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INTRODUCTION

Influenza viruses have posed a threat to animal and human health throughout history. Efforts to develop a universal vaccine or antiviral medications with sustained efficacy are frustrated by influenza viruses' tendency to mutate. As a result of the influenza viruses' propensity to change, people may not have immunity against a new influenza strain. A pandemic occurs when a novel influenza virus spreads within a human population with little or no preexisting immunity. The extent and severity of a pandemic depend on the specific characteristics of the virus. In the 20th century, the world witnessed three human pandemics, each producing clinically apparent illness in approximately 30 percent of the world's population. It is estimated that 200,000 to 2 million Americans may die during the next severe influenza pandemic.

Also, a modern pandemic could have a significant and prolonged disruptive impact on multiple social and economic sectors of a community. A high rate of absenteeism in workplaces as a result of illness or caring for ill family members, the imposition of public health interventions (such as school and business closings) and isolation measures, or fear of infection could threaten the critical infrastructure of society and result in disruption of essential services. To mitigate the consequences of a pandemic, comprehensive preparedness and response planning is imperative by all aspects and members of a community.

The Current Influenza Pandemic Threat

Although a novel influenza virus could emerge anywhere in the world at any time, scientists are particularly concerned about the avian influenza A/(H5N1) that is currently circulating in Asia, the Middle East, Africa, and Europe. Outbreaks of H5N1 have occurred among poultry in Asia since 1997. H5N1 viruses are endemic among birds in Southeast Asia and are spreading to Europe and Africa via the transport of infected poultry and the migration of wild birds, the natural reservoir of avian influenza viruses. As of July 2006, H5N1 outbreaks have been reported in more than 54 countries in Asia, Europe, the Middle East, and Africa. Continued spread is likely. Human H5N1 cases have been reported. The reported death rate for human cases has been between 50 and 57 percent, although the true number of people exposed to and infected by the H5N1 virus is unknown. Studies investigating the seroconversion, or the presence of antibodies against H5N1 in serum, are needed to accurately document the infection rate in humans. While most of the reported cases seem to have resulted from direct contact with infected poultry, the source of infection has not been documented in every instance. Of concern are the few instances in which transmission from person to person may have occurred.

Pandemic Planning Assumptions

As a result of the widespread emergence and spread of the H5N1 virus among birds, public health experts and Government officials are escalating and intensifying their pandemic preparedness. Preparedness planning must consider such factors as the ability of the virus to spread rapidly across communities and countries, the potential of asymptomatic persons transmitting the virus to others, and the likelihood of multiple outbreaks occurring simultaneously throughout the United States and thus limiting the ability of any jurisdiction to provide assistance and support to other jurisdictions. It must also be understood that, during a pandemic, enormous demands will be placed on all health care systems. There will be shortages of medical and diagnostic devices, and delays in the delivery of vaccines and antivirals. There will be disruption to national and community infrastructures and services.

Therefore, for the purposes of drafting the **HHS Implementation Plan,** the following specific planning assumptions, as outlined in the White House Homeland Security Council (HSC) **Implementation Plan,** have been used:

- An influenza pandemic will most likely originate overseas and not in the United States.
- Susceptibility to the pandemic influenza virus will be nearly universal.
- Efficient and sustained person to person transmission will signal an imminent pandemic.
- The clinical disease attack rate will likely be 30 percent or higher. Illness rates will be highest among school aged children (about 40 percent) and decline with age. Among working adults, an average of 20 percent will become ill during a community outbreak.
- Some persons will become infected, but not develop clinically significant symptoms. Asymptomatic or minimally symptomatic individuals can transmit infection and develop immunity to subsequent infection.
- The typical incubation period (interval between infection and onset of symptoms) for influenza will be approximately 2 days.
- Persons who become infected will shed virus and may transmit infection as much as a day before the onset of illness. Persons will transmit infection for at least 2 days after the onset of symptoms. Children will shed the greatest amount of virus and are likely to pose the greatest risk for disease transmission.
- On average, each infected person will transmit infection to approximately two other people.

- Fifty percent of those who become ill will seek outpatient medical care. With the availability of effective antiviral drugs for treatment, this proportion could be higher.
- The number of hospitalizations and deaths will depend on the virulence of the pandemic virus. Two scenarios are presented based on extrapolation of past pandemic experience (Table 1). HHS planning utilizes the more severe scenario.
- Risk groups for severe and fatal infection cannot be predicted with certainty, but will likely include infants, the elderly, pregnant women, and persons with chronic medical conditions.
- Rates of absenteeism in workplaces will depend on the severity of the pandemic. In a severe pandemic, absenteeism will reach 40 percent during the peak weeks of a community outbreak, with lower rates of absenteeism during the weeks before and after the peak.
- Certain public health measures (closing schools, quarantining household contacts of infected individuals, sheltering in place ["snow days"]) will increase rates of absenteeism in workplaces.
- In an affected community, a pandemic outbreak will last about 6 to 8 weeks.
- Multiple waves (periods during which community outbreaks occur across the country) of illness will occur, and each wave could last 2–3 months. Historically, the largest waves have occurred in the fall and winter, but the seasonality of a pandemic cannot be predicted with certainty.

