

ACP

AMERICAN COLLEGE OF PHYSICIANS
INTERNAL MEDICINE | *Doctors for Adults*

THE HEALTH CARE RESPONSE TO PANDEMIC INFLUENZA

American College of Physicians
A Position Paper—2006

THE HEALTH CARE RESPONSE TO PANDEMIC INFLUENZA

A Position Paper of the
American College of Physicians

This paper, written by Laura Barnitz, BJ, MA, was developed for the Health and Public Policy Committee of the American College of Physicians: Jeffrey P. Harris, MD, Chair; David L. Bronson, MD, Vice Chair; CPT Julie Ake, MC, USA; Patricia P. Barry, MD; Molly Cooke, MD; Herbert S. Diamond, MD; Joel S. Levine, MD; Mark E. Mayer, MD; Thomas McGinn, MD; Robert M. McLean, MD; Ashley E. Starkweather, MD; and Frederick E. Turton, MD. It was approved by the Board of Regents on 3 April 2006.

How to cite this paper:

American College of Physicians. The Health Care Response to Pandemic Influenza. Philadelphia: American College of Physicians; 2006: Position Paper. (Available from American College of Physicians, 190 N. Independence Mall West, Philadelphia, PA 19106.)

Copyright ©2006 American College of Physicians.

All rights reserved. Individuals may photocopy all or parts of Position Papers for educational, not-for-profit uses. These papers may not be reproduced for commercial, for-profit use in any form, by any means (electronic, mechanical, xerographic, or other) or held in any information storage or retrieval system without the written permission of the publisher.

For questions about the content of this Position Paper, please contact ACP, Division of Governmental Affairs and Public Policy, Suite 800, 2011 Pennsylvania Avenue NW, Washington DC 20006; telephone 202-261-4500. To order copies of this Position Paper, contact ACP Customer Service at 800-523-1546, extension 2600, or 215-351-2600.

Executive Summary

Substantial epidemiological research and medical evidence in recent years have highlighted the necessity of planning to safeguard the American public against the threat of pandemic influenza. Although no new strain of influenza virus has yet achieved the capacity for easy transmission between humans, experts are concerned that one will in the near future. The morbidity and mortality that could occur as a result of this development is not precisely predictable, but the impact would be felt by all human populations around the world.

Of particular concern is an influenza A subtype known as H5N1 or avian flu. Now spreading through bird populations across Asia and recently reaching into Europe, this new influenza strain has infected domesticated birds like ducks and chickens as well as long-range migratory birds. In 1997, the first recorded outbreak among people took place in Hong Kong. Avian flu struck again in late 2003 and has infected 184 people since then (1). Currently, avian flu is primarily an animal disease. Unless people come into direct, sustained contact with infected birds, it is unlikely they will contract the disease.

The American College of Physicians (ACP) supports the U.S. Government's foresight in developing a national strategic response plan and the efforts of state and local leadership in addressing this threat to public health. A comprehensive health care response to this threat is necessary to save lives, decrease illness, and avoid disruption to the economy. In order to achieve these goals, ACP believes that physicians in all health care settings will have to be fully integrated into plans for the health care response.

On November 2, 2005, the U.S. Department of Health and Human Services (HHS) issued the HHS Pandemic Influenza Plan (2) as a blueprint for preparing for pandemic influenza. It is in consideration of the assumptions, strategy and details of the HHS plan, which incorporates guidance to state and local leaders and public health authorities, that ACP offers the following public policy positions.

1. The Involvement of Physicians in Planning for Pandemic Influenza and Participating in the Health Care Response at all Levels

Position 1: ACP supports strengthening public health emergency preparedness efforts through supporting the development of local task forces that include physicians representing all practice settings.

Position 2: The effective utilization of volunteer physicians and health care providers in public health emergencies should be coordinated by federal or state agencies that are clearly authorized to determine licensing and register volunteers.

II. Effective Surveillance, Monitoring and Reporting During a Pandemic

Position 3: Effective surveillance, monitoring and reporting of patient health status during an influenza pandemic will be best accomplished by insuring that health care providers in every locality have access to two-way communications with public health authorities and health information technology tools.

Position 4: ACP policy recognizes the paramount importance of patient-doctor confidentiality. If breaching confidentiality is necessary, it should be done in a way that minimizes harm to the patient and that heeds applicable federal and state law.

Position 5: ACP believes that infection control measures should be clear, fair and the least restrictive means necessary to protect public health. Physicians should not be penalized for failure to follow emergency orders that are not clear and timely and do not provide for due process to resolve situations outside the physician's control.

III. The Provision of Vaccines and Antiviral Medications

Position 6: Ending the chronic delays in the delivery of vaccine and achieving vaccination targets for seasonal influenza is a public health prerequisite to developing a successful response to pandemic influenza and other public health emergencies.

Position 7: ACP supports measures to increase pandemic influenza vaccine and antiviral medications in the Strategic National Stockpile. ACP supports the national procurement of vaccine in an amount sufficient to protect the entire U.S. population and national procurement of antiviral medications to cover 25 percent of the U.S. population. ACP believes that additional courses of antiviral medications should be procured for all public safety officers and health care workers with direct patient contact in amounts sufficient to provide prophylaxis. In the event of pandemic influenza, stockpiled vaccine and antivirals should be distributed equitably to all states' public health authorities based on the numbers of people in high-risk and high-priority groups.

IV. The Necessity of Providing Care Outside of Hospital Settings

Position 8: ACP believes that an effective health care response to pandemic influenza will require utilizing all nonhospital-based health care providers to counsel, diagnose, treat and monitor patients outside of hospital settings in order to decrease the likelihood of surges that would overwhelm hospital capacity.

