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Report to the Chairman, Committee on Homeland Security, House of Representatives

February 2009

INFLUENZA PANDEMIC

Sustaining Focus on the Nation's Planning and Preparedness Efforts

GAO-09-334

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Highlights

Highlights of GAO-09-334, a report to the Chairman, Committee on Homeland Security, House of Representatives

Why GAO Did This Study

GAO has conducted a body of work over the past several years to help the nation better prepare for, respond to, and recover from a possible influenza pandemic, which could result from a novel strain of influenza virus for which there is little resistance and which therefore is highly transmissible among humans. GAO's work has pointed out that while the previous administration had taken a number of actions to plan for a pandemic, including developing a national strategy and implementation plan, much more needs to be done. However, national priorities are shifting as a pandemic has yet to occur, and other national issues have become more immediate and pressing. Nevertheless, an influenza pandemic remains a real threat to our nation and the world.

For this report, GAO synthesized the results of 11 reports and two testimonies issued over the past 3 years using six key thematic areas: (1) leadership, authority, and coordination; (2) detecting threats and managing risks; (3) planning, training, and exercising; (4) capacity to respond and recover; (5) information sharing and communication; and (6) performance and accountability. GAO also updated the status of recommendations in these reports.

What GAO Recommends

This report does not make new recommendations. However, the report discusses the status of GAO's prior recommendations on the nation's planning and preparedness for a pandemic.

To view the full product, including the scope and methodology, click on GAO-09-334. For more information, contact Bernice Steinhardt at (202) 512-6543 or steinhardtb@gao.gov.

What GAO Found

Leadership roles and responsibilities need to be clarified and tested, and coordination mechanisms could be better utilized. Shared leadership roles and responsibilities between the Departments of Health and Human Services (HHS) and Homeland Security (DHS) and other entities are evolving, and will require further testing and exercising before they are well understood. Although there are mechanisms in place to facilitate coordination between federal, state, and local governments and the private sector to prepare for an influenza pandemic, these could be more fully utilized.

Efforts are underway to improve the surveillance and detection of pandemic-related threats, but targeting assistance to countries at the greatest risk has been based on incomplete information. Steps have been taken to improve international disease surveillance and detection efforts. However, information gaps limit the capacity for comprehensive comparisons of risk levels by country.

Pandemic planning and exercising has occurred, but planning gaps remain. The United States and other countries, as well as states and localities, have developed influenza pandemic plans. Yet, additional planning needs still exist. For example, the national strategy and implementation plan omitted some key elements, and HHS found many major gaps in states' pandemic plans.

Further actions are needed to address the capacity to respond to and recover from an influenza pandemic. An outbreak will require additional capacity in many areas, including the procurement of additional patient treatment space and the acquisition and distribution of medical and other critical supplies, such as antivirals and vaccines for an influenza pandemic.

Federal agencies have provided considerable guidance and pandemic-related information, but could augment their efforts. Federal agencies, such as HHS and DHS, have shared information in a number of ways, such as through Web sites and guidance, but state and local governments and private sector representatives would welcome additional information on vaccine distribution and other topics.

Performance monitoring and accountability for pandemic preparedness needs strengthening. Although certain performance measures have been established in the National Pandemic Implementation Plan to prepare for an influenza pandemic, these measures are not always linked to results. Further, the plan does not contain information on the financial resources needed to implement it.

GAO has made 23 recommendations in its reports—13 of these have been implemented and 10 remain outstanding. Continued leadership focus on pandemic preparedness remains vital, as the threat has not diminished.

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Abbreviations

APHIS	Animal and Plant Health Inspection Service
CBO	Congressional Budget Office
CDC	Centers for Disease Control and Prevention
DHS	Department of Homeland Security
DOD	Department of Defense
EMAC	Emergency Management Assistance Compact
FAO	Food and Agriculture Organization
FCO	Federal Coordinating Officer
FEB	federal executive board
FEMA	Federal Emergency Management Agency
HHS	Department of Health and Human Services
HSC	Homeland Security Council
NGA	National Governors Association
National Pandemic Implementation Plan	*National Strategy for Pandemic Influenza Implementation Plan*
National Pandemic Strategy	*National Strategy for Pandemic Influenza*
NRF	*National Response Framework*
OIE	World Organisation for Animal Health
OPM	Office of Personnel Management
PFO	Principal Federal Official
SEC	Securities and Exchange Commission
UNSIC	United Nations System Influenza Coordinator
USAID	United States Agency for International Development
USDA	United States Department of Agriculture
WHO	World Health Organization

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Accountability * Integrity * Reliability

United States Government Accountability Office
Washington, DC 20548

February 26, 2009

The Honorable Bennie G. Thompson
Chairman
Committee on Homeland Security
House of Representatives

Dear Mr. Chairman:

As you know, we conducted a body of work over the past several years to help the nation better prepare for, respond to, and recover from a possible influenza pandemic. Our work has pointed out that while the previous administration had taken a number of actions to plan for a pandemic, including developing a national strategy and implementation plan, much more needs to be done. At the same time, however, national priorities are shifting as a pandemic has yet to occur, and the nation's financial crisis and other national issues have become more immediate and pressing. Nevertheless, an influenza pandemic remains a real threat to our nation and to the world. Strengthening preparedness for large-scale public health emergencies, such as an influenza pandemic, is one of the 13 urgent issues that we identified as among those needing the immediate attention of the new administration and Congress during this transition period.[1] As your Committee also recently reported, there are opportunities to renew federal efforts to protect our country against influenza pandemic in the new administration.[2]

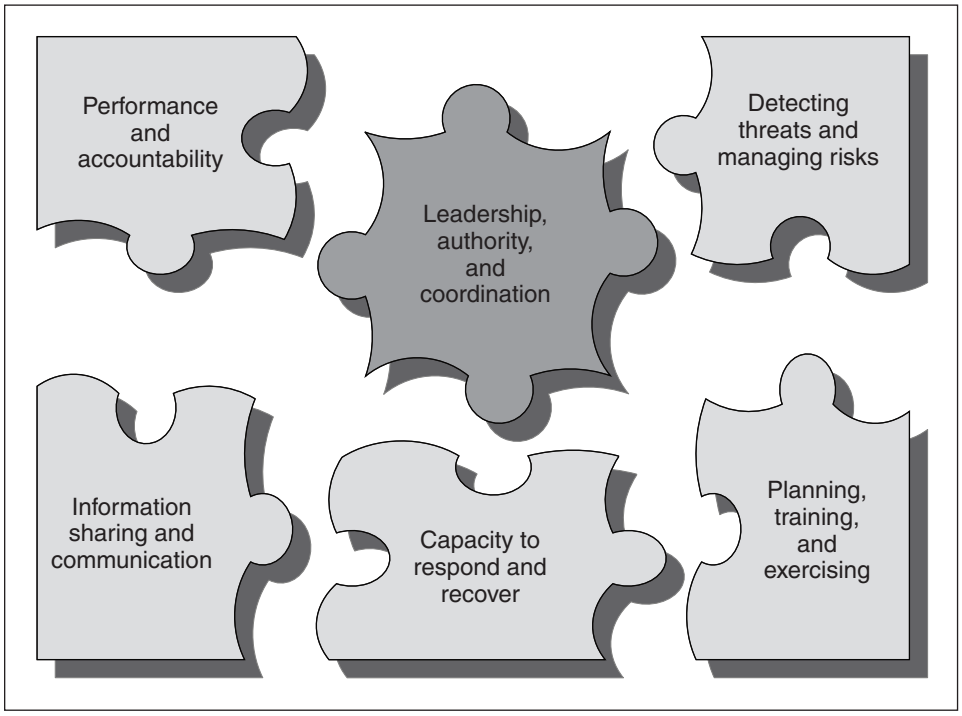
Given the consequences of a severe influenza pandemic, in 2006 we developed a strategy for our work that would help support Congress's decision making and oversight related to pandemic planning. Our strategy was built on a large body of work spanning two decades, including reviews of government responses to prior disasters such as Hurricanes Andrew and Katrina, the devastation caused by the 9/11 terror attacks, efforts to address the Year 2000 (Y2K) computer challenges, and assessments of public health capacities in the face of bioterrorism and emerging infectious diseases such as Severe Acute Respiratory Syndrome (SARS).

[1]GAO's 2009 Congressional and Presidential Transition Web site: http://www.gao.gov/transition_2009.

[2]House Committee on Homeland Security, *Getting Beyond Getting Ready for Pandemic Influenza*, a report prepared by the majority staff, 111th Cong., 1st sess., January 2009.

The strategy was built around six key themes as shown in figure 1. While all of these themes are interrelated, our earlier work underscored the importance of leadership, authority, and coordination, a theme that touches on all aspects of preparing for, responding to, and recovering from an influenza pandemic.

Figure 1: Key Themes of GAO's Pandemic Strategy



Source: GAO.

At your request, this report synthesizes the work thus far completed under this strategy. In the past 3 years, we have issued 11 reports and two testimonies on influenza pandemic planning, which address these key themes. We have made 23 recommendations based on the findings from many of these reports and testimonies. Thirteen of these recommendations have been acted upon by the responsible federal agencies, but while the responsible federal agencies have generally agreed with our recommendations, 10 recommendations have not yet been implemented. We also have three pandemic-related reviews underway on the following topics: (1) the status of implementing the *National Strategy for Pandemic Influenza Implementation Plan* (National Pandemic

Implementation Plan); (2) plans to protect the federal workforce in a pandemic; and (3) the effect of a pandemic on the telecommunications capacity needed to sustain critical financial market activities. A list of our open and implemented recommendations can be found in appendices I and II. While this report makes no new recommendations, we have updated the status of recommendations that have not yet been implemented. A list of our related GAO products that are referenced throughout this report is located after appendix III.

We also collaborated with several state and local audit offices on coordinated audits of state and local pandemic planning and consulted with audit offices from a number of countries on pandemic-related activities through our external partnerships. These countries include Austria, Belgium, Cambodia, Canada, Germany, Indonesia, Japan, Kazakhstan, Sweden, the United Kingdom, and Vietnam. We have also drawn from audits of pandemic planning and exercising conducted by audit officials in Portland, Oregon; Kansas City, Missouri; and New York state. Finally, we have incorporated recent studies conducted by the Congressional Budget Office (CBO), National Governors Association (NGA), United Nations System Influenza Coordinator (UNSIC), and the World Bank.

This report is largely based on our prior work, which was conducted in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Results in Brief

We have synthesized the results from our pandemic work over the past few years by the six key themes in our pandemic strategy, as follows:

Leadership roles and responsibilities need to be clarified and tested, and coordination mechanisms could be better utilized. Federal government leadership roles and responsibilities for pandemic preparedness and response are evolving, and will require further testing before the relationships among the many federal leadership positions are well understood. Such clarity in leadership is even more crucial now given the change in administration and the associated transition of senior federal officials. Although there are mechanisms in place to facilitate coordination between federal, state, and local governments and the private

sector to prepare for an influenza pandemic, these could be more fully utilized. For example, a system of coordinating councils that facilitates planning between government and the private sector for critical infrastructure protection could be better used to help resolve key challenges to public and private sector coordination. In addition, some federal executive boards (FEB), which bring together federal agencies and community leaders outside of Washington, D.C., have established relationships with state and local governments and community organizations that could be useful in pandemic preparedness and response. As a result of our recommendations, FEBs were included in the *National Response Framework* (NRF)[3] in January 2008 as one of the regional support structures that have the potential to contribute to the development of situational awareness during an emergency.