As with other natural disasters, during and after a pandemic, individuals will require intensive psychosocial support, including substance abuse and mental health services.

Table 1. Aggregate Number of Episodes of Illness, Health Care Utilization, and Death During Moderate and Severe Pandemic Influenza Scenarios*

Characteristic	Moderate (1958/68-like)	Severe (1918-like)
Illness	90 million (30%)	90 million (30%)
Outpatient medical care	45 million (50%)	45 million (50%)
Hospitalization	865,000	9,900,000
ICU care	128,750	1,485,000
Mechanical ventilation	64,875	745,500
Deaths	209,000	1,903,000

*Estimates based on extrapolation from past pandemics in the United States. Note that these estimates do not include the potential impact of interventions not available during the 20th century pandemics.

World Health Organization Pandemic Phases and U.S. Federal Government Response Stages

The World Health Organization's (WHO's) published guidance for national pandemic planning has classified pandemic activities into six phases. These six phases are characterized by the spread of a novel influenza strain through animals and humans. Each pandemic phase is associated with a range of preparedness and response actions. (See Table 2.)

The WHO phases reflect the progression of a pandemic worldwide, rather than in any one country. For domestic preparedness planning purposes, however, it is more useful to think in terms of the six U.S. Response Stages that reflect the immediate and specific threat of a pandemic virus that arises overseas and may pose a threat to Americans. (See Table 2.) While the WHO Phases provide a framework for evaluating the global situation, the U.S. Response Stages facilitate the implementation of domestic disease containment strategies and activities.

As of October 2006, we are in WHO Phase 3, in the Pandemic Alert Period. Current efforts of the U.S. Government are directed towards accelerating preparedness activities prior to WHO Phase 4, then initiating pandemic response actions at the onset of Phase 4, when epidemiological evidence exists that *increased human-to-human transmission* of an influenza virus with pandemic potential has occurred anywhere in the world.

The U.S. Government objectives, actions, policy decisions, and messaging considerations on pandemic influenza are identified for each of the U.S. Government Response Stages and are summarized in the **National Strategy for Pandemic Influenza Implementation Plan.** For the United States, the overarching goals are to:

- Prevent influenza transmission through consistent adherence to appropriate infection control practices across health care and community sectors during all U.S. Government Stages
- Delay the entry of a novel, pandemic influenza virus through the air- and seaports and land-border crossings of the United States and its trusts and territories during U.S. Government Stages 1–3
- Slow transmission within the United States during U.S. Government Stages 4 and 5 by implementing:
  - Non-pharmaceutical disease control methods (e.g., isolation, quarantine, school closures, and social distancing)
  - Pharmaceutical disease control methods (e.g., vaccination, antiviral medications)

Table 2. WHO Global Pandemic Phases and the Stages for Federal Government Response*

WHO Phases		U.S. Response Stages	
Inter-Pandemic Period			
1	No new influenza virus subtypes have been detected in humans. An influenza subtype that has caused human infection may be present in animals. If present in animals, the risk of human disease is considered to be low.	0	New domestic animal outbreak in at-risk country
2	No new influenza virus subtypes have been detected in humans. However, a circulating animal influenza virus subtype poses a substantial risk of human disease.		
Pandemic Alert Period			
3	Human infection(s) with a new subtype, but no human-to-human spread, or at most, rare instances of spread to a close contact	0	New domestic animal outbreak in at-risk country
		1	Suspected human outbreak overseas
4	Small cluster(s) with limited human-to-human transmission, but spread is highly localized, suggesting that the virus is not well adapted to humans.	2	Confirmed human outbreak overseas
5	Large cluster(s), but human-to-human spread still localized, suggesting that the virus is becoming increasingly better adapted to humans, but may not yet be fully transmissible (substantial pandemic risk).		
Pandemic Period			
6	Pandemic phase: increased and sustained transmission in general population.	3	Widespread human outbreak in multiple locations overseas
		4	First human case in North America
		5	Spread throughout the United States
		6	Recovery and preparation for subsequent waves

*U.S. Government stages 1 through 3 assume that the emergence of the pandemic strain will occur in another country. If the initial outbreak happened in the United States, U.S. Government Stage 4, the U.S. Government's goal would be to slow the spread of infection within the United States.

