

GAO

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INFLUENZA PANDEMIC

Challenges in Preparedness and Response

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Highlights of [GAO-05-863T](#), a testimony before the Committee on Government Reform, House of Representatives

Why GAO Did This Study

Shortages of influenza vaccine in the 2004–05 and previous influenza seasons and mounting concern about recent avian influenza activity in Asia have raised concern about the nation's preparedness to deal with a worldwide influenza epidemic, or influenza pandemic. Although the extent of such a pandemic cannot be predicted, according to the Centers for Disease Control and Prevention (CDC), an agency within the Department of Health and Human Services (HHS), it has been estimated that in the absence of any control measures such as vaccination or antiviral drugs, a "medium-level" influenza pandemic could kill up to 207,000 people in the United States, affect from 15 to 35 percent of the U.S. population, and generate associated costs ranging from \$71 billion to \$167 billion in the United States.

GAO was asked to discuss the challenges the nation faces in responding to the threat of an influenza pandemic, including the lessons learned from previous annual influenza seasons that can be applied to its preparedness and overall ability to respond to a pandemic. This testimony is based on GAO reports and testimony issued since 2000 on influenza vaccine supply, pandemic planning, emergency preparedness, and emerging infectious diseases and on current work examining the influenza vaccine shortage in the United States for the 2004–05 influenza season.

www.gao.gov/cgi-bin/getrpt?GAO-05-863T.

To view the full product, including the scope and methodology, click on the link above. For more information, contact Marcia Crosse at (202) 512-7119.

INFLUENZA PANDEMIC

Challenges in Preparedness and Response

What GAO Found

The nation faces multiple challenges to prepare for and respond to an influenza pandemic. First, key questions about the federal role in purchasing and distributing vaccines during a pandemic remain, and clear guidance on potential priority groups is lacking in HHS's current draft of its pandemic preparedness plan. For example, the draft plan does not establish the actions the federal government would take to purchase or distribute vaccine during an influenza pandemic. In addition, as was highlighted in the nation's recent experience responding to the unexpected influenza vaccine shortage for the 2004–05 influenza season, clear communication of the nation's response plan will be a major challenge. During the 2004–05 influenza season, state health officials reported that mixed messages created confusion. For example, CDC advised vaccination for persons aged 65 and older, and at the same time a state advised vaccination for persons aged 50 and older. Further challenges include ensuring an adequate and timely supply of influenza vaccine and antiviral drugs, which can help prevent or mitigate the number of influenza-related deaths. Particularly given the length of time needed to produce vaccines, influenza vaccine may be unavailable or in short supply and might not be widely available during the initial states of a pandemic. Finally, the lack of sufficient hospital and health care workforce capacity to respond to an infectious disease outbreak may also affect response efforts during an influenza pandemic. Public health officials we spoke with said that a large-scale outbreak, such as an influenza pandemic, could strain the available capacity of hospitals by requiring entire hospital sections, along with their staff, to be used as isolation facilities.

Mr. Chairman and Members of the Committee:

I am pleased to be here today as you discuss the nation's preparedness to respond to a worldwide influenza epidemic—known as a pandemic.¹ Shortages of influenza vaccine in the 2004–05 and previous annual influenza seasons, as well as mounting concern about recent avian influenza activity in Asia, have raised concern about the nation's preparedness to deal with a pandemic. Pandemic influenza, which arises periodically but unpredictably from a major genetic change in the influenza virus, can lead to worldwide disease and death.² Although the extent of the next pandemic cannot be predicted, modeling studies suggest that its effect in the United States could be severe. According to the Centers for Disease Control and Prevention (CDC), it has been estimated that in the absence of any control measures such as vaccination and drugs, a “medium-level” influenza pandemic in the United States could kill 89,000 to 207,000 people, affect from 15 to 35 percent of the U.S. population, and generate associated costs ranging from \$71 billion to \$167 billion. In the event of a pandemic, the nation will likely experience a vaccine shortage. The nation's experience responding to the unexpected shortage of annual influenza vaccine during the 2004–05 influenza season—in which public health officials sought to match available vaccine supply with demand—underscores the challenges that federal, state, and local entities would need to meet in the event of a pandemic. In addition, our recent work has highlighted other challenges in responding to pandemic influenza.