V. Physician Security During a Pandemic

Position 9: The safety of physicians and other health care providers must be provided for during public health emergencies, such as pandemic influenza. Physicians and other health care providers who are storing or administering vaccines, antiviral medications or pandemic-related medical supplies and equipment must be fully informed about preplanned security measures in the event of pandemic influenza.

Introduction

Concern about the potential for the development of an influenza pandemic has grown steadily among infectious disease experts as they have learned more about the historical development of pandemics and as more strains of influenza A have emerged in humans (3). New influenza subtypes emerge as a result of a process called antigenic shift, which causes a sudden and major change in influenza A viruses. Because these changes result in novel strains of influenza, human beings have little to no natural immunity to them. If such changes result in a new influenza A virus subtype that can infect humans and spread easily from person to person, an influenza pandemic can occur. No one knows if any of the current subtypes will develop into an influenza pandemic, or when, but most experts believe that another influenza pandemic will emerge (4).

Today, the H5N1 subtype of the influenza virus, also known as avian flu, has the potential to develop into a pandemic strain.(5) The H5N1 virus is now endemic in many bird species so eliminating the virus is not feasible. However, avian flu remains primarily an animal disease. Currently, unless people come into direct, sustained contact with infected birds, it is unlikely they will contract the disease. What is particularly alarming about this subtype for medical experts is the virulence of the infection.

Since 2003 avian flu has infected 184 people and killed 103—more than a 50-percent mortality rate (6). Symptoms of avian influenza in humans have ranged from typical human influenza-like symptoms (e.g., fever, cough, sore throat, and muscle aches) to eye infections, pneumonia, severe respiratory diseases (such as acute respiratory distress syndrome), and other severe and life-threatening complications (7). If the H5N1 subtype becomes easily transmissible between humans, it will pose a severe threat to human health.

The HHS Plan makes clear that U.S. officials believe that the threat of pandemic influenza is substantial. According to HHS, when a pandemic virus strain emerges, 25-35 percent (approximately 75-105 million people) of the U.S. population could develop the disease and a substantial number of these individuals could die (8). Extrapolating from past pandemics, HHS reports that there would be about a 10-fold difference between more or less severe projections for mortality as a result of a new influenza pandemic. A pandemic could cause the death of between 209,000 and 1,903,000 Americans.

The HHS pandemic plan is based on these assumptions:

- Susceptibility to the pandemic influenza subtype will be universal.
- The clinical disease attack rate will be 30% (approximately 90 million) in the overall U.S. population. Illness rates will be highest among school-aged children. Among working adults, an average of 20% will become ill during a community outbreak.
- Of those who become ill, 50% (approximately 45 million) will seek outpatient medical care.
- The number of hospitalizations and deaths will depend on the virulence of the virus.
- Risk groups for severe and fatal infections cannot be predicted with certainty.
- The typical incubation period for influenza averages two days.
- Persons who become ill may shed virus and can transmit infection for one-half to one day before the onset of illness. Children pose the greatest risk for transmission.
- On average about two secondary infections will occur as a result of transmission from someone who is ill.
- In an affected community, a pandemic outbreak will last 6-8 weeks.
- The seasonality of a pandemic cannot be predicted with certainty. The largest waves in the U.S. pandemic history have occurred in the fall and winter.

The HHS plan for responding to pandemic influenza is built upon a decentralized approach. The roles of federal departments and agencies are described, as well as the critical support to states and localities provided through plans to provide vaccine and antiviral medications from the Strategic National Stockpile, but the success of the health care response rests primarily in the hands of state and local public health authorities.

ACP's following policy positions are based on issues raised in the HHS plan that explicitly or implicitly call for the involvement of physicians.

ACP Public Policy Positions on the Health Care Response to Pandemic Influenza

I. The Involvement of Physicians in Planning for Pandemic Influenza and Participating in the Health Care Response at all Levels

Position 1: ACP supports strengthening public health emergency preparedness efforts through supporting the development of local task forces that include physicians representing all practice settings. In addition to capacities stipulated in the HHS Plan, task forces should:

- Provide state and local plans for the pandemic influenza health care response to all licensed physicians and update them on changes or developments;
- Determine how to procure and stock medical supplies for health care providers at all local care provision sites, including hospitals, clinics, private practices, and alternative care sites.

When a pandemic develops, the scope of the event will place extraordinary and sustained demands on the U.S. health care system and health care providers. ACP believes that the health care response to any public health emergency, including pandemic influenza, must fully integrate the nation's physicians, regardless of specialty or place of practice, in order to decrease the rates of patient morbidity and mortality and to minimize social and economic disruption. It is imperative that physicians in all health care settings be aware of the issues posed by pandemic influenza and be prepared to participate in the health care response.

The HHS plan recommends that state health authorities establish local pandemic influenza task forces that will ensure community readiness to provide emergency support to health care facilities (i.e. hospitals) on a city-wide or regional basis. Representatives from professional organizations of physicians as well as hospitals, nurses, and other health care workers, are encouraged to participate on the task forces.

The HHS report lists several responsibilities for these yet-to-be-created task forces in cooperation with local health departments and hospitals, including:

- Improve communication with medical care providers and health care organizations.
- Monitor local hospital resources.
- Address emergency health care staffing needs and other medical surge capacity issues.
- Encourage coordination among state and federal health care facilities.
- Conduct contingency planning with private sector groups that support hospital functions; public utilities; local law enforcement agencies that "can help maintain order" if a hospital is overwhelmed; identify alternative care sites for patient care and sites for quarantine; and identify community-based organizations that can provide psychological and social support to health care workers and other emergency responders.

It is unclear what kind of support these task forces would receive to carry out such broad responsibilities or how they would develop the capacities necessary to carry out these responsibilities, but local task forces provide one of the few defined methods in the HHS plan of integrating nonhospital-based physicians into the health care response to pandemic influenza. The ACP believes there are several other opportunities to integrate physicians into the health care response, which are described in subsequent sections of this paper.