Efforts are underway to improve the surveillance and detection of pandemic-related threats in humans and animals, but targeting assistance to countries at the greatest risk has been based on incomplete information. International disease surveillance and detection efforts serve as an early warning system that could prevent the spread of an influenza pandemic outbreak. The United States and its international partners are involved in efforts to improve pandemic surveillance, including diagnostic capabilities, so that outbreaks can be quickly detected. Yet, international capacity for surveillance has many weaknesses, particularly in developing countries. Animal surveillance is also a key part of this early warning system. Controlling an outbreak in poultry would be instrumental to reducing the risk of a human pandemic. While the U.S. Department of Agriculture (USDA) has created a National Avian Influenza Surveillance System to link existing avian influenza surveillance data from USDA, other federal and state agencies, and industry, federal and state officials generally do not know the numbers and locations of backyard birds so controlling an outbreak of avian influenza among these birds remains particularly difficult. Finally, at the time of our 2007 review, assessments by U.S. agencies and international organizations were used to target assistance to countries at risk, but the information on which those assessments were based was not sufficiently

[3]Issued in January 2008 by the Department of Homeland Security (DHS) and effective in March 2008, the NRF is a guide to how the nation conducts all-hazards incident response and replaces the *National Response Plan*. It focuses on how the federal government is organized to support communities and states in catastrophic incidents. The NRF builds upon the National Incident Management System, which provides a national template for managing incidents.

detailed or was incomplete, limiting their value for comprehensive comparisons of risk levels by country.

Pandemic planning and exercising has occurred in the United States and other countries, but planning gaps remain. The U.S. government has worked with its international partners to develop an overall global strategy that is compatible with the U.S. approach. Other countries, including Belgium, Japan, Sweden, and the United Kingdom, have also developed influenza pandemic plans and frameworks. While the *National Strategy for Pandemic Influenza* (National Pandemic Strategy) and National Pandemic Implementation Plan are important first steps in guiding national preparedness, important gaps exist that could hinder the ability of key stakeholders to effectively execute their responsibilities. For example, state and local jurisdictions that will play crucial roles in preparing for and responding to a pandemic were not directly involved in developing the National Pandemic Implementation Plan, even though it relies on these stakeholders' efforts. Further, USDA response plans did not identify entities responsible for carrying out tasks associated with an outbreak scenario. At the state level, we found that each state has developed a pandemic plan and conducted pandemic exercises as required by federal pandemic funding guidance. However, according to an interagency assessment, on average, states had "many major gaps" in their plans, and the Department of Health and Human Services (HHS) has recently reported that most states continue to have major gaps in their pandemic plans. Officials in states and localities reported that they would welcome additional guidance from the federal government to help them better plan and exercise for an influenza pandemic, for example, on how to implement community interventions such as closing schools. In the private sector, in response to our recommendation, financial market organizations were directed by their federal regulators to ensure that the pandemic plans they have in place are adequate to maintain critical operations during a severe outbreak.

Further actions are needed to address the capacity to respond to and recover from an influenza pandemic. Improving the nation's response capability to catastrophic disasters, such as an influenza pandemic, is essential. Following a mass casualty event, health care systems would need the ability to adequately care for a large number of patients or patients with unusual or highly specialized medical needs. The ability of local or regional health care systems to deliver services could be compromised, at least in the short term, because the volume of patients would far exceed the available hospital beds, medical personnel, pharmaceuticals, equipment, and supplies. Further, in natural and man-

made disasters, assistance from other states may be used to increase capacity, but in a pandemic, states would likely be reluctant to provide assistance to each other due to scarce resources and fears of infection. The federal government has provided some guidance and funding to help states plan for additional capacity. For example, the federal government provided guidance for states to use when preparing for medical surge and on prioritizing target groups for an influenza pandemic vaccine. However, an outbreak will require additional capacity in many areas, including the procurement of additional patient treatment space and the acquisition and distribution of medical and other critical supplies, such as antivirals and vaccines for an influenza pandemic.[4] In a severe pandemic, the demand would exceed the available hospital bed capacity, which would be further challenged by the existing shortages of health care providers and their potential high rates of absenteeism. In addition, the availability of antivirals and vaccines could be inadequate to meet demand due to limited production, distribution, and administration capacity.

Federal agencies have provided considerable guidance and pandemic-related information, but could augment their efforts. Federal agencies, including HHS and the Department of Homeland Security (DHS), have shared pandemic-related information in a number of ways, such as through Web sites, guidance, and state summits and meetings, and are using established networks, including the FEBs and coordinating councils for critical infrastructure protection, to share information about pandemic preparedness, response, and recovery. Federal agencies have established an influenza pandemic Web site (www.pandemicflu.gov) and disseminated pandemic preparedness checklists for workplaces, individuals and families, schools, health care, community organizations, and state and local governments. However, private sector and state and local government officials continue to look for additional guidance and clarification from the federal government for specific topics, such as state border closures and fatality management.

Performance monitoring and accountability for pandemic preparedness needs strengthening. While the National Pandemic Strategy and Implementation Plan identify overarching goals and objectives for pandemic planning, the documents are not altogether clear

[4]Antivirals can prevent or reduce the severity of a viral infection, such as influenza. Vaccines are used to stimulate the production of an immune system response to protect the body from disease.

on the roles, responsibilities, and requirements to carry out the plan. Some of the action items in the National Pandemic Implementation Plan, particularly those that are to be completed by state, local, and tribal governments or the private sector, do not identify an entity responsible for carrying out the action. Moreover, the National Pandemic Strategy and Implementation Plan do not provide information on the financial resources needed to implement them, which is one of six characteristics of an effective national strategy that we have identified.[5] As a result, the documents do not provide a picture of priorities or how adjustments might be made in view of resource constraints. In the case of the Department of Defense (DOD), although it had instituted reporting requirements for its components responsible for implementing action items tasked to DOD in the National Pandemic Implementation Plan, there were not similar oversight mechanisms in place for other pandemic-related tasks. For example, DOD did not require its components to report on their development or revision of their continuity of operations plans in preparation for an influenza pandemic.

Strengthening preparedness for large-scale public health emergencies, including the possibility of an influenza pandemic, is one of the urgent issues that we identified as among those needing the immediate attention of the new administration and Congress during this transition period. Although much has been done, many challenges remain, with almost half the recommendations that we have made over the past 3 years still not fully implemented. It will be essential for the administration to test the shared leadership roles that have been established between HHS and DHS, as these roles and responsibilities continue to evolve, as well as the relative roles, responsibilities and authorities for an influenza pandemic among the federal government, state and local governments, and the private sector. DHS and HHS should, in coordination with other federal agencies, continue to work with states and local governments to help them address identified gaps in their pandemic planning, as well as with the private sector through the critical infrastructure coordinating councils. Despite other more immediate national priorities, the threat of a severe influenza pandemic remains, and the administration should maintain momentum in preparing the nation.

[5]The six characteristics of an effective national strategy include: (1) purpose, scope, and methodology, (2) problem definition and risk assessment, (3) goals, subordinate objectives, activities, and performance measures, (4) resources, investments, and risk management, (5) organizational roles, responsibilities, and coordination, and (6) integration and implementation.

Background

Influenza pandemic—caused by a novel strain of influenza virus for which there is little resistance and which therefore is highly transmissible among humans—continues to be a real and significant threat facing the United States and the world. While some scientists and public health experts believe that the next influenza pandemic could be caused by a highly pathogenic strain of the H5N1 avian influenza virus (also known as "bird flu")[6] that is currently circulating in parts of Asia, Europe, and Africa, it is unknown when an influenza pandemic will occur, where it will begin, or whether an H5N1 virus or another strain would be the cause. Influenza pandemic poses a grave threat to global public health at a time when the United Nations' World Health Organization (WHO) has said that infectious diseases are spreading faster than at any time in history. Influenza pandemics have spread worldwide within months, and a future pandemic is expected to spread even more quickly given modern travel patterns.

Unlike incidents that are discretely bounded in space or time (e.g., most natural or man-made disasters), an influenza pandemic is not a singular event, but is likely to come in waves, each lasting weeks or months, and pass through communities of all sizes across the nation and the world simultaneously. While a pandemic will not directly damage physical infrastructure such as power lines or computer systems, it threatens the operation of critical systems by potentially removing the essential personnel needed to operate them from the workplace for weeks or months. In a severe pandemic, absences attributable to illnesses, the need to care for ill family members, and fear of infection may, according to the Centers for Disease Control and Prevention (CDC), reach a projected 40 percent during the peak weeks of a community outbreak, with lower rates of absence during the weeks before and after the peak.[7] In addition, an influenza pandemic could result in 200,000 to 2 million deaths in the United States, depending on its severity.

[6]Avian influenza viruses are classified as either "low pathogenic" or "highly pathogenic" based on their genetic features and the severity of the disease they cause in poultry. Highly pathogenic avian influenza viruses are associated with high morbidity and mortality in poultry. Health experts are concerned that should highly pathogenic H5N1 or another subtype, to which humans have no immunity, develop the capacity to spread easily from person to person, an influenza pandemic could occur in humans.

[7]GAO, *Influenza Pandemic: Further Efforts Are Needed to Ensure Clearer Federal Leadership Roles and an Effective National Strategy*, GAO-07-781 (Washington, D.C.: August 14, 2007).

In addition to the profound human costs in terms of illnesses and deaths, the economic and societal repercussions of a pandemic could be significant. In its December 2005 report on possible macroeconomic effects and policy issues related to a potential influenza pandemic, CBO stated that a severe influenza pandemic, similar to the 1918-1919 pandemic, might cause a decline in U.S. gross domestic product of about 4.25 percent.[8] CBO updated its report in July 2006 to include some estimates from medical experts that suggest that CBO may have initially underestimated the economic impact.[9] The report also noted that these medical experts stressed the uncertainty about the exact characteristics of the potential virus and suggested that the worst-case scenario could be much worse than the severe scenario that CBO considered, especially if the H5N1 virus acquires the ability to spread efficiently among humans without losing its extreme virulence. In addition, in September 2008, the World Bank reported that a severe pandemic could cause a 4.8 percent drop in world economic activity, which would cost the world economy more than $3 trillion.[10]

WHO has developed six phases of pandemic alert, each divided into three periods, as a system of informing the world of the seriousness of the pandemic threat. As seen in figure 2, according to WHO the world is currently in Phase 3 where a new influenza virus subtype is causing disease in humans, but is not yet spreading efficiently and sustainably among humans.

[8]Congressional Budget Office, *A Potential Influenza Pandemic: Possible Macroeconomic Effects and Policy Issues* (Washington, D.C., December 8, 2005; rev. July 27, 2006).

[9]Congressional Budget Office, *A Potential Influenza Pandemic: An Update on Possible Macroeconomic Effects and Policy Issues* (Washington, D.C., May 22, 2006; rev. July 27, 2006).

[10]Andrew Burns, Dominique van der Mensbrugghe, and Hans Timmer, *Evaluating the Economic Consequences of Avian Influenza* (Washington D.C.: World Bank, September 2008).