You asked us to provide our perspective on the nation's preparedness for responding to an influenza pandemic, including the lessons learned from previous annual influenza seasons that would be applicable to pandemic preparedness. In this testimony, I will discuss challenges we identified related to (1) planning for the purchase and distribution of influenza vaccine, including defining priority groups to be vaccinated; (2) communicating information about the situation and the response plan clearly and effectively among health officials, providers, and the public;

¹An influenza pandemic is defined by the emergence of a novel influenza virus, to which much or all of the population is susceptible, that is readily transmitted person to person, and causes outbreaks in multiple countries.

²Influenza pandemics can have successive “waves” of disease and last for up to 3 years. Three pandemics occurred in the 20th century: the “Spanish influenza” of 1918, which killed about 500,000 people in the United States; the “Asian influenza” of 1957, which killed about 70,000 people in the United States; and the “Hong Kong influenza” of 1968, which killed about 34,000 people in the United States.

(3) ensuring an adequate supply of vaccine and antiviral drugs; and
(4) addressing hospital and workforce capacity to respond to large-scale outbreaks of infectious disease, including pandemic influenza.

My testimony today is based on reports and testimony on influenza vaccine supply, pandemic planning, emergency preparedness, and emerging infectious diseases that we have issued since October 2000³ and on a review in progress for this committee on actions taken and lessons learned at federal, state, and local levels to ensure that high-risk individuals had access to vaccine during the 2004–05 influenza vaccine shortage. Our prior work includes analysis of information provided by and interviews with officials in the Department of Health and Human Services (HHS), specifically from CDC, the Food and Drug Administration (FDA), and the National Vaccine Program Office. We also interviewed public health department officials, vaccine manufacturers, and vaccine distributors; surveyed physician group practices; and reviewed HHS's August 2004 draft *Pandemic Influenza Preparedness and Response Plan*. Since March 2005 we have reviewed documents and interviewed officials from HHS, CDC, and the National Vaccine Program Office; national organizations, including the Association of State and Territorial Health Officials; organizations that conduct mass immunization clinics; a major vaccine manufacturer; and a large purchaser of influenza vaccine. We also conducted site visits at a judgmental sample of states and localities.⁴ We conducted our work in accordance with generally accepted government auditing standards. CDC and the National Vaccine Program Office provided comments on the facts contained in this statement, and we made changes as appropriate.

In summary, the nation faces multiple challenges to prepare for and respond to an influenza pandemic. First, key questions remain about the federal role in purchasing and distributing vaccines during a pandemic, and clear guidance on potential priority groups is lacking in HHS's current draft of its pandemic preparedness plan. In addition, as highlighted by the nation's recent experience responding to the unexpected influenza vaccine

³See "Related GAO Products" at the end of this testimony for a list of our earlier work related to infectious diseases, influenza vaccine supply, and pandemic planning.

⁴The states included California, Florida, Maine, Minnesota, and Washington, and the localities included San Diego and San Francisco, California; Miami-Dade County, Florida; Portland, Maine; Stearns County, Minnesota; and Seattle-King County, Washington. We selected these states and localities on the basis of geography, population size, and state vaccination success rates.

shortage for the 2004–05 influenza season, clear communication of the nation’s response plan will be a major challenge. Further challenges include ensuring an adequate and timely supply of influenza vaccine and antiviral drugs, which can help prevent or mitigate the number of influenza-related deaths. Finally, the lack of sufficient hospital and health care workforce capacity to respond to an infectious disease outbreak may also affect response efforts during an influenza pandemic.

Background

Influenza is more severe than some other viral respiratory infections, such as the common cold. Most people who contract influenza recover completely in 1 to 2 weeks, but some develop serious and potentially life-threatening medical complications, such as pneumonia. People aged 65 and older, people of any age with chronic medical conditions, children younger than 2 years, and pregnant women are generally more likely than others to develop severe complications from influenza.

Vaccination is the primary method for preventing influenza and its more severe complications. Produced in a complex process that involves growing viruses in millions of fertilized chicken eggs, influenza vaccine is administered annually to provide protection against particular influenza strains expected to be prevalent that year. Experience has shown that vaccine production generally takes 6 or more months after a virus strain has been identified; vaccines for certain influenza strains have been difficult to mass-produce. After vaccination, it takes about 2 weeks for the body to produce the antibodies that protect against infection. According to CDC recommendations, the optimal time for vaccination is October through November, because the annual influenza season typically does not peak until January or February. Thus, in most years vaccination in December or later can still be beneficial.