Position 2: The effective utilization of volunteer physicians and other health care providers in public health emergencies should be coordinated by federal or state agencies that are clearly authorized to determine licensing and register volunteer health care providers.

In the wake of tremendous health emergencies created by hurricanes and other natural disasters, thousands of U.S. health care providers have been motivated to seek ways to serve the people in need. There was recently an outpouring of generosity by physicians and health care providers who volunteered to help the ill and injured stuck in Hurricane Katrina's wake or displaced to other states. The health emergency created by pandemic influenza will create different dynamics where the need for health care volunteers will probably increase at the same time that the necessity of imposing infection control measures will decrease opportunities to mobilize a volunteer response. Considering pandemic conditions, in conjunction with lessons learned about utilizing volunteers in other emergencies, should provide a framework for improved organization of volunteer health care providers.

Once a pandemic begins, it will probably spread throughout the country very rapidly. The HHS plan depicts the pandemic environment as one where the public will not be encouraged to evacuate, as in other public emergencies like hurricanes or floods. Rather, measures will be taken by federal and state authorities to limit the movement of individuals within areas where cases of pandemic influenza have been discovered and to restrict travel to other areas. Opportunities to utilize volunteers from other areas will probably be limited. The HHS plan emphasizes that communities must be prepared in advance to bear a surge in infections on their own (9). Every community will be stressed, and there will be little surplus of health care providers, supplies or medications to take from one place and give to another. In this situation, maintaining the health and security of health care providers in every community will be critically important. If there is opportunity to utilize volunteers, physicians and other health care providers must be fully informed about how to participate.

Ensuring that volunteer physicians and health care providers are licensed to provide medical care is the responsibility of government. In times of crisis, local organizations must be assured that the volunteers they are receiving are who they represent themselves to be, but they will not have the time or capacity on the ground to make those determinations. The same state or federal government agencies insuring licensing and identification of volunteers providing health care can subsequently provide the terms of service, security, support and oversight of volunteers exclusively or in partnership with nongovernmental organizations. All pandemic preparedness plans should identify the agencies with responsibility for overseeing volunteer physicians and health care providers as well as the process for local authorities to request volunteers.

II. Effective Surveillance, Monitoring and Reporting During a Pandemic

Position 3: Effective surveillance, monitoring and reporting of patient health status during an influenza pandemic will be best accomplished by insuring that health care providers in every locality have access to two-way communications with public health authorities and health information technology tools. Public health authorities should:

- Identify interoperable communications systems available to public safety agencies in each locality and determine how health information during a public health emergency, such as a pandemic, can be communicated via those systems;
- Work closely with the Centers for Disease Control and Prevention (CDC) and other federal agencies to identify rapid diagnostics tools to identify cases of pandemic influenza;
- Plan for the rapid expansion of the Sentinel Providers Network and provide physicians with information and training in the use of rapid diagnostics tools;
- Involve local health care providers in the development of syndromic surveillance systems that will aid in the rapid detection of infectious disease outbreaks.

The HHS plan acknowledges that decreasing illness and saving lives during an influenza pandemic will require physician participation in rapid diagnosis and communication of confirmed influenza cases to public health authorities; implementation of best-practices for controlling the spread of the disease; and careful monitoring of infected patients and their response to treatment. These activities are necessary not only for the benefit of individual patients, but for the benefit of public health.

The HHS plan indicates that surveillance of influenza infections and the emergence of new strains will be handled through components of the existing national influenza surveillance system, which incorporates veterinary surveillance of animals and birds (10). Physicians in ambulatory care settings are integrated into this system primarily through the Sentinel Provider Network—consisting of approximately 2,300 health care providers nationwide who report the number of weekly outpatient visits for incidents linked to influenza and submit specimens from subsets of patients to state public health laboratories for testing. State public health offices are the primary point of contact for communicating surveillance with the CDC.

The HHS plan (11) encourages public health offices to support health care providers by making available specimen submission forms, rapid communication of test results and guidance on the use of commercially available rapid diagnostic tests for the detection of influenza. In addition, the development of city-wide and regional “syndrome-based” disease surveillance systems could be encouraged as a means of detecting early outbreaks of infectious diseases, such as pandemic influenza. Some early models of syndromic surveillance systems (12) show promise that these systems, utilizing electronic technologies, can be designed to support effective, two-way communications between health care providers in ambulatory settings and public health officials. For physicians, it is important that these systems are easily accessible, that reporting doesn’t take much time, and that the cost of participating is affordable.

Position 4: ACP policy recognizes the paramount importance of patient-doctor confidentiality. If breaching confidentiality is necessary, it should be done in a way that minimizes harm to the patient and that heeds applicable federal and state law. Public health authorities should:

- Provide clear and timely information to physicians to insure they understand when a public health emergency, such as pandemic influenza, creates legal obligations to adjust standard physician-patient confidentiality practices;
- Encourage physicians to continue to undertake an informed consent process whenever individuals are examined, tested, or treated, even in situations where physicians are obligated to override patient refusal of consent;
- Inform the public of the consequences of not consenting to a necessary examination, test, or treatment.

Doctor-patient confidentiality stems from the special relationship created when a prospective patient seeks the advice, care, and/or treatment of a physician. It is based upon the general principle that individuals seeking medical help or advice should not be inhibited by fear that their medical conditions will be disclosed to others. In the event of a public health emergency like pandemic influenza, some expectations of confidentiality will likely be altered or suspended.

It is critical that the public and health care providers clearly understand the laws governing surveillance, monitoring and reporting during a pandemic. The public health provision of the Health Insurance Portability and Accountability Act (HIPAA) permits, but does not require, covered entities, such as health care providers, to make public health disclosures. This provision is intended to allow continuation of current voluntary reporting practices that are critically important to public health and safety. The rule also permits covered entities to disclose protected health information when required for public health purposes by state or other law (13).