Figure 2: WHO Global Pandemic Phases

Inter-pandemic phase New virus in animals, no human cases	Low risk of human cases	1
	Higher risk of human cases	2
Pandemic alert New virus causes no human cases	No or very limited human-to-human transmission	3
	Evidence of increased human-to-human transmission	4
	Evidence of increased human-to-human transmission	5
Pandemic	Efficient and sustained human-to-human transmission	6

Source: WHO.
Note: Circle indicates WHO assessment of current global phase.

The Homeland Security Council (HSC) took an active approach to this potential disaster by, among other things, issuing the National Pandemic Strategy in November 2005, and the National Pandemic Implementation Plan in May 2006. The National Pandemic Strategy is intended to provide a high-level overview of the approach that the federal government will take to prepare for and respond to an influenza pandemic. It also provides expectations for nonfederal entities—including state, local, and tribal governments; the private sector; international partners; and individuals—to prepare themselves and their communities. The National Pandemic Implementation Plan is intended to lay out broad implementation requirements and responsibilities among the appropriate federal agencies and clearly define expectations for nonfederal entities. The National Pandemic Implementation Plan contains 324 action items related to these requirements, responsibilities, and expectations, most of which are to be completed before or by May 2009. HSC publicly reported on the status of the action items that were to be completed by 6 months, 1 year and 2 years in December 2006, July 2007, and October 2008 respectively. HSC indicated in its October 2008 progress report that 75 percent of the action items have been completed. As previously mentioned, we have ongoing work assessing the status of implementing this plan.

Leadership Roles and Responsibilities Need to Be Clarified and Tested, and Coordination Mechanisms Could Be Better Utilized

Our prior work evaluating catastrophic event preparedness, response, and recovery has shown that in the event of a catastrophic disaster, the leadership roles, responsibilities, and lines of authority for the response at all levels must be clearly defined and effectively communicated to facilitate rapid and effective decision making, especially in preparing for and in the early hours and days after the event.[11] However, federal government leadership roles and responsibilities for preparing for and responding to a pandemic continue to evolve and will require further clarification and testing before the relationships of the many leadership positions are well understood.[12] Such clarity in leadership is even more crucial now given the change in administration and the associated transition of senior federal officials.

Most of these federal leadership roles involve shared responsibilities between HHS and DHS, and it is not clear how these would work in practice. According to the National Pandemic Strategy and Plan, the Secretary of Health and Human Services is to lead the federal medical response to a pandemic, and the Secretary of Homeland Security will lead the overall domestic incident management and federal coordination. In addition, under the Post-Katrina Emergency Management Reform Act of 2006, the Administrator of the Federal Emergency Management Agency (FEMA) was designated as the principal domestic emergency management advisor to the President, the HSC, and the Secretary of Homeland Security, adding further complexity to the leadership structure in the case of a pandemic.[13] To assist in planning and coordinating efforts to respond to a pandemic, in December 2006 the Secretary of Homeland Security predesignated a national Principal Federal Official (PFO) for influenza pandemic and established five pandemic regions each with a regional PFO and Federal Coordinating Officers (FCO) for influenza pandemic. PFOs are responsible for facilitating federal domestic incident planning and coordination, and FCOs are responsible for coordinating federal resources support in a presidentially-declared major disaster or emergency.

However, the relationship of these roles to each other as well as with other leadership roles in a pandemic is unclear. Moreover, as we testified in July

[11]GAO, *Hurricane Katrina: GAO's Preliminary Observations Regarding Preparedness, Response, and Recovery*, GAO-06-442T (Washington, D.C.: Mar. 8, 2006).

[12]GAO, *Influenza Pandemic: Opportunities Exist to Clarify Federal Leadership Roles and Improve Pandemic Planning*, GAO-07-1257T (Washington, D.C.: Sept. 26, 2007).

[13]Pub. L. No. 109-295, Title VI.

2007, state and local first responders were still uncertain about the need for both FCOs and PFOs and how they would work together in disaster response.[14] Accordingly, we recommended in our August 2007 report on federal leadership roles and the National Pandemic Strategy that DHS and HHS develop rigorous testing, training, and exercises for influenza pandemic to ensure that federal leadership roles and responsibilities for a pandemic are clearly defined and understood and that leaders are able to effectively execute shared responsibilities to address emerging challenges.[15] In response to our recommendation, HHS and DHS officials stated in January 2009 that several influenza pandemic exercises had been conducted since November 2007 that involved both agencies and other federal officials, but it is unclear whether these exercises rigorously tested federal leadership roles in a pandemic.

With respect to control of an outbreak in poultry, which would be instrumental to reducing the risk of a human pandemic, both USDA and DHS may become involved, depending on the level of the outbreak. USDA is responsible for acting to prevent, control, and eradicate foreign animal diseases in domestic livestock and poultry, in coordination with a number of other entities, including states. The Secretary of Homeland Security assumes responsibility for coordinating the federal response under certain circumstances, such as an outbreak serious enough for the President to declare an emergency or a major disaster. In a June 2007 report on USDA's planning for avian influenza, we found that USDA was not planning for DHS to assume the lead coordinating role if an outbreak among poultry occurred that is sufficient in scope to warrant these declarations. To address challenges that limit the national ability to quickly and effectively respond to highly pathogenic avian influenza, we recommended that the Secretaries of Agriculture and Homeland Security clarify their respective roles and how they will work together in the event of a declared presidential emergency or major disaster, and test the effectiveness of this coordination during exercises.[16] Both USDA and DHS agreed that they should develop additional clarity and better define their coordination roles in these circumstances, and have taken preliminary steps to do so. For

[14]GAO, *Homeland Security: Observations on DHS and FEMA Efforts to Prepare for and Respond to Major and Catastrophic Disasters and Address Related Recommendations and Legislation*, GAO-07-1142T (Washington, D.C.: July 31, 2007).

[15]GAO-07-781.

[16]GAO, *Avian Influenza: USDA Has Taken Important Steps to Prepare for Outbreaks, but Better Planning Could Improve Response*, GAO-07-652 (Washington, D.C.: June 11, 2007).

example, according to USDA and DHS officials, the two agencies meet on a regular basis to discuss such coordination issues.

Roles and responsibilities for influenza pandemic preparedness can also be unclear within individual federal agencies. In two reports on DOD and its combatant commands' pandemic preparedness efforts, we noted that while DOD and the combatant commands had taken numerous actions to prepare for a pandemic, roles and responsibilities for pandemic preparedness within the department and the commands had not been clearly defined or communicated.[17] Our September 2006 report on DOD's pandemic preparedness noted that neither the Secretary nor the Deputy Secretary of Defense had clearly and fully defined and communicated lead and supporting roles and responsibilities with clear lines of authority for DOD's influenza pandemic planning, and we recommended that DOD do so. In response, DOD communicated departmentwide that the Deputy Secretary of Defense had designated the Assistant Secretary of Defense for Homeland Defense and Americas' Security Affairs, working with the Assistant Secretary of Defense for Health Affairs, to lead DOD's pandemic efforts. Similarly, in a June 2007 report, we recommended that DOD take steps to clarify U.S. Northern Command's roles and responsibilities for pandemic planning and preparedness efforts.[18] In response, DOD clarified U.S. Northern Command's roles and responsibilities in guidance and plans.

In addition to concerns about clarifying federal roles and responsibilities for a pandemic and how shared leadership roles would work in practice, private sector officials have told us that they are unclear about the respective roles and responsibilities of the federal and state governments during a pandemic emergency. The National Pandemic Implementation Plan states that in the event of an influenza pandemic, the distributed nature and sheer burden of the disease across the nation would mean that the federal government's support to any particular community is likely to

[17]GAO, *Influenza Pandemic: DOD Has Taken Important Actions to Prepare, but Accountability, Funding, and Communications Need to be Clearer and Focused Departmentwide*, GAO-06-1042 (Washington, D.C.: Sept, 21, 2006); and GAO, *Influenza Pandemic: DOD Combatant Command's Preparedness Efforts Could Benefit from More Clearly Defined Roles, Resources, and Risk Mitigation*, GAO-07-696 (Washington, D.C.: June 20, 2007).

[18]As operational commanders, DOD's unified combatant commands are an essential part of the department's influenza pandemic planning. There are currently nine combatant commands—five with geographical responsibilities and four with functional responsibilities. A sixth geographical combatant command—the U.S. Africa Command—became operational in October 2008.

be limited, with the primary response to a pandemic coming from states and local communities. Further, federal and private sector representatives we interviewed at the time of our October 2007 report identified several key challenges they face in coordinating federal and private sector efforts to protect the nation's critical infrastructure in the event of an influenza pandemic.[19] One of these was a lack of clarity regarding the roles and responsibilities of federal and state governments on issues such as state border closures and influenza pandemic vaccine distribution.

Coordination Mechanisms

Mechanisms and networks for collaboration and coordination on pandemic preparedness between federal and state governments and the private sector exist, but they could be better utilized. In some instances, the federal and private sectors are working together through a set of coordinating councils, including sector-specific and cross-sector councils. To help protect the nation's critical infrastructure, DHS created these coordinating councils as the primary means of coordinating government and private sector efforts for industry sectors such as energy, food and agriculture, telecommunications, transportation and water.[20] Our October 2007 report found that DHS has used these critical infrastructure coordinating councils primarily to share pandemic information across sectors and government levels rather than to address many of the challenges identified by sector representatives, such as clarifying the roles and responsibilities between federal and state governments.[21] We recommended in the October 2007 report that DHS encourage the councils

[19]GAO, *Influenza Pandemic: Opportunities Exist to Address Critical Infrastructure Protection Challenges That Require Federal and Private Sector Coordination*, GAO-08-36 (Washington, D.C.: Oct. 31, 2007).

[20]The 18 critical infrastructure and key resource sectors are: food and agriculture; banking and finance; chemical; commercial facilities; commercial nuclear reactors, materials, and water; dams; defense industrial base; drinking water and water treatment systems; emergency services; energy; governmental facilities; information technology; national monuments and icons; postal and shipping; public health and healthcare; telecommunications; transportation systems; and critical manufacturing. Critical infrastructure are systems and assets, whether physical or virtual, so vital to the United States that their incapacity or destruction would have a debilitating effect on national security, national economic security, and national public health or safety, or any combination of those matters. Key resources are publicly or privately controlled resources essential to minimal operations of the economy or government, including individual targets whose destruction would not endanger vital systems but could create a local disaster or profoundly damage the nation's morale or confidence.