At present, two vaccine types are recommended for protection against influenza in the United States: an inactivated virus vaccine injected into muscle and a live virus vaccine administered as a nasal spray. The injectable vaccine—which represents the large majority of influenza vaccine administered in this country—can be used to immunize healthy individuals and those at highest risk for complications, including those with chronic illness and those aged 65 and older, but the nasal spray vaccine is currently approved for use only among healthy individuals aged 5 to 49 years who are not pregnant. Vaccine manufacture and purchase

take place largely within the private sector: for the 2004–05 influenza season, two companies (one producing the injectable vaccine and one producing the nasal spray) manufactured vaccine for the U.S. market.⁵

Although vaccination is the primary strategy for protecting individuals who are at greatest risk of serious complications and death from influenza, antiviral drugs can also contribute to the treatment and prevention of influenza. Four antiviral drugs have been approved for treatment. If taken within 2 days after symptoms begin, these drugs can reduce symptoms and make someone with influenza less contagious to others. Three of the four antiviral drugs are also approved for prevention; according to CDC, they are about 70 to 90 percent effective for preventing illness in healthy adults.

HHS has primary responsibility for coordinating the nation's response to public health emergencies. As part of its mission, the department has a role in the planning needed to prepare for and respond to an influenza pandemic. One action the department has taken is to develop a draft national pandemic influenza plan, titled *Pandemic Influenza Preparedness and Response Plan*, which was released in August 2004 for a 60-day comment period. Within HHS, CDC is the principal agency for protecting the nation's health and safety. CDC's activities include efforts to prevent and control diseases and to respond to public health emergencies. CDC and its Advisory Committee on Immunization Practices (ACIP) recommend which population groups should be targeted for vaccination each year and, when vaccine supply allows, recommends that any person who wishes to decrease his or her risk of influenza-like illness be vaccinated. FDA, another HHS agency, also plays a role in preparing for the annual influenza season and for a potential pandemic. FDA is responsible for ensuring that new vaccines and drugs are safe and effective. The agency also regulates and licenses vaccines and antiviral agents.⁶

HHS has limited authority to control vaccine production and distribution directly; influenza vaccine supply and marketing are largely in the hands of

⁵HHS also located and purchased about 1.5 million doses of vaccine from manufacturers not licensed in the United States. Although this vaccine could be made available to be administered under special protocols, according to HHS officials, none of the vaccine was used in the 2004–05 influenza season.

⁶In addition, FDA develops influenza reference strains and reagents and makes them available to manufacturers for vaccine development and evaluation.

the private sector.⁷ Although the Public Health Service Act authorizes the Secretary of HHS to “take such action as may be appropriate” to respond to a public health emergency, as determined and declared by the Secretary, it is not clear whether or to what extent the Secretary could directly influence the manufacture or distribution of influenza vaccine to respond to an influenza pandemic.⁸ The appropriateness of the Secretary’s response would depend on the nature of the public health emergency, for example on the available evidence relating to a pandemic. According to a senior HHS official involved in HHS emergency preparedness activities, manufacturers of vaccine for the U.S. market have agreed in principle to switch to production of pandemic influenza vaccine should the need arise and proper compensation and indemnification be provided; therefore, he said, it would probably be unnecessary for the federal government to nationalize vaccine production, although the federal government has the legal authority to do so if circumstances warrant it.

For the 2004–05 influenza season, CDC estimated as late as September 2004 that about 100 million doses of vaccine would be available for the U.S. market.⁹ CDC and ACIP recommended vaccination for about 185 million people, including roughly 85 million people at high risk for complications.¹⁰ On October 5, 2004, however, one manufacturer announced that it could not provide its expected production of 46–48 million doses—roughly half of the U.S. supply of expected vaccine.¹¹

⁷Under the Federal Food, Drug, and Cosmetic Act, FDA ensures compliance with good manufacturing practice. FDA has limited authority to prohibit the resale of prescription drugs, including influenza vaccine, that have been purchased by health care entities such as public or private hospitals. This authority would not extend to resale of the vaccine for emergency medical reasons. The term “health care entity” does not include wholesale distributors.

⁸According to the act, to declare a public health emergency, the Secretary must determine that (1) a disease or disorder presents a public health emergency or (2) a public health emergency, including significant outbreaks of infectious disease or bioterrorist attacks, otherwise exists. Public Health Service Act § 319 (current version at 42 U.S.C. § 247d).