Position 5: ACP believes that infection control measures should be clear, fair and the least restrictive means necessary to protect public health. Physicians should not be penalized for failure to follow emergency orders that are not clear and timely and do not provide for due process to resolve situations outside the physician's control. Public health authorities should:

- Inform and advise the public and physicians about infection control measures in advance;
- Monitor whether infection control measures are creating barriers to patients receiving care.

The HHS plan lists recommendations to state and local partners on the use of disease containment strategies to prevent or decrease transmission (14). State and local partners are called upon to identify potential isolation and quarantine facilities; to establish procedures for medical evaluation and isolation of persons who exhibit signs of influenza-like illness; to establish procedures for delivering medical care, food and services to persons in isolation or quarantine; and establish procedures for issues related to employment compensation and job security.

Voluntary isolation or quarantine of contacts during an infectious period is preferable but the HHS plan notes that states and localities must make legal preparations to enforce isolation and quarantine measures if it is determined necessary to protect the public's health. Measures that affect the whole community, such as closure of offices, schools and public transportation, will be considered if there is moderate to extensive disease transmission in the area or cases are increasing among contacts of influenza patients.

Infection control practices that are not adequately explained to the public in advance may result in barriers to health care. Some patients may harbor fear of the infection-control practices they may be subjected to if they are infected and may refuse to seek treatment because of that fear.

III. The Provision of Vaccines and Antiviral Medications

Position 6: Ending the chronic delays in the delivery of vaccine and achieving vaccination targets for seasonal influenza is a public health prerequisite to developing a successful response to pandemic influenza and other public health emergencies. Public health authorities promoting seasonal influenza vaccination programs should:

- Develop local working groups with physicians that 1) plan for successful accounting of and outreach to high-risk populations; 2) streamline seasonal influenza vaccine procurement and distribution methods; 3) plan methods of introducing the public to the practice of vaccinating high-risk and high-priority groups first;
- Ensure that physicians in every locality have access to sufficient quantities of seasonal influenza and pneumococcal polysaccharide vaccines as well as antiviral medications to provide to patients in high-risk groups;
- Kick off seasonal influenza vaccination campaigns with pre-season vaccinations of all public safety officers and health care providers in direct contact with patients.

Analyzing local and state seasonal influenza vaccination programs could help to inform public health authorities on measures to take to better prepare for pandemic influenza. Unfortunately, the United States has not achieved vaccination rate targets and physicians serving at-risk patients have suffered from vaccine distribution delays. If these problems cannot be solved for the prevention and better management of seasonal influenza, the emergence of pandemic influenza may completely overwhelm the U.S. health care system.

The seventh leading cause of death in the United States among older adults is the combination of seasonal influenza and pneumonia and complications from these infections (15). Although numerous studies have demonstrated the value of these vaccines, annual immunization rates for influenza are less than 70 percent for people ages 65 and older (16). The rate of vaccination for pneumonia is approximately 50 percent for all people age 65 and older (17). Additionally, among adults at high-risk for complications due to influenza, CDC studies show that only 23 percent of those ages 18 to 49 receive influenza vaccinations and only 45 percent of those ages 50 to 64 receive influenza vaccinations (18).

It also must be noted that the rate of vaccination for annual influenza among health care workers is low. The CDC estimates that only 36 percent of health care workers (19), including all employees in health care settings with direct contact with patients, are vaccinated each year for influenza.

There are multiple reasons for the low rates of influenza vaccinations among adults in the United States, including the widespread perception that vaccinations are only for children, that “the flu” isn’t a serious disease and the lack of a vaccination requirement such as exists throughout the states for children’s enrollment in public schools. There also are economic disincentives for companies to produce vaccines due to safety and liability concerns, unpredictable public demand, the lengthy development process, and one-time sales to end-use customers. But in between the hurdles of producing vaccines and convincing people to seek vaccination, remain barriers caused by the lack of a streamlined system for distributing and administering existing vaccine to the people who need it most. Problems with seasonal influenza vaccine shortages and delayed distribution have plagued the United States for several years.

There have been two recent influenza vaccine shortages in the United States. In 2003, an unusually early onset of severe influenza outbreaks resulted in strong consumer demand for influenza vaccine. In the fall of 2004, CDC was notified by a vaccine manufacturer that none of its influenza vaccine would be available for distribution in the United States for the 2004-2005 influenza season thus reducing the expected supply of the trivalent inactivated vaccine (flu shots) by approximately one half (20).

In 2005, over 80 million doses of influenza vaccine were ordered by health care providers, one of the highest amounts of influenza vaccine ever ordered. In the fall public health officials, including the CDC, announced that there would not be an influenza vaccine shortage, but there would be delays in the delivery of vaccine to some health care providers. In November, during the National Influenza Vaccine Summit (21), physicians were notified that many communities and providers appeared to have ample supplies of influenza vaccine, some providers appeared to have used most of their influenza vaccine supplies, and other providers would still receive vaccine over the coming weeks. Some manufacturers were distributing partial orders to health care providers as vaccine became available. In the fall of 2005, it appeared that some businesses and large health care groups received priority for vaccine orders over physicians in small practices (22). CDC officials reported that they and other public health officials were working to make sure that the vaccine would eventually reach all high-risk groups.

The lack of an efficient vaccine distribution method that responds to public health priorities will have even more devastating consequences for Americans’ health should a pandemic emerge.

Based on the understanding that the pandemic vaccine will be in short supply, the HHS plan includes the recommendations of the Advisory Committee on Immunization Practices (ACIP) and the National Vaccine Advisory Committee (NVAC) for establishing tiers of priority groups to receive vaccine, in order to achieve equitable allocation as vaccine is produced. The primary goal considered was to decrease morbidity and death; the secondary goal included minimizing societal and economic impacts. ACIP and NVAC emphasize that their recommendations are based on the history of past influenza pandemics.