[21]GAO-08-36.

to consider and address the range of coordination challenges in a potential influenza pandemic between the public and private sectors for critical infrastructure. DHS concurred with our recommendation and DHS officials informed us in February 2009 that the department is working on initiatives to address it, such as developing pandemic contingency plan guidance tailored to each of the critical infrastructure sectors, and holding a series of "webinars" with a number of the sectors.[22]

Federal executive boards (FEB) bring together federal agency and community leaders in major metropolitan areas outside of Washington, D.C., to discuss issues of common interest, including an influenza pandemic. The Office of Personnel Management (OPM), which provides direction to the FEBs, and the FEBs have designated emergency preparedness, security, and safety as an FEB core function. The FEB's emergency support role with its regional focus may make the boards a valuable asset in pandemic preparedness and response. As a natural outgrowth of their general civic activities and through activities such as hosting emergency preparedness training, some of the boards have established relationships with, for example, federal, state, and local governments; emergency management officials; first responders; and health officials in their communities. In a May 2007 report on the FEBs' ability to contribute to emergency operations, we found that many of the selected FEBs included in our review were building capacity for influenza pandemic response within their member agencies and community organizations by hosting influenza pandemic training and exercises.[23] We recommended that, since FEBs are well positioned within local communities to bring together federal agency and community leaders, the Director of OPM work with FEMA to formally define the FEBs' role in emergency planning and response. As a result of our recommendation, FEBs were included in the *National Response Framework* (NRF) in January 2008 as one of the regional support structures that have the potential to contribute to development of situational awareness during an emergency. OPM and FEMA also signed a memorandum of understanding in August 2008 in which FEBs and FEMA agreed to work collaboratively in carrying out their respective roles in the promotion of the national emergency response system.

[22]GAO-08-36.

[23]GAO, *The Federal Workforce: Additional Steps Needed to Take Advantage of Federal Executive Boards' Ability to Contribute to Emergency Operations*, GAO-07-515 (Washington, D.C.: May 4, 2007).

Efforts Are Underway to Improve the Surveillance and Detection of Pandemic-Related Threats in Humans and Animals, but Targeting Assistance to Countries at the Greatest Risk Has Been Based on Incomplete Information

International disease surveillance and detection efforts serve to address the threat posed by infectious diseases, such as an influenza pandemic, before they develop into widespread outbreaks. Such efforts also provide national and international public health authorities with information for planning and managing efforts to control diseases such as an influenza pandemic. However, as we have reported in the past, domestic and international disease surveillance efforts need improvement.[24] For example, some state public health departments' initiatives to enhance disease reporting have been incomplete, and there is a need for national standards and interoperability in information collection and sharing to detect outbreaks. Globally, in December 2007 we reported that the United States and its international partners are involved in efforts to improve global influenza surveillance, including diagnostic capabilities, so that pandemic strains can be quickly detected.[25] Yet, international capacity for influenza surveillance still has many weaknesses, particularly in developing countries. For example, some countries experiencing H5N1 human influenza outbreaks, like Indonesia, had at times not promptly shared human virus samples with the international community, thus further weakening international surveillance efforts.

Efforts are also being made both within the United States and internationally to improve surveillance and detection for highly pathogenic avian influenza. As stated earlier, controlling an outbreak in poultry would be instrumental to reducing the risk of a human pandemic. Within the United States, USDA is taking many important measures to help the nation prepare for outbreaks of highly pathogenic avian influenza. In a June 2007 report on avian influenza, we stated that USDA had developed several surveillance programs to detect highly pathogenic avian influenza, including a long-standing voluntary program that systematically tests samples of birds from participating poultry operators' flocks for the virus.[26] Further, we also stated that USDA's Animal and Plant Health Inspection Service (APHIS) is working with the Department of the Interior, state

[24]GAO, *Emerging Infectious Diseases: Review of State and Federal Disease Surveillance Efforts*, GAO-04-877 (Washington, D.C.: Sept. 30, 2004) and GAO, *Information Technology: Federal Agencies Face Challenges in Implementing Initiatives to Improve Public Health Infrastructure*, GAO-05-308 (Washington, D.C.: June 10, 2005).

[25]GAO, *Influenza Pandemic: Efforts Under Way to Address Constraints on Using Antivirals and Vaccines to Forestall a Pandemic*, GAO-08-92 (Washington, D.C.: Dec. 21, 2007).

[26]GAO-07-652.

wildlife agencies, and others to increase surveillance of wild birds in Alaska and the 48 contiguous states in addition to working with states and industry to conduct surveillance of birds at auctions, swap meets, flea markets, and public exhibitions. APHIS has also formed the National Avian Influenza Surveillance System, designed to link existing avian influenza surveillance data from USDA, other federal and state agencies, and industry.

However, in the United States, federal and state officials generally do not know the numbers and locations of backyard birds so controlling an outbreak of highly pathogenic avian influenza among these birds remains particularly difficult. We recommended that the Secretary of Agriculture work with states to determine how to overcome potential problems associated with unresolved issues, such as the difficulty in locating backyard birds and disposing of carcasses and materials. USDA agreed with our recommendation and efforts are underway. For example, according to USDA officials, the agency has developed online tools to help states make effective decisions about carcass disposal. In addition, USDA has created a secure Internet site that contains draft guidance for disease response, including highly pathogenic avian influenza, and it includes a discussion about many of the unresolved issues.

International surveillance networks for influenza in birds and other animals have also been established and efforts are under way to improve data sharing among scientists.[27] However, global surveillance of the disease among domestic animals has serious shortfalls. The World Organisation for Animal Health (OIE) and the Food and Agriculture Organization (FAO) collaborate to obtain and confirm information on suspected highly pathogenic H5N1 cases. According to the October 2008 report by the UNSIC and the World Bank on the state of pandemic readiness,[28] data obtained from national authorities indicate that 75 percent of countries[29] report having a surveillance system that is

[27]GAO-08-92.

[28]United Nations System Influenza Coordinator and the World Bank, *Responses to Avian Influenza and State of Pandemic Readiness, Fourth Global Progress Report*, (New York, N.Y., and Washington, D.C., October 2008).

[29]Of the 178 countries that UNSIC surveyed, 148 of those surveyed responded to the entire survey for an overall response rate of approximately 83 percent, whereas 30 of those surveyed did not respond. 105 countries, or 75 percent of 140 respondents addressing surveillance systems, reported having an operational surveillance system capable of detecting highly pathogenic avian influenza.

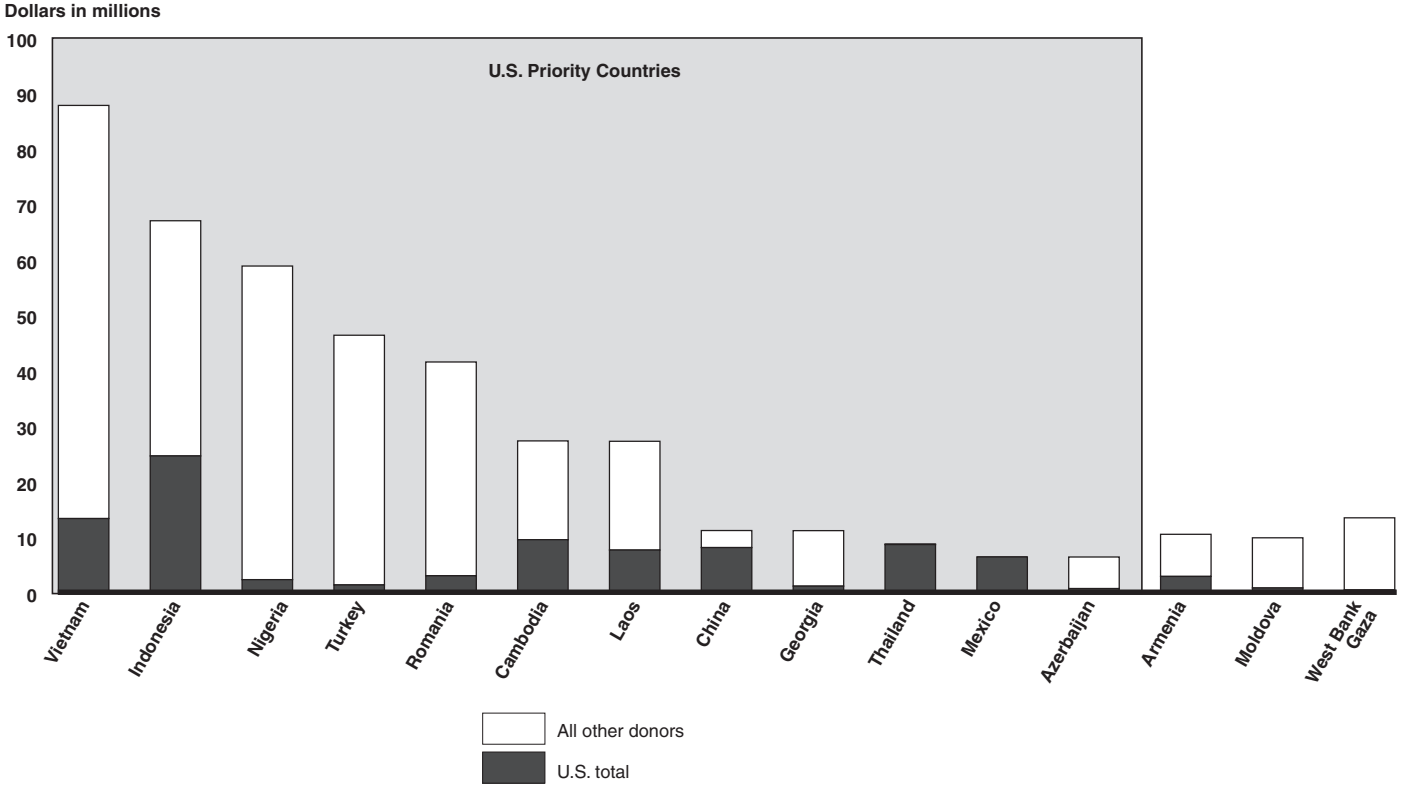
operational and capable of detecting highly pathogenic avian influenza. In addition, estimates of risk for disease transmission from one country to another, as well as among regions within countries, are difficult to make because of uncertainties about how factors such as trade in poultry and other birds and wild bird migration affect the movement of the disease.

Risk-Based Targeting of Assistance to Priority Countries

Assessments by U.S. agencies and international organizations identified widespread risks of the emergence of influenza pandemic, and the United States identified priority countries for assistance. Our June 2007 report on international efforts to assess and respond to an influenza pandemic risk noted that the bulk of U.S. and other donors' country-specific commitments had been made to countries that the United States had designated as priorities, with funding concentrated among certain of these countries. We reported that through 2006, the United States had committed about $377 million to improve global preparedness for avian and influenza pandemic, 27 percent of the $1.4 billion committed by all donors, which is the greatest share of funds of all donors. Since we issued our June 2007 report, the UNSIC and the World Bank reported that as of April 2008, the United States had committed $629 million, which is approximately 31 percent of the $2.05 billion committed by all donors, for avian and pandemic influenza efforts.

Figure 3 shows the distribution of committed global and U.S. funding across major recipient countries as of December 2006. Of the top 15 recipients of committed international funds, 11 were U.S. priority countries. More recent data on U.S. funding patterns show similar focuses on certain countries, with Indonesia the largest recipient, followed by Vietnam and Cambodia.

Figure 3: Top 15 Recipients of Committed, Country-Specific International Avian and Influenza Pandemic Funding as of December 2006



Source: GAO analysis of data compiled by the World Bank.

Notes: More recent data reported by the UNSIC and the World Bank on the distribution of U.S. commitments, as of April 30, 2008, show a similar focus on certain countries, with Indonesia the largest recipient of U.S. country-specific commitments (about $48 million), followed by Vietnam (about $21 million), and Cambodia (about $14 million).