⁹See Centers for Disease Control and Prevention, “Supplemental Recommendations about Timing of Influenza Vaccination, 2004–05 Season,” *Morbidity and Mortality Weekly Report*, vol. 53, no. 37 (2004): 878–879.

¹⁰Not everyone in target populations receives a vaccination each year. See Centers for Disease Control and Prevention, “Prevention and Control of Influenza Recommendations of the Advisory Committee on Immunization Practices (ACIP),” *Morbidity and Mortality Weekly Report*, vol. 53, no. RR-06 (2004): 1–40.

¹¹The license for this manufacturer, with production facilities in Liverpool, England, was temporarily suspended by British regulatory authorities.

Because a large proportion of vaccine produced by the other major manufacturer of injectable vaccine had already been shipped before October 5, 2004, about 25 million doses of injectable vaccine for high-risk individuals and others, and about 1 million doses of the nasal spray vaccine for healthy people, were available after the announcement to be distributed to Americans who wanted an influenza vaccination.

Preparing for and responding to an influenza pandemic differ in several respects from preparing for and responding to a typical influenza season. For example, past influenza pandemics have affected healthy young adults who are not typically at high risk for complications associated with influenza, and a pandemic could result in an overwhelming burden of ill persons requiring hospitalization or outpatient medical care. In addition, the demand for vaccine may be greater in a pandemic.

Planning for Purchase and Distribution of Vaccine and Defining Priority Groups

Challenges remain in planning for purchase and distribution of vaccine and defining priority groups in the event of a pandemic. HHS has not finalized planning for an influenza pandemic, leaving unanswered questions about the nation's ability to prepare for and respond to such an outbreak. For the past 5 years, we have been urging HHS to complete its pandemic influenza plan. The document remains in draft form, although federal officials said in June 2005 that an update of the plan is being completed and is expected to be available in summer 2005. Key questions about the federal role in purchasing and distributing vaccines during a pandemic remain, and clear guidance on potential groups that would likely have priority for vaccination is lacking in the current draft plan.

One challenge is that the draft pandemic plan does not establish the actions the federal government would take to purchase or distribute vaccine during an influenza pandemic. Rather, it describes options for vaccine purchase and distribution, which include public-sector purchase of all pandemic influenza vaccine; a mixed public-private system where public-sector supply may be targeted to specific priority groups; and maintenance of the current largely private system. The draft plan does not specifically recommend any of these options. According to the draft plan, the federal government's role may change over the course of a pandemic, with greater federal involvement early, when vaccine is in short supply. Noting that several uncertainties make planning vaccination strategies difficult, the draft plan states that national, state, and local planning needs to address possible contingencies, so that appropriate strategies are in place for whichever situation arises.

If public-sector vaccine purchase is an option, establishing the funding sources, authority, or processes to do so quickly may be needed. During the 2004–05 shortage, some state health officials reported problems with states’ ability, with regard to both funding and the administrative process, to purchase influenza vaccine. For example, during the effort to redistribute vaccine to locations of greatest need, the state of Minnesota tried to sell its available vaccine to other states seeking additional vaccine for their high-risk populations. According to federal and state health officials, however, certain states lacked the funding or authority under state law to purchase the vaccine when Minnesota offered it. In response to problems encountered during the 2004–05 shortage, the Association of Immunization Managers proposed in 2005 that federal funds be set aside for emergency purchase of vaccine by public health agencies and that cost not be a barrier in acquiring vaccine to distribute to the public.¹²

Although an influenza pandemic may differ from an annual influenza season, experience during the 2004–05 shortage illustrates the importance of having a distribution plan in place ahead of time to prevent delays when timing is critical:

- **Collaborating with stakeholders to create a workable distribution plan is time consuming.** After the October 5, 2004, announcement of the sharp reduction in influenza vaccine supply, CDC began working with the sole remaining manufacturer of injectable vaccine on plans to distribute this manufacturer’s remaining supply to providers across the country. The plan had two phases and benefited from voluntary compliance by the manufacturer to share proprietary information to help identify geographic areas of greatest need for vaccine. The first phase, which began in October 2004, filled or partially filled orders from certain provider types, including state and local public health departments and long-term care facilities. The second phase, which began in November 2004, used a formula to apportion the remaining doses across the states according to each state’s estimated percentage of the national unmet need. States could then allocate doses from their apportionment to providers and facilities, which would purchase the vaccine through a participating distributor. The state ordering process under the second phase continued through mid-January. Health officials in several states commented on the late availability of this vaccine; officials in one state, for example, remarked that the phase two vaccine was “too much, too late.”