Vaccine Priority Group Recommendations (23)

Tier 1 Groups in order of priority:

1. Vaccine and antiviral manufacturers and others essential to manufacturing and critical support (approximately 40,000 people).
2. Medical workers and public health workers involved in direct patient contact, other support services essential for direct patient care and vaccinators (9 million).
3. Persons age 65 or higher with one or more influenza high-risk conditions, not including essential hypertension (18.2 million).
4. Persons six months to 64 years with two or more influenza high-risk conditions, not including essential hypertension (7 million).
5. Persons six months or older with a history of hospitalization for pneumonia or influenza or other influenza high-risk condition in the past year (740,000).
6. Pregnant women (3 million).
7. Household contacts of severely immunocompromised persons who would not be vaccinated due to likely poor response to vaccine (2.7 million).
8. Household contacts of children under six months old (5 million).
9. Public health emergency response workers critical to pandemic response (150,000).
10. Key government leaders.

Tier 1 covers approximately 46 million people. The remaining 247 million Americans fall in Tier 2.

During a pandemic, local vaccination and treatment plans must insure provision of care to physicians' patients who are in high-risk or high-priority groups. Allowing vaccine to be distributed first to customers who ordered more or ordered first will undermine efforts to provide health care fairly to those most in need.

Antiviral medications also need to be accessible to physicians providing care to high-risk and high-priority patients. Heightened public concern in 2005 resulted in a surge of prescriptions for antivirals that were believed to be effective against avian flu. If these medications are not secured for physicians treating patients, the HHS plan recommendations for treating the most ill patients first will not be realized. Stockpiling antiviral medications by individuals will not only contribute to an overall shortage of needed medication, but also may result in the misuse of the medications and result in building resistance to the drugs' effectiveness.

Position 7: ACP supports measures to increase pandemic influenza vaccine and antiviral medications in the Strategic National Stockpile. ACP supports the national procurement of vaccine in an amount sufficient to protect the entire U.S. population and national procurement of antiviral medications to cover 25 percent of the U.S. population. ACP believes that additional courses of antiviral medications should be safeguarded in the Strategic National Stockpile for all public safety officers and health care workers with direct patient contact in amounts sufficient to provide prophylaxis. In the event of pandemic influenza, stockpiled vaccine and antivirals should be distributed equitably to all states' public health authorities based on the numbers of people in high-risk and high-priority groups. Congress and federal agencies should:

- Provide funding on an as-needed basis for the federal procurement of pandemic influenza vaccine to cover the entire U.S. population and antiviral medications sufficient to treat 25 percent of the U.S. population, plus additional courses sufficient to provide prophylaxis for all public safety officers and health care workers in direct contact with patients;
- Establish equitable cost-sharing and subsidy plans with states that plan to procure antiviral medications in amounts exceeding their share of the Strategic National Stockpile;
- Establish equitable cost-sharing and subsidy plans with states that plan to procure other medications indicated for pandemic preparedness, such as antibiotics and pneumococcal polysaccharide vaccine.

National plans to stockpile vaccines and antiviral medications for use during an influenza pandemic are warranted given the scope of the threat to public health across the nation. Although the HHS plan indicates that only 20 million doses of prepandemic, experimental vaccine would be purchased by the federal government, with subsidies available to states to purchase more from manufacturers and distributors, the Bush administration has indicated that it plans to procure 40 million experimental doses and provide incentives to vaccine manufacturers to increase capacity and develop experimental vaccine in order that, by 2010, 600 million doses of pandemic influenza vaccine could be produced for the benefit of the entire U.S. population within six months of the start of a pandemic (24). ACP supports the goal of procurement of prepandemic vaccine for the entire population as manufacturing capacity improves, even though prepandemic vaccines cannot be precisely targeted to the pandemic strain. It is vital that prepandemic vaccine is purchased as available and procurement for the Strategic National Stockpile is not delayed for lack of appropriated funds.

The HHS plan indicates that 75 million courses of antiviral medication will be needed to cover 25 percent of the U.S. population (25). As of October 2005, HHS reported that the Strategic National Stockpile included 2.3 million treatment courses of oseltamivir (Tamiflu®) and 84,000 treatment courses of zanamivir (Relenza®). The Strategic National Stockpile expected delivery of an additional 2 million courses of Tamiflu by the end of 2005. The federal government has planned to purchase 44 million antiviral doses for treatment and another 6 million doses for domestic containment, while states would remain responsible for purchasing the remaining 31 million antiviral doses with some federal subsidy support (26).

This strategy is inefficient in securing an equitable distribution of antiviral medications. Requiring states to purchase antivirals individually will increase barriers to care for ill patients in states with less public funds available or that simply order antiviral medications too late. ACP recommends that the federal government purchase all 75 million doses of antiviral medication and utilize a distribution plan to the states similar to the plan for vaccine. States could still plan for the commercial purchase of antiviral medications in case they determine that they need to cover a larger number of people than their share of the Strategic National Stockpile dosages.

In the HHS plan, recommendations for priority groups to receive antiviral medications were based on the assumptions that two neuraminidase inhibitors (oseltamivir (Tamiflu®) and zanamivir (Relenza®)) will be effective; that symptoms will develop quickly and successful treatment will necessitate provision of antivirals within 48 hours of symptom onset; and that recommended amounts of antivirals will be stockpiled in advance of the onset of a pandemic. Treatment, rather than prophylaxis, is the preferred strategy of administering antiviral drugs for all groups except for health care workers in emergency departments, intensive care units, dialysis centers, and emergency medical service (EMS) providers; high-risk outpatients; and, last in the priority listing, other health care workers with direct patient contact. Physicians in inpatient and outpatient care settings are included in the second highest priority group for receiving antivirals as treatment.