The World Bank defines a commitment as the result of an agreement between the donor and recipient for designated purposes or a firm decision, such as a legislative appropriation, that prevents the use of an allocated amount for other purposes.

Totals include funds from donor countries, international organizations, and the World Bank administered Avian and Human Influenza Facility.

However, we reported that gaps in available information from other countries limited the capacity for comprehensive, well-informed

comparisons of risk levels by country.[30] For example, in 2007 we reported that the United States Agency for International Development's (USAID) environmental risk assessment of areas at greatest risk for avian influenza outbreaks included a limited understanding of the role of poultry trade or wild birds. USAID, the Department of State, and the United Nations had also gathered information that was not sufficiently detailed or complete enough to permit well-informed country comparisons. Despite these limitations, the HSC has used available information to designate priority countries for assistance. The UNSIC and the World Bank stated in the 2008 report that reports from national authorities responding to a UNSIC survey indicate that 68 percent of countries[31] had conducted a risk assessment. As we previously reported in June 2007, adopting a risk management approach can help manage the uncertainties in an influenza pandemic and identify the most appropriate course of action.[32] However, the FAO's detailed evaluation concluded that very few countries have a surveillance plan that is based on an "elaborated" risk-analysis.

Pandemic Planning and Exercising Has Occurred in the United States and Other Countries, but Planning Gaps Remain

By their very nature, catastrophic events involve extraordinary levels of mass casualties, damage, or disruption that can overwhelm state and local responders—making sound planning for catastrophic events crucial. Strong advance planning, both within and among federal, state, and local governments and other organizations, as well as robust training and exercise programs to test these plans in advance of a real disaster, are essential to best position the nation to prepare for, respond to, and recover from major catastrophes such as an influenza pandemic. Capabilities are built upon the appropriate combination of people, skills, processes, and assets. Ensuring that needed capabilities are available requires effective planning and coordination as well as training and exercises in which the capabilities are realistically tested, problems identified and lessons learned, and subsequently addressed in partnership with other federal, state, and local stakeholders. We have also noted that

[30]GAO, *Influenza Pandemic: Efforts to Forestall Onset Are Under Way; Identifying Countries at Greatest Risk Entails Challenges*, GAO-07-604 (Washington, D.C.: June 20, 2007).

[31]Of the 178 countries that UNSIC surveyed, 148 of those surveyed responded to the entire survey for an overall response rate of approximately 83 percent, whereas 30 of those surveyed did not respond. 95 countries, or approximately 68 percent of 139 respondents addressing surveillance systems, had actually conducted a risk assessment.

[32]GAO-07-604.

an incomplete understanding of roles and responsibilities under the *National Response Plan* has often led to misunderstandings, problems, and delays—an area where training could be helpful. Key officials must actively and personally participate so that they are better prepared to deal with real life situations. In addition, as we previously reported on the federal response to Hurricane Katrina, lessons learned from exercises must be incorporated and used to improve emergency plans.[33]

Pandemic Planning and Exercising in Other Countries

A number of countries in addition to the United States have developed pandemic plans, along with state and local governments, and the private sector. We reported in June 2007 that the U.S. government has worked with its international partners to develop an overall global strategy that is compatible with the U.S. approach. These steps included the appointment of a UNSIC and periodic global conferences to review progress and refine the strategy.

Other countries, including Belgium, Japan, Sweden, and the United Kingdom, have developed influenza pandemic plans and frameworks. In July 2006, Belgium issued the *Belgian pandemic flu preparedness plan* which provides basic information on various topics such as leadership, antivirals, vaccines, surveillance, logistics, and public communication.[34] Similar to Belgium's pandemic plan, Japan used WHO's six influenza pandemic phases in drafting government policies and response efforts in its *Pandemic Influenza Preparedness Action Plan of the Japanese Government* issued in November 2005.[35] Sweden's National Audit Office reported in its February 2008 audit that Sweden's *Preparedness planning for pandemic influenza – National Actions* is focused only on infection control services and the health sector and does not cover the rest of society.[36] To address this, the government of Sweden agreed to further develop its plan by March 2010. Further, the Sweden's National Audit

[33]GAO, *Catastrophic Disasters: Enhanced Leadership, Capabilities, and Accountability Controls Will Improve the Effectiveness of the Nation's Preparedness, Response, and Recovery System*, GAO-06-618 (Washington, D.C.: Sept 6, 2006).

[34]Interministerial Influenza Commission, *Belgian pandemic flu preparedness plan, Version 1* (Belgium: July 2006).

[35]Inter-ministerial Avian Influenza Committee, *Pandemic Influenza Preparedness Action Plan of the Japanese Government* (Japan: rev. October 2007).

[36]Riksrevisionen, Swedish National Audit Office, *Pandemics—Managing Threats to Human Health* (Sweden: February 2008).

Office found that there is very limited knowledge of the extent to which municipalities can provide essential services in the event of an influenza pandemic. Within the United Kingdom, the government issued *The National Framework for Responding to an Influenza Pandemic* and the *Scottish National Framework for Responding to an Influenza* Pandemic in November 2007 and March 2007, respectively. Both frameworks provide information and guidance to assist and support public and private organizations across all sectors in understanding the nature of the challenges and in making the appropriate preparations for an influenza pandemic.[37]

According to a UNSIC global survey, 141 countries, or 97 percent of those that responded, have pandemic preparedness plans.[38] However, further analysis conducted by the UNSIC's Pandemic Influenza Contingency Team and other institutions suggested that the quality and comprehensiveness of these plans continue to vary significantly between countries. UNSIC and the World Bank also found that there had been a moderate increase in the number of countries that have undertaken simulation exercises.[39] Specifically, where testing has occurred, 25 percent of respondents (37 of 145 countries), reported that testing took place at both the national and local levels. In addition, 37 percent of respondents (45 of 120 countries) have incorporated the lessons learned from simulations into plan revisions.

Federal, State, and Local Government Pandemic Planning and Exercising

In our August 2007 report on the National Pandemic Strategy and Implementation Plan, we found that while these documents are an important first step in guiding national preparedness, they do not fully address all six characteristics of an effective national strategy, as

[37]United Kingdom Cabinet Office, *National Risk Register* (London, U.K.: 2008).

[38]Of the 178 countries that UNSIC surveyed, 148 of those surveyed responded to the entire survey for an overall response rate of approximately 83 percent, whereas 30 of those surveyed did not respond. Of 145 respondents addressing pandemic planning 141 countries, or 97 percent, said that they had a pandemic plan in place. Four respondents from Africa indicated that they did not have a pandemic plan.

[39]A comparison of countries that replied to UNSIC's surveys in 2007 and 2008 showed that 34 of 69 respondents reported having conducted a simulation in 2008 that had not done so in 2007.

identified in our work.[40] The documents fully address only one of the six characteristics, by reflecting a clear description and understanding of problems to be addressed. Further, the National Pandemic Strategy and Implementation Plan do not address one characteristic at all, containing no discussion of what it will cost, where resources will be targeted to achieve the maximum benefits, and how it will balance benefits, risks, and costs. Moreover, the documents do not provide a picture of priorities or how adjustments might be made in view of resource constraints. Although the remaining four characteristics are partially addressed, important gaps exist that could hinder the ability of key stakeholders to effectively execute their responsibilities. For example, state and local jurisdictions that will play crucial roles in preparing for and responding to a pandemic were not directly involved in developing the National Pandemic Implementation Plan, even though it relies on these stakeholders' efforts. Stakeholder involvement during the planning process is important to ensure that the federal government's and nonfederal entities' responsibilities are clearly understood and agreed upon. Further, relationships and priorities among actions were not clearly described, performance measures were not always linked to results, and insufficient information was provided about how the documents are integrated with other response related plans, such as the NRF. We recommended that the HSC establish a process for updating the National Pandemic Implementation Plan and that the updated plan should address these and other gaps. HSC did not comment on our recommendation and has not indicated if it plans to implement it.

Concerning federal government planning for an outbreak in animals, we reported in 2007 that although USDA had also taken important steps to prepare for outbreaks of highly pathogenic avian influenza, there were still gaps in its planning. We noted that USDA was drafting response plans for highly pathogenic avian influenza and was also working with the HSC and other key federal agencies to produce an "interagency playbook" intended to clarify how primary federal responders would initially interact to respond to six scenarios of detection of highly pathogenic H5N1. USDA had also begun preliminary exercises to test aspects of these plans with

[40]The six characteristics of an effective national strategy include: (1) purpose, scope, and methodology, (2) problem definition and risk assessment, (3) goals, subordinate objectives, activities, and performance measures, (4) resources, investments, and risk management, (5) organizational roles, responsibilities, and coordination, and (6) integration and implementation. GAO, *Combating Terrorism: Evaluation of Selected Characteristics in National Strategies Related to Terrorism*, GAO-04-408T (Washington, D.C.: Feb. 3, 2004).

federal, state, local, and industry partners. However, USDA response plans did not identify the capabilities needed to carry out the tasks associated with an outbreak scenario—that is, the entities responsible for carrying them out, the resources needed, and the source of those resources. To address these gaps, we recommended that the Secretary of Agriculture identify these capabilities, use this information to develop a response plan that identifies the critical tasks for responding to the selected outbreak scenario and, for each task, identifies the responsible entities, the location of resources needed, time frames, and completion status, and test these capabilities in ongoing exercises to identify gaps and ways to overcome those gaps. USDA concurred, and officials told us that it has created a draft preparedness and response plan that identifies federal, state, and local actions, timelines, and responsibilities for responding to highly pathogenic avian influenza, but the plan has not been issued yet.

At the state and local levels, we reported in June 2008 that, according to CDC, all 50 states and the 3 localities that received federal pandemic funds have developed influenza pandemic plans and conducted pandemic exercises in accordance with federal funding guidance. All of the 10 localities that we reviewed had also developed plans and conducted exercises. Further, all of the 10 localities and the five states that we reviewed had incorporated lessons learned from pandemic exercises into their planning.[41] However, an HHS-led interagency assessment of states' plans found on average that states had "many major gaps" in their influenza pandemic plans in 16 of 22 priority areas, such as school closure policies and community containment, which are community-level interventions designed to reduce the transmission of a pandemic virus. The remaining 6 priority areas were rated as having "a few major gaps." Since we issued our report in June 2008, HHS led another interagency assessment of state influenza pandemic plans. HHS reported in January 2009 that, based on this assessment, although states have made important progress toward preparing for combating an influenza pandemic, most

[41]We conducted site visits to the five most populous states including California, Florida, Illinois, New York, and Texas for a number of reasons, including that these states constituted over one-third of the United States population, received over one-third of the total funding from HHS and DHS that could be used for planning and exercising efforts, and were likely entry points for individuals coming from another country given that the states either bordered Mexico or Canada or contained major ports, or both. Within each state, we also interviewed officials at 10 localities, which consisted of five urban areas and five rural counties.

states still have major gaps in their pandemic plans.[42] As we had reported in June 2008, HHS, in coordination with DHS and other federal agencies, had convened a series of regional workshops for states in five influenza pandemic regions across the country. Because these workshops could be a useful model for sharing information and building relationships, we recommended that HHS and DHS, in coordination with other federal agencies, convene additional meetings with states to address the gaps in the states' pandemic plans. HHS and DHS generally concurred with our recommendation, but have not yet held these additional meetings. HHS and DHS recently indicated that while no additional meetings are planned at this time, states will have to continuously update their pandemic plans and submit them for review.