¹²The Association of Immunization Managers is an organization that represents 64 state, territorial, and urban-area immunization programs funded by CDC.

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- **Identifying priority groups in local populations also takes time.** Federal, state, and local officials need to have information on the population of the priority groups and the locations where they can be vaccinated to know how, where, and to whom to distribute vaccine in the event of an influenza pandemic. During the 2004–05 influenza season, federal officials developed a distribution plan to allocate a limited amount of vaccine, but the states also had to determine how much vaccine was needed and where to distribute it within their own borders. For example, state health officials in Florida did not know exactly how many high-risk individuals needed vaccination, so they surveyed long-term care facilities and private providers to estimate the amount of vaccine needed to cover high-risk populations. It took nearly a month for state officials to compile the results of the surveys, to decide how many doses needed to be distributed to local areas, and to receive and ship vaccine to the counties.
 - **Distributing the vaccine to a state or locality is not the same as administering the vaccine to an individual.** Once vaccine has been distributed to a state or local agency, individuals living in those areas still need to be vaccinated. Vaccinating a large number of people is challenging, particularly when demand exceeds available supply. For example, during the 2004–05 influenza season, many places giving vaccinations right after the shortage was announced were overwhelmed with individuals wanting to be vaccinated. Certain local public health departments in California, including the Santa Clara County Public Health Department, provided chairs and extra water for people waiting in long lines outdoors in warm weather. Fear of a more virulent pandemic influenza strain could exacerbate such scenarios. A number of states reported that they did not have the capacity to immunize large numbers of people and partnered with other organizations to increase their capacity. For example, in 2004–05, according to state health officials in Florida, county health departments, including those in Orange and Broward Counties, worked with a national home health organization to immunize high-risk individuals by holding mass immunization clinics and setting up clinics in providers’ offices to help administer available vaccine quickly. Other locations, including the local health department in Portland, Maine, held lotteries for available vaccine; according to local health officials, however, administrative time was required to arrange and publicize the lottery.

HHS’s draft pandemic plan does not define priority groups for vaccination, although the plan states that HHS is developing an initial list of suggested priority groups and soliciting public comment on the list. The draft plan instructs the states to define priority groups for early vaccination and indicates that as information about virus severity becomes available,

recommendations will be formulated at the national level. According to the plan, setting priorities will be iterative, tied to vaccine availability and the pandemic's progression. Without agreed-upon identification of potential priority groups in advance, however, problems can arise. During the 2004–05 season, for example, CDC and ACIP acted quickly on October 5, 2004, to narrow the priority groups for available vaccine, giving the narrowed groups equal importance.¹³ In some places, however, there was not enough available vaccine to cover everyone in these narrowed priority groups, so states set their own priorities among these groups. Maine, for example, excluded health care workers from the state's early priority groups because state officials estimated that there was not enough vaccine to cover everyone in CDC and ACIP's priority groups.

Communicating Information about the Situation and Response Plan Clearly and Effectively

Another challenge in responding to a pandemic will be to clearly communicate information about the situation and the nation's response plans to public health officials, providers, and the public. Experience during the 2004–05 vaccine shortage illustrates the critical role communication plays when information about vaccine supply is unclear.¹⁴

- **Communicating a consistent message and clearly explaining any apparent inconsistencies.** In a pandemic, clear communication on who should be vaccinated will be important, particularly if the priority population differs from those targeted for annual influenza vaccination, or if the priority groups in one area of the country differ from those in others. During the 2004–05 influenza season, health officials in Minnesota reported that some confusion resulted when the state determined that

¹³On October 5, 2004, CDC, in coordination with ACIP, issued interim recommendations for influenza vaccination during the 2004–05 season that took precedence over earlier recommendations. The season's priority groups for vaccination with injectable influenza vaccine were considered to be of equal importance. They included all children aged 6–23 months, adults aged 65 years and older, persons aged 2–64 years with underlying chronic medical conditions, all women who would be pregnant during the influenza season, residents of nursing homes and long-term care facilities, children aged 6 months–18 years on chronic aspirin therapy, health care workers involved in direct patient care, and out-of-home caregivers and household contacts of children younger than 6 months. See Centers for Disease Control and Prevention, "Interim Influenza Vaccination Recommendations, 2004–05 Influenza Season," *Morbidity and Mortality Weekly Report*, vol. 53, no. 39 (2004): 923–924.