Given the critical importance of all health care providers in a successful health care response to pandemic influenza, ACP recommends that all physicians and health care providers in direct contact with patients be given antiviral medications from the Strategic National Stockpile in amounts sufficient to provide prophylaxis. Also, the preparedness and health of public safety officers will be critically important during a pandemic. ACP recommends that all public safety officers be given antiviral medications from the Strategic National Stockpile in amounts sufficient to provide prophylaxis.

ACP supports measures to increase domestic production of vaccines and antiviral medications, including providing liability protections to decrease barriers to manufacturing while maintaining protections for individuals injured from the use of vaccines and antiviral medications. Although recommending vaccine development and production methods is not explicitly part of the HHS plan, there is support from national leaders for increasing new vaccine development methods and for supporting U.S.-based production of vaccine to combat pandemic influenza (27). Simultaneous to the effort to bolster vaccine production, immense pressure has been placed on the companies holding patents for the antiviral medications oseltamivir and zanamivir to increase production and license other companies to produce these antivirals in countries around the world. At least one new facility that will produce oseltamivir is planned for the United States (28). At the close of 2005, Congress passed the Public Readiness and Emergency Preparedness Act, which provides liability protections for those who produce and administer drugs and vaccines used in a declared public health emergency.

IV. The Necessity of Providing Care Outside of Hospital Settings

Position 8: ACP believes that an effective health care response to pandemic influenza will require utilizing all nonhospital-based health care providers to counsel, diagnose, treat and monitor patients outside of hospital settings in order to decrease the likelihood of surges that would overwhelm hospital capacity. Public health authorities should:

- Insure that vaccine is available, with safeguards insuring access by high-risk and high-priority groups first, in settings outside of hospitals in every locality;
- Insure that antiviral medications are available to health care providers in all care settings;
- Consult with local physicians to identify alternative community-based care sites for the provision of patient diagnosis, counseling and treatment;
- Identify community-based physician leadership for staffing alternative care sites and insure sites have access to public safety communications systems and security;
- Insure that alternative care sites are provided with medical supplies and diagnostics tools;
- Work closely with all health care providers in ambulatory care and hospital-based care settings in every locality to increase coordination of care management plans for patients inside and outside of hospitals;
- Assist physicians and other health care providers in developing community-based care management plans incorporating protocols for treating and monitoring patients at home;
- Consult with local physicians to develop risk communications tailored to each county and city to inform the public of when, how and where to seek health care in the event of pandemic influenza.

In the HHS plan Supplement 3: Health Care Planning, the roles and responsibilities for health care providers and public health partners are summarized. The report states that, based on extrapolation of the 1957 and 1968 pandemics, there could be up to 9 million hospitalizations and 42 million outpatient visits (29). The focus of the supplement is on the provision of care in hospitals, although there is a brief description of alternatives to hospital site usage. Recommendations for designing systems for home health care and follow-up on patients who return home is not much discussed. The limited consideration for treating patients outside of hospitals and the lack of guidance to health care providers outside of hospitals is the greatest weakness of the HHS plan.

This supplement highlights the planning elements for the interpandemic and pandemic alert periods with recommendations radiating out from a basic assumption that the provision of care will be centered at hospitals. Directives for the planning process are hospital-based and encourage planning committees to work with public health offices at all levels and to include representatives on the planning committees from “safety-net” providers in the local community. Physicians in ambulatory care settings are mentioned only within this context in the planning process recommendations.

The stark deficiencies in the capacity of the nation's hospitals to handle patient surges have been noted by many experts (30, 31). Most hospitals do not have a reserve of staff, isolation beds or equipment to treat a large increase of patients with pandemic influenza. The HHS plan notes that even a less-severe pandemic could overwhelm the surge capacity of the nation's hospitals. Yet planning for the health care response focuses on hospitals as the source of care not only for the most ill patients, but also the source of access to treatment. If the public perceives that treatment and medications during a pandemic are only available in hospitals, overwhelming surges on hospitals may be inevitable.

The section of the HHS plan covering provision of care in non-hospital settings notes the necessity of appropriate management of outpatient influenza cases to reduce demand for inpatient care and states "Most persons who seek care can be managed appropriately by outpatient providers." The supplement recommends that the management of outpatient care be based on an approach utilizing telephone hotlines to provide advice to the ill as to whether to stay home or seek care. The necessity of providing alternative care sites for large numbers of ill people is mentioned, but leadership in that regard is left to communities.

V. Physician Security During a Pandemic

Position 9: The safety of physicians and other health care providers must be provided for during public health emergencies, such as pandemic influenza. Physicians and other health care providers who are storing or administering vaccines, antiviral medications or pandemic-related medical supplies and equipment must be fully informed about preplanned security measures in the event of pandemic influenza.

When a pandemic develops, the American public will be frightened and uneasy. Physicians and other health care providers will be in direct contact with people who are worried about being infected and worried about accessing treatment. There will be high demand for a limited supply of medication. Unless the public understands and accepts the necessity of prioritizing treatment among certain groups and following infection control measures, there will be fear, confusion, anxiety and anger. Physicians and health care providers will need to plan for providing their own personal security, and to insure that preparedness plans include measures for providing for their security if the need arises.

Conclusion

The HHS Pandemic Influenza Plan provides a much-needed step forward in preparing for a potential public health emergency that would have severe consequences for the United States in terms of health and economic disruption. The plan provides a thorough overview of the impact of pandemic influenza and the components of an effective health care response. Guidance to state and local public health authorities touches on all the components for crafting a response, although the means of coordinating a comprehensive response between the relevant federal agencies and state and local public health offices are not given enough detailed explanation. Two aspects of the plan, which are discussed throughout this paper, raise particular concern for physicians.

