 12 months. Measure of performance: guidance developed and disseminated on the use of community control.
- 6.3.2.4. As appropriate, DOD, in consultation with its Combatant Commanders (COCOM), shall implement movement restrictions and individual protection and social distancing strategies (including unit shielding, ship sortie, cancellation of public gatherings, drill, training, etc.) within their posts, installations, bases, and stations. DOD personnel and beneficiaries living off-base should comply with local community containment guidance with respect to activities not directly related to the installation. DOD shall be prepared to initiate within 18 months. Measure of performance: the policies/procedures are in place for at-risk DOD posts, installations, bases, stations, and for units to conduct an annual training evaluation that includes restriction of movement, shielding, personnel protection measures, health unit isolation, and other measures necessary to prevent influenza transmission.
- 6.3.2.5. All HHS-, DOD-, and VA-funded hospitals and health facilities shall develop, test, and be prepared to implement infection control campaigns for pandemic influenza, within 3 months. Measure of performance: guidance materials on infection control developed and disseminated on www.pandemicflu.gov and through other channels.
- 6.3.2.6. All health care facilities should develop, test, and be prepared to implement infection control campaigns for pandemic influenza, within 6 months.
- 6.3.2.7. HHS, in coordination with DHS, DOC, DOL, and Sector-Specific Agencies, and in collaboration with medical professional and specialty societies, shall develop and disseminate infection control guidance for the private sector, within 12 months. Measure of performance: validated, focus group-tested guidance developed, and published on www.pandemicflu.gov and in other forums.

6.3.3. Emphasize the roles and responsibilities of the individual in preventing the spread of an outbreak, and the risk to others if infection control practices are not followed.

- 6.3.3.1. HHS, in coordination with DHS, VA, and DOD, shall develop and disseminate guidance that explains steps individuals can take to decrease their risk of acquiring or transmitting influenza infection during a pandemic, within 3

months. Measure of performance: guidance disseminated on www.pandemicflu.gov and through VA and DOD channels.

- 6.3.3.2. HHS, in coordination with DHS, DOD, VA, and DOT and in collaboration with State, local, and tribal partners, shall develop and disseminate lists of social distancing behaviors that individuals may adopt within 6 months and update guidance as additional data becomes available. Measure of performance: guidance disseminated on www.pandemicflu.gov and through other channels.

b. Leveraging National Medical and Public Health Surge Capacity

6.3.4. Implement State, local, and tribal public health and medical surge plans, and leverage all Federal medical facilities, personnel, and response capabilities to support the national surge requirement.

- 6.3.4.1. Major medical societies and organizations, in collaboration with HHS, DHS, DOD, and VA, should develop and disseminate protocols for changing clinical care algorithms in settings of severe medical surge. Measure of performance: evidence-based protocols developed to optimize care that can be provided in conditions of severe medical surge.
- 6.3.4.2. HHS, in coordination with DHS, DOD, and VA, and in collaboration with States, localities, tribal entities, and private sector health care facilities, shall develop strategies and protocols for expanding hospital and home health care delivery capacity in order to provide care as effectively and equitably as possible, within 6 months. Measure of performance: guidance and protocols developed and disseminated.
- 6.3.4.3. HHS shall work with State Medicaid and SCHIP programs to ensure that Federal standards and requirements for reimbursement or enrollment are applied with the flexibilities appropriate to a pandemic, consistent with applicable law. Preliminary strategies shall be developed within 6 months. Measure of performance: draft policies and guidance developed concerning emergency enrollment in and reimbursement through State Medicaid and SCHIP programs during a pandemic.
- 6.3.4.4. DHS assets, including NDMS medical materiel and mobile medical units, and HHS assets, such as the USPHS Commissioned Corps and FMSs, shall be deployed in a manner consistent with pre-defined strategic considerations. Measure of performance: development, within 6 months, of strategic principles for deployment of Federal medical assets in a pandemic; consistency of deployments during a pandemic with these principles.
- 6.3.4.5. DHS shall activate NDMS teams, if available, to augment efforts of State, local, and tribal governments as part of the Federal response. Measure of performance: number of NDMS teams activated and deployed during a pandemic.
- 6.3.4.6. HHS shall deploy the USPHS Commissioned Corps and FMSs, if available and in combination or separately as circumstances warrant, to augment efforts of