¹⁴According to CDC officials, as part of preparations for the 2005–06 influenza season, the agency is preparing communication strategies with appropriate messages to respond to the fluctuations in supply and demand anticipated throughout the season. CDC has developed the communication plan but has not released the plan, as it is in the clearance process.

vaccine was sufficient to meet demand among the state's narrower priority groups and made vaccine available to other groups, such as healthy individuals aged 50–64 years, earlier than recommended by CDC. Health officials in California reported a similar situation. State health officials pointed out that in mid-December, local radio stations in California were running two public service announcements—one from CDC advising those 65 and older to be vaccinated and one from the California Department of Health Services advising those 50 and older to be vaccinated. State officials emphasized that these mixed messages created confusion.

- **Communicating information from a primary source.** Having a primary and timely source of information will be important in a pandemic. In the 2004–05 influenza season, individuals seeking vaccine could have found themselves in a communication loop that provided no answers. For example, CDC advised people seeking influenza vaccine to contact their local public health department; in some cases however, individuals calling the local public health department would be told to call their primary care provider, and when they called their primary care provider, they would be told to call their local public health department. This lack of a reliable source of information led to confusion and possibly to high-risk individuals' giving up and not receiving the protection of an annual influenza vaccination.¹⁵
- **Recognizing that different communication mechanisms are important and require resources.** Another challenge in communicating plans in the event of a pandemic will be to ensure that the communication mechanisms used reach all affected populations. During the 2004–05 influenza season, public health officials reported the importance of different methods of communication. For example, officials from the Seattle–King County Public Health Department in Washington State reported that it was important to have a hotline as well as information posted on a Web site, because some seniors calling Seattle–King County's hotline reported that they did not have access to the Internet. According to state and local health officials, however, maintaining these communication mechanisms took time and strained personnel resources. In Minnesota, for example, to supplement state employees, the state health department

¹⁵ According to data collected during December 1–11, 2004, on self-reported vaccination during September 1 through November 30, 2004, among adults in priority groups who had not yet received influenza vaccine, about 23 percent reported that they attempted to obtain vaccination but could not. See Centers for Disease Control and Prevention, "Estimated Influenza Vaccination Coverage among Adults and Children—United States, September 1–November 30, 2004," *Morbidity and Mortality Weekly Report*, vol. 53, no. 49 (2004): 1147–1150.

asked public health nursing students to volunteer to staff the state's influenza vaccine hotline.

- **Educating health care providers and the public about all available vaccines.** For the 2004–05 season, approximately 3 million doses of nasal spray vaccine were ultimately available for vaccinating healthy individuals aged 5–49 years who were not pregnant, including some individuals (such as health care workers in this age group and household contacts of children younger than 6 months) in the priority groups defined by CDC and ACIP, yet some of these individuals were reluctant to use this vaccine because they feared that the live virus in the nasal spray could be transmitted to others. State health officials in Maine, for example, reported that the state purchased about 1,500 doses of the nasal spray vaccine for their emergency medical service personnel and health care workers, yet administered only 500 doses.

Ensuring Supply of Influenza Vaccine and Antiviral Drugs

Challenges in ensuring an adequate and timely supply of influenza vaccine and antiviral drugs—which can help prevent or mitigate the number of influenza-related deaths until an pandemic influenza vaccine becomes available—may be exacerbated during an influenza pandemic. Particularly given the time needed to produce vaccines, influenza vaccine may be unavailable or in short supply and may not be widely available during the initial stages of a pandemic. According to CDC, maintaining an abundant annual influenza vaccine supply is critically important for protecting the public's health and improving our preparedness for an influenza pandemic. The shortages of influenza vaccine in 2004–05 and previous seasons have highlighted the fragility of the influenza vaccine market and the need for its expansion and stabilization.