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Doctrine for HHS Pandemic Influenza Planning and Response

Because of the current ongoing outbreaks of avian influenza A/(H5N1) in Asia and the progression from the interpandemic period (the period prior to human infections) to a pandemic alert (once human infections have occurred), HHS has accelerated its preparedness planning and activities. In addition to the characteristics of the pandemic and planning assumptions noted above, the following principles guide HHS preparedness planning and response activities:

- Preparedness requires coordination among Federal, State, local, and tribal governments and private sector partners.
- Sustained human to human transmission anywhere in the world (WHO Phase 6) is the triggering event for a U.S. response.
- When possible and appropriate, basic public health measures will be employed to reduce person to person virus spread and prevent or delay influenza outbreaks.
- An informed and responsive public is essential for minimizing the health, social, and economic impact of a pandemic.
- At the start of a pandemic, vaccines, which will initially be in short supply, will be procured and distributed to State, local, and tribal health departments for the vaccination of predetermined priority groups.
- Domestic vaccine production capacity sufficient to provide vaccination for the entire U.S. population is critical.
- Quantities of antiviral drugs sufficient to treat 25 percent of the U.S. population will be stockpiled.
- Antiviral drugs from public stockpiles will be distributed to predetermined priority groups.

Priorities for HHS Pandemic Preparedness and Response Activities

Given the scope of pandemic preparedness and response activities presented in this Plan, prioritization is necessary. Although specific conditions and circumstances may dictate a revision of these priorities for action, the current priorities are:

- Advance international capacity for early warning and response
  - Enhance international communication and cooperation
  - Build international capacity
  - Facilitate rapid response

- Limit the arrival and spread of a pandemic into the United States
  - Ensure early warning and situational awareness
  - Establish a border and transportation strategy to delay entry into the United States of a pandemic virus detected overseas
  - Establish screening protocols at U.S. ports of entry and implementation agreements with other countries for screening passengers at airports and seaports
- Provide clear guidance to all stakeholders
  - Ensure effective risk communications including the development and provision of educational campaigns
  - Provide guidance on maximizing surge capacity with available resources
  - Provide comprehensive guidance on community shielding
  - Provide clear guidance for the private sector and institutions
- Accelerate the development of countermeasures
  - Develop rapid diagnostics
  - Establish stockpiles of pre-pandemic vaccine and antivirals
  - Advance technology and production capacity for influenza vaccine and research into the development of a universal influenza vaccine
  - Support research into new and improved antivirals

HHS has aggressively embarked on preparing for a pandemic. Many of the actions presented in this Plan are a continuation of already existing initiatives.

Since a pandemic might not unfold in a completely predictable way, regular assessments and adjustments to HHS actions and strategies will be made over time to reflect changing circumstances. HHS will monitor and evaluate its interventions, and will communicate lessons learned to health care providers, public health agencies, and others on the effectiveness of clinical and public health responses. As possible, HHS will assist State, local, and tribal health agencies in responding to outbreaks by deploying medical personnel, equipment, and supplies to augment health care capacity in affected areas. HHS will work with private industry partners and stakeholders to facilitate the production and distribution of antiviral drugs and pandemic vaccine. HHS will monitor antiviral drug and pandemic vaccine distribution, effectiveness, and any serious adverse events.

Summary of HHS Implementation Plan

This document, the **HHS Implementation Plan,** provides a roadmap for the Department's pandemic preparedness and response. It outlines specific steps to implement the actions and expectations assigned to HHS in the HSC **National Strategy for Pandemic Influenza Implementation Plan** and identified in the **HHS Strategic Plan.** (See http://www.whitehouse.gov/homeland/pandemic-influenza-implementation.html.)

Part I of this **HHS Implementation Plan** contains eight chapters on cross cutting issues covering international activities, domestic surveillance, public health interventions, the Federal medical response, vaccines, antiviral drugs, and communications, as well as State, local, and tribal preparedness. The topic of each chapter is introduced by a discussion of its importance, key planning assumptions, and HHS roles. Then each chapter presents HHS implementation steps undertaken to fulfill the HSC directives in the **National Strategy for Pandemic Influenza.** Achievement of these goals is contingent on the availability of resources.

Part II includes detailed continuity of operations plans that ensure that the essential functions of each HHS operating division are identified and maintained in the presence of the expected decreased staffing levels during a pandemic event.

As a roadmap, this **HHS Implementation Plan** is intended to facilitate coordination of Department pandemic preparedness and response programs and activities. It is a planning tool only. This document does not prescribe every intermediary step, process, or project. Rather it points the direction to more general steps or actions that the Department might undertake in its pandemic planning efforts. HHS will continue to review, revise, and update the **HHS Implementation Plan** as necessary.