- State/local governments as part of the Federal response. Measure of performance: USPHS Commissioned Corps personnel trained on FMSs within 9 months; Commissioned Corps personnel and FMSs deployed within 72 hours of order to mobilize during a pandemic.
- 6.3.4.7. DOD shall enhance its public health response capabilities by: (1) continuing to assign epidemiologists and preventive medicine physicians within key operational settings; (2) expanding ongoing DOD participation in CDC's EIS Program; and (3) within 18 months, fielding specific training programs for PHEOs that address their roles and responsibilities during a public health emergency. Measure of performance: all military PHEOs fully trained within 18 months; increase military trainees in CDC's EIS program by 100 percent within 5 years.
- 6.3.4.8. All hospitals should be prepared to treat patients with pandemic influenza (i.e., equipped and ready to care for: (1) a limited number of patients infected with a pandemic influenza virus, or other novel strain of influenza, as part of normal operations; and (2) a large number of patients in the event of escalating transmission of pandemic influenza).
- 6.3.4.9. All hospitals and health care systems should develop, test, and be ready to employ business continuity plans and identify the critical links in their supply chains as well as sources of emergency.
- 6.3.4.10. All health care systems, individually or collaborating with other facilities to develop local or regional stockpiles maintained under vendor managed inventory systems, should consider stockpiling consumable critical medical materiel (including but not limited to food, fuel, water, N95 respirators, surgical and /or procedural masks, gowns, and ethyl-alcohol based gels) sufficient for the peak period of a pandemic wave (2-3 weeks).
- 6.3.5. Activate plans to distribute medical countermeasures, including non-medical equipment and other material, from the Strategic National Stockpile and other distribution centers to Federal, State, local, and tribal authorities.**
- 6.3.5.1. HHS, in coordination with DHS, DOL, Education, VA, and DOD, shall develop and disseminate guidance and educational tools that explain steps individuals can take to decrease their risk of acquiring or transmitting influenza infection during a pandemic, within 6 months. Measure of performance: interim guidance disseminated on www.pandemicflu.gov and through VA, DOD, and other channels within 3 months; complementary educational tools on social distancing, personal hygiene, mask use, and other infection control precautions developed within 6 months.
- 6.3.5.2. HHS, in collaboration with State, local, and tribal governments, shall develop and disseminate recommendations for the use, if any, of antiviral stockpiles for targeted post-exposure prophylaxis in civilian populations, within 3 months. Measure of performance: States, localities, and tribal entities have received recommendations for incorporation into response plans.

6.3.5.3. HHS, in coordination with DHS, shall allocate and assure the effective and secure distribution of public stocks of antiviral drugs and vaccines when they become available. HHS and DHS are currently prepared to distribute stockpile as soon as countermeasures become available. Measure of performance: number of doses of vaccine and treatment courses of antiviral medications distributed.

6.3.6. Address barriers to the flow of public health, medical, and veterinary personnel across State and local jurisdictions to meet local shortfalls in public health, medical, and veterinary capacity.

6.3.6.1. Prior to the declaration of a public health emergency, State, local, and tribal public health authorities should examine existing Federal laws, regulations, and requirements, State public health and medical licensing laws, the provisions of interstate emergency management compacts and mutual aid agreements, and other legal and regulatory arrangements to determine the extent to which they address barriers to the flow of qualified public health and medical personnel across jurisdictional lines or between health care facilities.

c. Sustaining Infrastructure, Essential Services, and the Economy

6.3.7. Determine the spectrum of infrastructure-sustainment activities that the U.S. military and other government entities may be able to support during a pandemic, contingent upon primary mission requirements, and develop mechanisms to activate them.

6.3.7.1. HHS, in coordination with DHS, DOD, VA, and DOT, and as the lead for ESF #8, shall identify public health and medical capabilities required to support a pandemic response and work with other supporting agencies to identify and deploy or otherwise deliver the required capability or asset, if available. Measure of performance: inventory of public health and medical capabilities within 6 months; available public health or medical capabilities or assets deployed or delivered during a pandemic.

6.3.7.2. DOD and VA assets and capabilities shall be postured to provide care for military personnel and eligible civilians, contractors, dependants, other beneficiaries, and veterans and shall be prepared to augment the medical response of State, territorial, tribal, or local governments and other Federal agencies consistent with their ESF #8 support roles, within 3 months. Measure of performance: DOD and VA pandemic preparedness plans developed; in a pandemic, adequate health response provided to military and associated personnel.

6.3.7.3. VA shall develop draft emergency policies and directives allowing VA personnel and resources to be used for the treatment of non-veteran patients with pandemic influenza within 3 months. Measure of performance: emergency policies and directives drafted.

6.3.7.4. VA shall develop, test, and implement protocols and policies allowing VA personnel and resources to be used for the treatment of non-veteran patients during health emergencies, within 3 months. Measure of performance: protocols and policies developed and implemented.

- 6.3.7.5. DOD shall develop and implement guidelines defining conditions under which Reserve Component medical personnel providing health care in non-military health care facilities should be mobilized and deployed, within 18 months. Measure of performance: guidelines developed and implemented.

d. Ensuring Effective Risk Communication

- 6.3.8. Ensure that timely, clear, coordinated messages are delivered to the American public from authoritative sources at all levels of government and assist the governments of affected nations to do the same.**
- 6.3.8.1. HHS, in coordination with DHS, DOD, and VA, shall develop and disseminate a risk communication strategy within 6 months, updating it as required. Measure of performance: implementation of risk communication strategy on **www.pandemicflu.gov** and elsewhere.
- 6.3.8.2. DOD and VA, in coordination with HHS, shall develop and disseminate educational materials, coordinated with and complementary to messages developed by HHS but tailored for their respective departments, within 6 months. Measure of performance: up-to-date risk communication material published on DOD and VA pandemic influenza websites, HHS website **www.pandemicflu.gov**, and in other venues.