We have also reported on the need for more guidance from the federal government to help states and localities in their planning. In June 2008, we reported that although the federal government has provided a variety of guidance, officials of the states and localities we reviewed told us that they would welcome additional guidance from the federal government in a number of areas, such as community containment, to help them to better plan and exercise for an influenza pandemic. State and local officials have identified similar concerns. An October 2007 Kansas City Auditor's Office report on influenza pandemic preparedness in the city noted that Kansas City Health Department officials would like the federal government to provide additional guidance on some of the same issues we found, including clarifying community interventions such as school closings.[43] In addition, according to the National Governors Association's (NGA) September 2008 issue brief on states' pandemic preparedness, states are concerned about a wide range of school-related issues, including when to close schools or dismiss students, how to maintain curriculum continuity during closures, and how to identify the appropriate time at which classes could resume.[44] In addition, NGA reported that states generally have very little awareness of the status of disease outbreaks, either in real time or in

[42]Departments of Health and Human Services and Homeland Security and other agencies, *Assessment of States' Operating Plans to Combat Pandemic Influenza: Report to Homeland Security Council*, (Washington, D.C.: January 2009).

[43]City Auditor's Office, City of Kansas City, Missouri, *Performance Audit: Pandemic Flu Preparedness* (October 2007).

[44]National Governors Association Center for Best Practices, *Issue Brief: Pandemic Preparedness in the States—An Assessment of Progress and Opportunity* (September 2008).

near real time, to allow them to know precisely when to recommend a school closure or reopening in a particular area. NGA reported that states wanted more guidance in the following areas: (1) workforce policies for the health care, public safety, and private sectors; (2) schools; (3) situational awareness such as information on the arrival or departure of a disease in a particular state, county, or community; (4) public involvement; and (5) public-private sector engagement.

Private Sector Pandemic Planning

The private sector has also been planning for an influenza pandemic, but many challenges remain. To better protect critical infrastructure, federal agencies and the private sector have worked together across a number of sectors to plan for a pandemic, including developing general pandemic preparedness guidance, such as checklists for continuity of business operations during a pandemic. However, federal and private sector representatives have acknowledged that sustaining preparedness and readiness efforts for an influenza pandemic is a major challenge, primarily because of the uncertainty associated with a pandemic, limited financial and human resources, and the need to balance pandemic preparedness with other, more immediate, priorities, such as responding to outbreaks of foodborne illnesses in the food sector and, now, the effects of the financial crisis.

In our March 2007 report on preparedness for an influenza pandemic in one of these critical infrastructure sectors—financial markets—we found that despite significant progress in preparing markets to withstand potential disease pandemics, securities and banking regulators could take additional steps to improve the readiness of the securities markets.[45] Although the seven organizations that we reviewed—which included exchanges, clearing organizations, and payment-system processors—were working on planning and preparation efforts to reduce the likelihood that a worldwide influenza pandemic would disrupt their critical operations, only one of the seven had completed a formal plan. To increase the likelihood that the securities markets will be able to function during a pandemic, we recommended that the Chairman, Federal Reserve; the Comptroller of the Currency; and the Chairman, Securities and Exchange Commission (SEC), consider taking additional actions to ensure that

[45]GAO, *Financial Market Preparedness: Significant Progress Has Been Made, but Pandemic Planning and Other Challenges Remain*, GAO-07-399 (Washington, D.C.: March 29, 2007).

market participants adequately prepare for a pandemic outbreak. In response to our recommendation, the Federal Reserve and the Office of the Comptroller of the Currency, in conjunction with the Federal Financial Institutions Examination Council, and the SEC directed all banking organizations under their supervision to ensure that the pandemic plans the financial institutions have in place are adequate to maintain critical operations during a severe outbreak. SEC issued similar requirements to the major securities industry market organizations.

Further Actions Are Needed to Address the Capacity to Respond to and Recover from an Influenza Pandemic

Improving the nation's response capability to catastrophic disasters, such as an influenza pandemic, is essential. Following a mass casualty event of injured or ill victims, health care systems would need the ability to adequately care for a large number of patients or patients with unusual or highly specialized medical needs. The ability of local or regional health care systems to deliver services consistent with established standards of care[46] could be compromised, at least in the short term, because the volume of patients would far exceed the available hospital beds, medical personnel, pharmaceuticals, equipment, and supplies. Providing such care would require the allocation of scarce resources.

Medical Surge Capacity

In contrast to discrete events such as hurricanes and most terrorist attacks, the widespread and iterative nature of a pandemic—likely to occur in waves as it spreads simultaneously through different communities and regions—presents continuing challenges in preparing for a medical surge in a mass casualty event such as a pandemic. Under such conditions, emergency management approaches that have been used in the past to increase capacity when responding to other types of disasters, such as assistance from other states or the deployment of military resources, may not be viable options since these groups may need to hold onto resources in order to meet their own needs should they be affected by the disease. We reported in June 2007 that state officials informed us that the Emergency Management Assistance Compact (EMAC), a collaborative arrangement among member states that provides a legal framework for requesting resources and that has been used in emergencies such as Hurricane Katrina, would not work in an influenza

[46]A standard of care is the diagnostic and treatment process that a provider should follow for a certain type of patient or illness, or certain clinical circumstances. It is how similarly qualified health care providers would manage the patient's care under the same or similar circumstances.

pandemic.[47] State officials reported their reluctance to send personnel into an infected area, expressed their concern that resources would not be available, and believed that personnel would be reluctant to volunteer to go to another state. Further, NGA reported in its September 2008 issue brief on state pandemic preparedness that EMAC is seen as unreliable during a pandemic because states would likely be unwilling to share scarce resources or deploy personnel into a location where the disease is active and thus expose those individuals to a high-risk environment.

HHS estimates that in a severe influenza pandemic, almost 10 million people would require hospitalization, which would exceed the current capacity of U.S. hospitals and necessitate difficult choices regarding rationing of resources. HHS also estimates that almost 1.5 million of these people would require care in an intensive care unit and about 740,000 people would require mechanical ventilation. In our September 2008 report on HHS's influenza pandemic planning efforts, we reported that although HHS has initiated efforts to improve the surge capacity of health care providers, these efforts will be challenged during a severe pandemic because of the widespread nature of such an event, the existing shortages of health care providers, and the potential high absentee rate of providers. Given the uncertain effectiveness of efforts to increase surge capacity, HHS has developed guidance to assist health care facilities in planning for altered standards of care; that is, for providing care while allocating scarce equipment, supplies, and personnel in a way that saves the largest number of lives in mass casualty events.[48] As we reported in June 2008, 7 out of 20 states reviewed had adopted or were drafting altered standards of care for specific medical issues. Three of the 7 states had adopted some altered standards of care guidelines.[49] We also found that 18 of the 20 states reviewed were selecting alternate care sites, which deliver medical care outside of a hospital setting for patients who would normally be treated as inpatients.

[47]GAO, *Emergency Management Assistance Compact: Enhancing EMAC's Collaborative and Administrative Capacity Should Improve National Disaster Response*, GAO-07-854 (Washington, D.C.: June 29, 2007).

[48]GAO, *Influenza Pandemic: HHS Needs to Continue Its Actions and Finalize Guidance for Pharmaceutical Interventions*, GAO-08-671 (Washington, D.C.: Sept. 30, 2008).

[49]GAO, *Emergency Preparedness: States Are Planning for Medical Surge, but Could Benefit from Shared Guidance for Allocating Scarce Medical Resources*, GAO-08-668 (Washington, D.C.: June 13, 2008).

In addition, we reported that the federal government has provided funding, guidance, and other assistance to help states prepare for medical surge in a mass casualty event, such as an influenza pandemic. Further, the federal government has provided guidance for states to use when preparing for medical surge, including *Reopening Shuttered Hospitals to Expand Surge Capacity*, which contains a checklist that states can use to identify entities that could provide more resources in preparing for a medical surge and also provided other assistance such as conferences and electronic bulletin boards for states to use in preparing for medical surge. Some state officials reported, however, that they had not begun work on altered standards of care guidelines, or had not completed drafting guidelines, because of the difficulty of addressing the medical, ethical, and legal issues involved. We recommended that HHS serve as a clearinghouse for sharing among the states altered standards of care guidelines developed by individual states or medical experts. HHS did not comment on the recommendation, and it has not indicated if it plans to implement it.[50] Further, in our June 2008 report on state and local planning and exercising efforts for an influenza pandemic, we found that state and local officials reported that they wanted federal influenza pandemic guidance on facilitating medical surge, which was also one of the areas that the HHS-led assessment rated as having "many major gaps" nationally among states' influenza pandemic plans.[51]

[50]GAO-08-668.

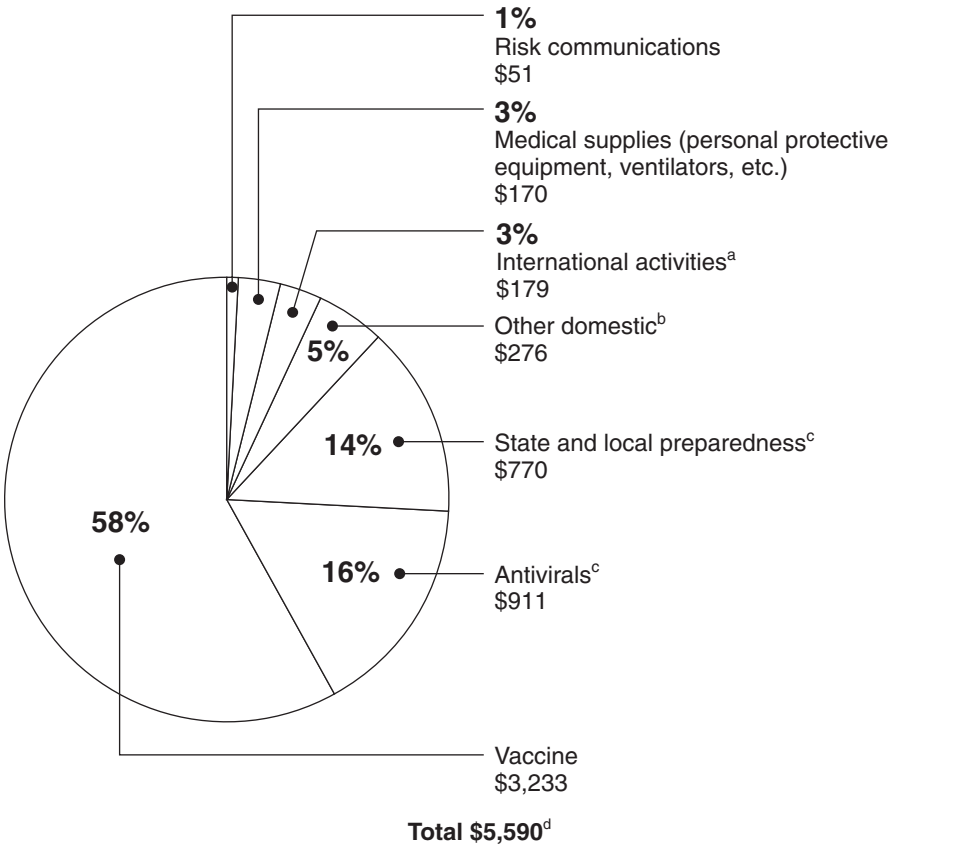
[51]GAO-08-539.