The first is the clear assertion that, when a pandemic emerges, health care will have to be rationed. This assertion appears accurate, yet the plan fails to provide details how this fundamental change in the provision of health care will be achieved without the clear guidance and involvement of federal authorities to 1) educate the U.S. public about the need to respect schemes for prioritizing certain high-risk and high-priority groups for treatment and 2) provide leadership in the equitable distribution of vaccine and medicines to all Americans (according to group prioritization) without economic competition among the states and health care providers. The current discrepancies in seasonal influenza vaccine distribution throughout the country point out both a fundamental obstacle to providing treatment to those who need it most in a predictable and timely fashion, and an opportunity for developing better methods to address a health issue that is clearly parallel to the need to provide patient treatment and care in a pandemic.

The second major concern for physicians is the plan's failure to thoroughly incorporate the role of physicians in nonhospital-based settings in playing a leading role in the health care response. Failure to integrate physicians in local and state health care response plans will result in the underutilization of a key community resource and may contribute to an unnecessary bottleneck in the provision of patient care that will only serve to further strain the capacity of the nation's hospitals for treating the most severely ill. Although the state and local public health authorities can do much to further integrate physicians in the health care response efforts, leadership and commitment at a national level is needed to support physician involvement by providing the infrastructure and technological tools for decentralized communication, disease surveillance and diagnostics, and monitoring patient health in nonhospital settings.

Glossary

- Avian Flu** Avian influenza is an infection caused by avian (bird) influenza (flu) viruses. These influenza viruses occur naturally among birds. Wild birds worldwide carry the viruses, but usually do not get sick from them. However, avian influenza is very contagious among birds and can make some domesticated birds, including chickens, ducks, and turkeys, very sick and kill them.
- CDC** The Centers for Disease Control and Prevention: one of the 13 major operating components of the Department of Health and Human Services (HHS).
- H5N1** There are many different subtypes of type A influenza viruses. These subtypes differ because of changes in certain proteins on the surface of the influenza A virus (hemagglutinin [HA] and neuraminidase [NA] proteins). There are 16 known HA subtypes and 9 known NA subtypes of influenza A viruses. Many different combinations of HA and NA proteins are possible. Each combination represents a different subtype. The H5N1 virus is an influenza A virus subtype that occurs mainly in birds, is highly contagious among birds, and can be deadly to them. Of the few avian influenza viruses that have crossed the species barrier to infect humans, H5N1 has caused the largest number of detected cases of severe disease and death in humans.
- HHS** U.S. Department of Health and Human Services: the principal U.S. government agency responsible for health care.
- Pandemic Flu** An influenza pandemic is a global outbreak of disease that occurs when a new influenza A virus appears or “emerges” in the human population, causes serious illness, and then spreads easily from person to person worldwide.
- Seasonal Flu** Seasonal influenza outbreaks are caused by subtypes of influenza viruses that already circulate among people.
- WHO** World Health Organization: the United Nations specialized agency for health.

Notes

1. Cumulative Number of Confirmed Human Cases of Avian Influenza A/(H5N1) Reported to WHO. World Health Organization, Epidemic and Pandemic Alert and Response (EPR). March 21, 2006. Accessed at www.who.int/csr/disease/avian_influenza/country/cases_table_2006_03_21/en/index.html on 21 March 2006.
2. HHS Pandemic Influenza Plan, U.S. Department of Health and Human Services. November 2, 2005. Accessed at www.hhs.gov/pandemicflu/plan/ on 3 November 2005.
3. Bhat N. “Avian Flu: When? Where? How? And What We Can Do About It,” [speech]. PhRMA Alliance Development Briefing, St. Regis Hotel, Washington, DC. November 30, 2005.
4. National Strategy for Pandemic Influenza. White House. November 1, 2005. Accessed at www.whitehouse.gov/homeland/pandemic-influenza.html on 2 November 2005.
5. Avian flu frequently asked questions. World Health Organization, Epidemic and Pandemic Alert and Response (EPR). Accessed at www.who.int/csr/disease/avian_influenza/avian_faqs/en/index.html#whatare on 15 January 2006.
6. Cumulative Number of Confirmed Human Cases of Avian Influenza A/(H5N1) Reported to WHO. World Health Organization, Epidemic and Pandemic Alert and Response (EPR). March 21, 2006. Accessed at www.who.int/csr/disease/avian_influenza/country/cases_table_2006_03_21/en/index.html on 21 March 2006.
7. Key Facts About Avian Influenza (Bird Flu) and Avian Influenza A (H5N1) Virus. Centers for Disease Control and Prevention Control. January 10, 2006 Accessed at www.cdc.gov/flu/avian/gen-info/facts.htm on 11 January 2006.
8. Part 1: Strategic Plan. HHS Pandemic Influenza Plan. U.S. Department of Health and Human Services. November 2, 2005. Accessed at www.hhs.gov/pandemicflu/plan/part1.html on 3 November 2005.
9. Part 1: Strategic Plan. HHS Pandemic Influenza Plan. November 2, 2005. Accessed at www.hhs.gov/pandemicflu/plan/part1.html on 3 November 2005. See also, Bush Unveils Pandemic Flu Plan, MacNeil/Lehrer News Hour, Public Broadcasting Service [transcript]. November 1, 2005. Accessed at www.mindfully.org/Health/2005/Bush-Pandemic-Flu1nov05.htm on 11 January 2006.
10. Supplement 1 Pandemic Influenza Surveillance. HHS Pandemic Influenza Plan. November 2, 2005. Accessed at www.hhs.gov/pandemicflu/plan/sup1.html on 3 November 2005.
11. Supplement 2 Laboratory Diagnostics. HHS Pandemic Influenza Plan. November 2, 2005. Accessed at www.hhs.gov/pandemicflu/plan/sup2.html on 3 November 2005.
12. Ward T and Camden T. Experience with Syndrome-based Disease Surveillance in Lubbock, Texas: 1999-Present. [unpublished paper]. Released 2 February 2005.
13. Health Information Privacy and Civil Rights: Questions & Answers. US Department of Health and Human Services. Accessed at healthprivacy.answers.hhs.gov/cgi-bin/hipaa.cfg/php/enduser/std_alp.php?p_cv=1.7%3B2.u0&%20p_cats=7%2C0&%20cat_lvl1=7&cat_lvl2=0&p_search_text on 1 February 2006.
14. Supplement 4 Infection Control. HHS Pandemic Influenza Plan. November 2, 2005. Accessed at www.hhs.gov/pandemicflu/plan/sup4.html on 3 November 2005.
15. Immunization Issues: Adult Immunizations. National Network for Immunization Information. February 2, 2005. Accessed at www.immunizationinfo.org/immunization_issues_detail.cfv?id=97 on 11 January 2006.
16. The National Health Interview Survey, 1999. National Center for Health Statistics, Centers for Disease Control and Prevention. Accessed at www.cdc.gov/nip/coverage/NHIS/tables/NHIS-toc-99.htm on 14 December 2005.
17. The National Health Interview Survey, 1999. National Center for Health Statistics, Centers for Disease Control and Prevention. Accessed at www.cdc.gov/nip/coverage/NHIS/tables/NHIS-toc-99.htm on 14 December 2005.