In its budget request for fiscal year 2006, CDC reports that it plans to take steps to ensure an expanded influenza vaccine supply. The agency's fiscal year 2006 budget request includes \$30 million for CDC to enter into guaranteed-purchase contracts with vaccine manufacturers to ensure the production of bulk monovalent influenza vaccine. If supplies fall short, this bulk product can be turned into a finished trivalent influenza vaccine product for annual distribution.¹⁶ If supplies are sufficient, the bulk vaccine can be held until the following year's influenza season and developed into finished vaccines if the bulk products maintain their

¹⁶ Monovalent influenza vaccine protects against a single strain of influenza; trivalent influenza vaccine protects against three strains of influenza.

potency and the circulating strains remain the same. According to CDC, this guarantee will help expand the influenza market by providing an incentive to manufacturers to expand capacity and possibly encourage additional manufacturers to enter the market. In addition, CDC's fiscal year 2006 budget request includes an increase of \$20 million to support influenza vaccine purchase activities.¹⁷

In the event of a pandemic, before a vaccine is available or during a period of limited vaccine supply, use of antiviral drugs could have a significant effect. Antiviral drugs can be used against all strains of pandemic influenza and, because they can be manufactured and stored before they are needed, could be available both to prevent illness and, if administered within 48 hours after symptoms begin, to treat it. Like vaccine, antiviral drugs take several months to produce from raw materials, and according to one antiviral drug manufacturer, the lead time needed to scale up production capacity and build stockpiles may make it difficult to meet any large-scale, unanticipated demand immediately. HHS' National Vaccine Program Office also reported that in a pandemic, the manufacturing capacity and supply of antiviral drugs is likely to be less than the global demand. For these reasons, the National Vaccine Program Office reported that analysis is under way to determine optimal strategies for antiviral drug use when supplies are suboptimal; the office also noted that antiviral drugs have been included in the national stockpile. HHS has purchased more than 7 million doses of antiviral drugs for the national stockpile.

Nevertheless, this stockpile is limited, and it is unclear how much will be available in the event of a pandemic, given existing production capacity. Moreover, some influenza virus strains can become resistant to one or more of the four approved influenza antiviral drugs, and thus the drugs may not always work. For example, the avian influenza virus strain (H5N1) identified in human patients in Asia in 2004 and 2005 has been resistant to two of four existing antiviral drugs.

¹⁷The \$20 million increase is for CDC's Immunization Grant Program that provides vaccines for children, adolescents, and adults who present primarily at local health departments but are not eligible for CDC's Vaccines for Children program.

Hospital and Workforce Capacity to Respond to Large-Scale Infectious Disease Outbreaks

The lack of sufficient hospital and workforce capacity is another challenge that may affect response efforts during an influenza pandemic. The lack of sufficient capacity could be more severe during an influenza pandemic compared with other natural disasters, such as a tornado or hurricane, or with an intentional release of a bioterrorist agent because it is likely that a pandemic would result in widespread and sustained effects. Public health officials we spoke with said that a large-scale outbreak, such as an influenza pandemic, could strain the available capacity of hospitals by requiring entire hospital sections, along with their staff, to be used as isolation facilities. In addition, most states lack surge capacity—the ability to respond to the large influx of patients that occurs during a public health emergency. For example, few states reported having the capacity to evaluate, diagnose, and treat 500 or more patients involved in a single incident. In addition, few states reported having the capacity to rapidly establish clinics to immunize or treat large numbers of patients. Moreover, shortages in the health care workforce could occur during an influenza pandemic because higher disease rates could result in high rates of absenteeism among workers who are likely to be at increased risk of exposure and illness or who may need to care for ill family members.

Concluding Observations

Important challenges remain in the nation's preparedness and response should an influenza pandemic occur in the United States. As we learned in the 2004–05 influenza season, when vaccine supply, relative to demand, is limited, planning and effective communication are critical to ensure timely delivery of vaccine to those who need it. HHS's current draft plan lacks some key information for planning our nation's response to a pandemic. It is important for the federal government and the states to work through critical issues—such as how vaccine will be purchased, distributed, and administered; which population groups are likely to have priority for vaccination; what communication strategies are most effective; and how to address issues related to vaccine and antiviral supply and hospital and workforce capacity—before we are in a time of crisis. Although HHS contends that agency flexibility is needed during a pandemic, until key federal decisions are made, public health officials at all levels may find it difficult to plan for an influenza pandemic, and the timeliness and adequacy of response efforts may be compromised.

Mr. Chairman, this concludes my prepared statement. I would be happy to respond to any questions you or other Members of the Committee may have at this time.

GAO Contact and Staff Acknowledgments

For further information about this testimony, please contact Marcia Crosse at (202) 512-7119. Jennifer Major, Nick Larson, Gay Hee Lee, Kim Yamane, George Bogart, and Ellen W. Chu made key contributions to this statement.

Related GAO Products

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