Antivirals and Vaccine Capacity

In fiscal year 2006, Congress appropriated $5.62 billion in supplemental funding to HHS for, among other things, (1) monitoring disease spread to support rapid response, (2) developing vaccines and vaccine production capacity, (3) stockpiling antivirals and other countermeasures, (4) upgrading state and local capacity, and (5) upgrading laboratories and research at CDC. Figure 4 shows that the majority of this supplemental funding—about 77 percent—was allocated for developing antivirals and vaccines for a pandemic, and purchasing medical supplies. Also, a portion of the funding for state and local preparedness—$170 million—was allocated for state antiviral purchases for their state stockpiles.

Figure 4: HHS Influenza Pandemic Supplemental Appropriations, Fiscal Year 2006

Dollars in millions



Source: GAO, HHS.

Notes: Data are from the Department of Health and Human Services, *Pandemic Planning Update III: A Report from Secretary Michael O. Leavitt* (Washington, D.C.: Nov. 13, 2006).

[a]International activities includes: international preparedness, surveillance, response, and research.

[b]Other domestic includes: surveillance, quarantine, lab capacity, rapid tests.

[c]State and local preparedness includes funding for state subsidies of antiviral drugs.

[d]This chart does not include $30 million in supplemental funding that was transferred to the U.S. Agency for International Development.

According to HHS's *Pandemic Influenza Implementation Plan*, HHS seeks to ensure the availability of antiviral treatment courses for at least 25 percent of the U.S. population or at least 81 million treatment courses.[52] As of May 2008, both HHS and states had stockpiled a total of 72 million treatment courses. Specifically, HHS had stockpiled 44 million courses of antivirals for treatment in the HHS-managed Strategic National Stockpile, which is a national repository of medical supplies that is designed to supplement stockpiles from state and local jurisdictions in the event of a public health emergency, and had reserved an additional 6 million courses from its federally stockpiled antivirals for containment of an initial outbreak. HHS also subsidized the purchase of 31 million treatment courses by state and local jurisdictions for storage in their own stockpiles, of which 22 million treatment courses had been stockpiled.

In our December 2007 report on using antivirals and vaccines to forestall a pandemic, we found that the availability of antivirals and vaccines in a pandemic could be inadequate to meet demand due to limited production, distribution, and administration capacity.[53] As we reported, WHO estimated that the quantity of antivirals required to forestall a pandemic would be enough treatment courses for 25 percent of the population. In addition, there would need to be enough preventative courses to last 20 days for the remaining 75 percent of the population in the outbreak contamination zone. Further, due to the time required to detect the virus and develop and manufacture a targeted vaccine for a pandemic, pandemic vaccines are likely to play little or no role in efforts to stop or contain a pandemic at least in its initial phases. According to a September 2008 CBO report on the United States' policy regarding pandemic vaccines, if an influenza pandemic were to occur today, it would be impossible to vaccinate the entire population of about 300 million people

[52]Department of Health and Human Services, *Pandemic Influenza Implementation Plan* (November 2006).

[53]GAO-08-92.

within the following 6 months because current capacity for domestic production would be completely inadequate.[54]

The United States, its international partners, and the pharmaceutical industry are investing substantial resources to address constraints on the availability and effectiveness of antivirals and vaccines, but some of these efforts face limitations. We reported in September 2008 that HHS was making large investments in domestic vaccine manufacturing capacity by supporting vaccine research with contracts that require manufacturers to establish vaccine-producing facilities within U.S. borders.[55] Through these contracts, one U.S. facility has expanded its manufacturing capacity and a second facility was recently established in the United States. Further, according to a January 2009 report by HHS, the department awarded $120 million to vaccine manufacturers to retrofit their existing U.S. vaccine manufacturing facilities for egg-based vaccines[56] while also planning to build domestic cell-based vaccine[57] production facilities within the U.S. by awarding approximately $500 million in contracts in fiscal year 2009.[58]

CBO also reported that HHS is not only encouraging the expansion and refurbishing of existing facilities but also funding the development of new adjuvants, substances that can be added to influenza vaccines to reduce the amount of active ingredient (also called antigen) needed per dose of vaccine. By using adjuvants for egg-based and cell-based vaccines, domestic manufacturers could produce more doses in existing facilities, which means that fewer new facilities would be needed to manufacture

[54]Congressional Budget Office, *U.S. Policy Regarding Pandemic-Influenza Vaccines* (Washington, D.C.: September 2008).

[55]GAO-08-671.

[56]The standard egg-based technology is essentially the same, whether producing seasonal or influenza pandemic vaccines. However, with egg-based technology, an influenza pandemic vaccine would require at least 6 months to produce.

[57]Cell-based vaccines hold the potential to shorten the time between the identification of a pandemic virus and full-scale production of the vaccine for the U.S. population. In place of eggs, cell-based vaccine production uses laboratory-grown cell lines that can host a growing virus.

[58]HHS, *Pandemic Planning Update VI: A Report from Secretary Michael O. Leavitt*, (Washington, D.C.: Jan. 8, 2009).

cell-based formulations and smaller stockpiles could be used to protect a larger population.[59]

However, increasing production capacity of vaccines and antivirals will take several years, as new facilities are built and necessary materials acquired. Also, weaknesses within the international influenza surveillance system impede the detection of strains, which could limit the ability to promptly administer or develop effective antivirals and vaccines to treat and prevent cases of infection to prevent its spread. The delayed use of antivirals and the emergence of antiviral resistance in influenza strains could limit their effectiveness. In addition, limited support for clinical trials could hinder their ability to improve understanding of the use of antivirals and vaccines against a pandemic strain.

In light of this anticipated limitation in supply, HHS released guidance on prioritizing target groups for a pandemic vaccine. Because of the uncertainties surrounding the availability of a pandemic vaccine, in September 2008, we recommended that the Secretary of Health and Human Services expeditiously finalize guidance to assist state and local jurisdictions to determine how to effectively use limited supplies of antivirals, and the pre-pandemic vaccine, which is developed prior to an outbreak using strains that have the potential to cause an influenza pandemic.[60] In December 2008, HHS released final guidance on antiviral drug use during an influenza pandemic.[61] In addition, HHS officials informed us in February 2009 that it is drafting guidance on pre-pandemic influenza vaccination.

In addition to antiviral and vaccine stockpiles for an influenza pandemic for the general population, our June 2007 report on avian influenza planning concluded that USDA had significant gaps in its planning for providing antivirals to individuals responsible for responding to an outbreak of highly pathogenic avian influenza.[62] USDA has coordinated with DHS and other federal agencies to create a National Veterinary

[59]Congressional Budget Office, *U.S. Policy Regarding Pandemic-Influenza Vaccines*.

[60]HHS has launched studies to determine how long the stockpiled pre-pandemic vaccines remain safe and effective, but in the meanwhile it assumes a 2-year shelf life.

[61]HHS, *Guidance on Antiviral Drug Use during an Influenza Pandemic* (Washington, D.C.: Dec. 16, 2008).

[62]GAO-07-652.

Stockpile. This stockpile is intended to be the nation's repository of animal vaccines, personal protective equipment, and other critical veterinary products to respond to the most dangerous foreign animal diseases, including highly pathogenic avian influenza. However, at the time of the report, USDA had not yet estimated the amount of antiviral medication that it would need in the event of a highly pathogenic avian outbreak or resolved how to provide such supplies within the first 24 hours of an outbreak. According to Occupational Safety and Health Administration guidelines, poultry workers responding to an outbreak of highly pathogenic avian influenza should take antiviral medication daily. Further, the National Veterinary Stockpile is required to contain sufficient amounts of antiviral medication to respond to the most damaging animal diseases that affect human health and the economy and has not yet obtained any antiviral medication for highly pathogenic avian influenza. However, HHS officials told National Veterinary Stockpile officials that the antiviral medication in the Strategic National Stockpile was reserved only for use during a human pandemic. We therefore recommended that the Secretary of Agriculture determine the amount of antiviral medication that USDA would need in order to protect animal health responders, given various highly pathogenic avian influenza scenarios, and determine how to obtain and provide supplies within 24 hours of an outbreak. In commenting on our recommendation, USDA officials told us that the National Veterinary Stockpile now contains enough antiviral medication to protect 3,000 animal health responders for 40 days. However, USDA officials told us that they have yet to determine the number of individuals that would need medicine based on a calculation of those exposed to the virus under a specific scenario. Further, USDA officials said that a contract for additional medication for the stockpile has not yet been secured, which would better ensure that medications are available in the event of an outbreak of highly pathogenic avian influenza.

Federal Agencies Have Provided Considerable Guidance and Pandemic-Related Information, but Could Augment Their Efforts

Our work evaluating public health and natural disaster catastrophe preparedness, response, and recovery has shown that insufficient collaboration among federal, state, and local governments created challenges for sharing public health information and developing interoperable communications for first responders. In 2005, we designated establishing appropriate and effective information-sharing mechanisms to improve homeland security as a high-risk area. Over the past several years, we have identified potential information-sharing barriers, critical success factors, and other key management issues that should be considered to facilitate information sharing among and between government entities and the private sector.

Citizens should be given an accurate portrayal of risk, without overstating the threat or providing false assurances of security. Risk communication principles have been used in a variety of public warning contexts, from alerting the public to severe weather, to less commonplace warnings of infectious disease outbreaks. In general, these principles seek to maximize public safety by ensuring the public has sufficient information to determine what actions to take to prevent or respond to emergencies. Appropriately warning the public of threats can help save lives and reduce costs of disasters. Federal, state and local officials and risk management experts who participated in an April 2008 Comptroller General's forum on strengthening the use of risk management principles in homeland security identified and ranked the challenges in applying these principles. Improving risk communication to the public was one of the top three challenges identified by the forum participants.[63]

Our prior work identified several instances when risk communication proved less than effective. For example, during the 2004-2005 flu season, demand for the flu vaccine exceeded supply, and information about future vaccine availability was uncertain (as could happen in a future pandemic). Although CDC communicated regularly through a variety of media as the situation evolved, state and local officials identified several communications lessons. These included the need for consistency among federal, state, and local communications, the importance of using diverse media to reach different audiences, and the importance of disseminating clear, updated information when responding to changing circumstances.[64]

[63]GAO, *Highlights of a Forum: Strengthening the Use of Risk Management Principles in Homeland Security*, GAO-08-627SP (Washington, D.C.: April 2008).

[64]GAO, *Influenza Vaccine: Shortages in 2004-05 Season Underscore Need for Better Preparation*, GAO-05-984 (Washington, D.C.: Sept. 30, 2005).