18. The National Health Interview Survey, 1999, National Center for Health Statistics, Centers for Disease Control and Prevention. Accessed at www.cdc.gov/nip/coverage/NHIS/tables/NHIS-toc-99.htm on 14 December 2005. Persons categorized as “high-risk” for influenza-related complications self-reported one or more of the following conditions: diabetes, emphysema, coronary heart disease, angina, heart attack or other heart condition, being diagnosed with cancer in the last 12 months, or ever being told by a physician that they have lymphoma, leukemia or blood cancer, chronic bronchitis, weak or failing kidneys, or reporting an asthma episode or attack in the last 12 months.
19. Prevention and control of influenza: Recommendations of the Advisory Committee on Immunization Practices (ACIP). Centers for Disease Control and Prevention. *MMWR Weekly*. 2003;52(RR8):1-34.
20. Interim Influenza Vaccination Recommendations, 2004-05 Influenza Season. Centers for Disease Control and Prevention. *MMWR Weekly*. October 8, 2004;53(39): 923-924. Accessed at www.cdc.gov/mmwr/preview/mmwrhtml/mm5339a6.htm on 9 January 2006.
21. The National Influenza Vaccine Summit is a meeting hosted by the American Medical Association and the Centers for Disease Control and Prevention. Information about the outcomes of the 2005 meeting can be accessed at www.ama-assn.org/ama/pub/category/15887.html.
22. Fact Sheet on the 2005-2006 Influenza Vaccine Supply: Key Messages from the National Influenza Vaccine Summit. American College of Physicians-Adult Immunization Initiative. November 10, 2005. Accessed at www.acponline.org/aii/immuno_news.htm on 11 December 2005.
23. Appendix D: NVAC/ACIP Recommendations for Prioritization of Pandemic Influenza Vaccine and NVAC Recommendations on Pandemic Antiviral Drug Use. HHS Pandemic Influenza Plan. November 2, 2005. Accessed at www.hhs.gov/pandemicflu/plan/appendixd.html on 3 November 2005.
24. President Outlines Pandemic Influenza Preparations and Response. White House [press release]. November 1, 2005. Accessed at www.whitehouse.gov/news/releases/2005/11/20051101-1.html on 2 November 2005. See also, Gonyea D. Bush Unveils National Flu Pandemic Strategy. National Public Radio. November 1 2005. Accessed at www.npr.org/templates/story/story.php?storyId=4985281 on 3 December 2005.
25. Part 1: Strategic Plan. HHS Pandemic Influenza Plan. November 2, 2005. Accessed at www.hhs.gov/pandemicflu/plan/part1.html on 3 November 2005. The WHO recommends that nations be prepared to provide antiviral medications to at least 25 percent of their populations in the event of a pandemic. HHS has based its planning for provision of antivirals on the WHO recommendation.
26. Supplement 7 Antiviral Drug Distribution and Use. HHS Pandemic Influenza Plan. November 2, 2005. Accessed at www.hhs.gov/pandemicflu/plan/sup7.html on 3 November 2005. See also statement by HHS Secretary Michael O. Leavitt before the U.S. Senate Committee on Appropriations, Subcommittee on Labor, Health and Human Services, and Education. November 2 2005. Accessed at www.hhs.gov/asl/testify/t051102.html on 9 January 2006.
27. President Outlines Pandemic Influenza Preparations and Response. White House [press release]. November 1, 2005. Accessed at www.whitehouse.gov/news/releases/2005/11/20051101-1.html on 2 November 2005.
28. Roche to build Tamiflu plant in US. CIDRAP (Center for Infectious Disease Research and Policy) News. October 18, 2005. Accessed at www.cidrap.umn.edu/cidrap/content/influenza/biz-plan/news/oct1805roche.html on 14 December 2005.
29. Supplement 3 Healthcare Planning. HHS Pandemic Influenza Plan. November 2, 2005. Accessed at www.hhs.gov/pandemicflu/plan/sup3.html on 3 November 2005.
30. Hospital Preparedness: Most Urban Hospitals Have Emergency Plans but Lack Certain Capacities for Bioterrorism Response, Government Accountability Office, August 2003; GAO-03-924.
31. Jeff Goldsmith. Facing Reality in Preparing for Biological Warfare: A Conversation with George Poste. *Health Affairs*. Web exclusive interview; June 5 2002. Accessed at content.healthaffairs.org/cgi/content/full/hlthaff.w2.219v1/DC1 on 16 January 2006.



Product #520764000