Another example, from our October 1999 report on DOD's anthrax vaccine immunization program, illustrated the importance of providing accurate and sufficient information to personnel. Although DOD and the military services used a variety of measures to educate military personnel about the program, military personnel wanted more information on the program, and over one-half of respondents that participated in our survey said that the information they received was less than moderately helpful or that they did not receive any information.[65]

The National Pandemic Implementation Plan emphasizes that government and public health officials must communicate clearly and continuously with the public throughout a pandemic. The plan recognizes that timely, accurate, credible, and coordinated messages will be necessary. The federal government has undertaken a number of communications efforts to provide information on a possible pandemic and how to prepare for it. HHS (including CDC), DHS, and other federal agencies have provided a variety of influenza pandemic information and guidance for states and local communities through Web sites and meetings with states. These efforts included:

- establishing an influenza pandemic Web site (www.pandemicflu.gov);
- including pandemic information on another Web site, Lessons Learned Information Sharing System (LLIS) (www.llis.dhs.gov), which is a national network of lessons learned and best practices for emergency responders and homeland security officials;
- sponsoring state pandemic summits with all 50 states and additional regional state workshops;
- disseminating pandemic preparedness checklists for workplaces, individuals and families, schools, health care, community organizations, and state and local governments; and
- providing additional guidance for the public, such as on pandemic vaccine targeting and allocation and pre-pandemic community planning.[66]

[65]GAO, *Medical Readiness: DOD Continues to Face Challenges in Implementing Its Anthrax Vaccine Immunization Program*, GAO/T-NSIAD-00-157 (Washington, D.C.: Apr. 13, 2000).

[66]Department of Health and Human Services and Department of Homeland Security, *Guidance on Allocating and Targeting Pandemic Influenza Vaccine* (July 23, 2008) and Department of Health and Human Services and Centers for Disease Control and Prevention, *Interim Pre-Pandemic Planning Guidance: Community Strategy for Pandemic Influenza Mitigation in the United States* (February 2007).

There are established coordination networks that are being used to provide information to state and local governments and to the private sector about pandemic planning and preparedness. For example, the FEBs are charged with providing timely and relevant information to support emergency preparedness and response coordination, and OPM expects the boards to establish notification networks and communications plans to be used in emergency and nonemergency situations. The boards are also expected to disseminate relevant information received from OPM and other agencies regarding emergency preparedness information and to relay local emergency situation information to parties such as OPM, FEB members, media, and state and local government authorities. FEB representatives generally viewed the boards as an important communications link between Washington and the field and among field agencies. Each of the selected boards we reviewed reported conducting communications activities as a key part of its emergency support service. In addition, critical infrastructure coordinating councils have been also primarily used as a means to share information and develop pandemic-specific guidance across the industry sectors, such as banking and finance and telecommunications, and across levels of government.

However, as noted earlier, state and local officials from all of the states and localities we interviewed wanted additional federal influenza pandemic guidance from the federal government on specific topics, such as implementing community interventions, fatality management, and facilitating medical surge. Although the federal government has issued some guidance, it may not have reached state and local officials or may not have addressed the particular concerns or circumstances of the state and local officials we interviewed. In addition, private sector officials have told us that they would like clarification about the respective roles and responsibilities of the federal and state governments during an influenza pandemic emergency, such as in state border closures and influenza pandemic vaccine distribution.

Performance Monitoring and Accountability for Pandemic Preparedness Needs Strengthening

As indicated earlier, in August 2007 we reported that although the National Pandemic Strategy and Implementation Plan identified the overarching goals and objectives for pandemic planning, the documents had some gaps. Most of the implementation plan's performance measures consist of actions to be completed, such as disseminating guidance, but the measures are not always clearly linked with intended results. This lack of clear linkages makes it difficult to ascertain whether progress has in fact been made toward achieving the national goals and objectives described in the National Pandemic Strategy and Implementation Plan. Without a clear linkage to anticipated results, these measures of activities do not give an indication of whether the purpose of the activity is achieved. For example, most of the action items' performance measures consist of actions to be completed, such as guidance developed and disseminated. Further, 18 of the action items have no measure of performance associated with them. In addition, the National Pandemic Implementation Plan does not establish priorities among its 324 action items, which becomes especially important as agencies and other parties strive to effectively manage scarce resources and ensure that the most important steps are accomplished. This is further complicated by the lack of a description of the financial resources needed to implement the action items, which is one of six characteristics of an effective national strategy.

We also found that some action items, particularly those that are to be completed by state, local, and tribal governments or the private sector, do not identify an entity responsible for carrying out the action. Although the plan specifies actions to be carried out by states, local jurisdictions, and other entities, including the private sector, it gives no indication of how these actions will be monitored, how their completion will be ensured, or who will be responsible for making sure that these actions are completed. Also, it appears that HSC's determination of completeness has not been accurately applied for all of the action items. Several of the action items that were reported by the HSC as being completed were still in progress. For example, our June 2007 report on U.S. agencies' international efforts to forestall an influenza pandemic found that eight of the plan's international-related action items included in the HSC's progress report as completed either did not directly address the associated performance measure or did not indicate that the completion deadline had been met.[67] As stated earlier, we are currently assessing the implementation of the plan.

[67]GAO-07-604.

We have also reported that, although DOD instituted reporting requirements for its components responsible for implementing 31 action items tasked to DOD in the National Pandemic Implementation Plan, there were not similar oversight mechanisms in place for pandemic-related tasks that were not specifically part of the National Plan.[68] For example, DOD did not require DOD components to report on their development or revision of their continuity of operations plans in preparation for an influenza pandemic. Over time, a lack of clear lines of authority, oversight mechanisms, and goals and performance measures could hamper the leadership's abilities to ensure that planning efforts across the department are progressing as intended as DOD continues its influenza pandemic planning and preparedness efforts. Additionally, without clear departmentwide goals, it would be difficult for all DOD components to develop effective plans and guidance. In response to our recommendation, DOD designated an official to lead DOD's pandemic efforts, established a Pandemic Influenza Task Force, and communicated this information throughout the department. DOD also assigned responsibility to the U.S. Northern Command for directing, planning, and synchronizing DOD's global response to an influenza pandemic and disseminated this information throughout the department.

There have been some other instances where performance and accountability has been strengthened. The FEBs have recently established performance measures for their emergency support role. In our May 2007 report, we recommended that OPM continue its efforts to establish performance measures and accountability for the emergency support responsibilities of the FEBs before, during, and after an emergency event that affects the federal workforce outside Washington, D.C.[69] In response to our recommendation, the FEB strategic plan for fiscal years 2008 through 2012 includes operational goals with associated measures for its emergency preparedness, security, and employee safety line of business. The data intended to support these measures include methods such as stakeholder and participant surveys, participant lists, and emergency preparedness test results.

In providing funding to states and certain localities to help them to prepare for a pandemic, HHS has instituted a number of accountability requirements. As described above, HHS received $5.62 billion in

[68]GAO-06-1042.

[69]GAO-07-515.

supplemental appropriations specifically available for pandemic influenza-related purposes in fiscal year 2006. As shown in figure 4, a total of $770 million, or about 14 percent of the supplemental appropriations, went to states and localities for preparedness activities. Of the $770 million, $600 million was specifically provided by Congress for state and local planning and exercising. The HHS pandemic funding was administered by CDC and required all 50 states and 3 localities to, among other things, develop influenza pandemic plans and conduct influenza pandemic exercises. According to CDC officials, all 50 states and the localities that received direct funding have met these requirements.

Concluding Observations

Strengthening preparedness for large-scale public health emergencies, including the possibility of an influenza pandemic, is one of the issues that we identified as among those needing the urgent attention of the new administration and Congress during this transition period. Although much has been done, many challenges remain, as is evidenced by the fact that almost half of the recommendations that we have made over the past 3 years have still not been fully implemented. Given the change in administration and the associated transition of senior federal officials, it will be essential for this administration to continue to exercise and test the shared leadership roles that have been established between HHS and DHS, as well as the relative roles, responsibilities, and authorities for a pandemic among the federal government, state and local governments and the private sector. In the area of critical infrastructure protection, DHS should continue to work with other federal agencies and private sector members of the critical infrastructure coordinating councils to help address the challenges required to coordinate between the federal and private sectors before and during a pandemic. These challenges include clarifying roles and responsibilities of federal and state governments. DHS and HHS should also, in coordination with other federal agencies, continue to work with states and local governments to help them address identified gaps in their pandemic planning. To help improve international disease surveillance and detection efforts, the United States should continue to work with international organizations and other countries to help address gaps in available information, which limit the capacity for comprehensive, well-informed comparisons of risk levels by countries.

Continued leadership focus on pandemic preparedness is particularly crucial now as the attention on influenza pandemic may be waning as attention shifts to other more immediate national priorities. In addition, as leadership changes across the executive branch, the new administration should recognize that the threat of an influenza pandemic remains

unchanged and should therefore continue to maintain momentum in preparing the nation for a possible influenza pandemic.

As agreed with your office, we plan no further distribution of this report until 30 days from its date, unless you publicly announce its contents earlier. At that time, we will send copies to other interested parties. In addition, this report is available at no charge on GAO's Web site at http://www.gao.gov.

If you or your staff have any further questions about this report, please contact me at (202) 512-6543 or steinhardtb@gao.gov, or Sarah Veale, Assistant Director, at (202) 512-6890 or veales@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. Major contributors to this report are listed in appendix III.

Sincerely yours,

Bernice Steinhardt
Director, Strategic Issues

Appendix I: Open Recommendations from GAO's Work on an Influenza Pandemic as of February 2009

Title and GAO product number	Summary of open recommendations	Status
Influenza Pandemic: HHS Needs to Continue Its Actions and Finalize Guidance for Pharmaceutical Interventions, GAO-08-671, September 30, 2008	The Secretary of Health and Human Services should expeditiously finalize guidance to assist state and local jurisdictions to determine how to effectively use limited supplies of antivirals and pre-pandemic vaccine in a pandemic, including prioritizing target groups for pre-pandemic vaccine.	In December 2008, HHS released final guidance on antiviral drug use during an influenza pandemic. HHS officials informed us that they are drafting the guidance on pre-pandemic influenza vaccination.
Influenza Pandemic: Federal Agencies Should Continue to Assist States to Address Gaps in Pandemic Planning, GAO-08-539, June 19, 2008	The Secretaries of Health and Human Services and Homeland Security should, in coordination with other federal agencies, convene additional meetings of the states in the five federal influenza pandemic regions to help them address identified gaps in their planning.	HHS and DHS officials indicated that while no additional meetings are planned at this time, states will have to continuously update their pandemic plans and submit them for review.
Influenza Pandemic: Opportunities Exist to Address Critical Infrastructure Protection Challenges That Require Federal and Private Sector Coordination, GAO-08-36, October 31, 2007	The Secretary of Homeland Security should work with sector-specific agencies and lead efforts to encourage the government and private sector members of the councils to consider and help address the challenges that will require coordination between the federal and private sectors involved with critical infrastructure and within the various sectors, in advance of, as well as during, a pandemic.	DHS officials informed us that the department is working on initiatives, such as developing pandemic contingency plan guidance tailored to each of the critical infrastructure sectors, and holding a series of "webinars" with a number of the sectors.

Title and GAO product number	Summary of open recommendations	Status
Influenza Pandemic: Further Efforts Are Needed to Ensure Clearer Federal Leadership Roles and an Effective National Strategy, GAO-07-781, August 14, 2007 *Influenza Pandemic: Opportunities Exist to Clarify Federal Leadership Roles and Improve Pandemic Planning*, GAO-07-1257T, September 26, 2007	(1) The Secretaries of Homeland Security and Health and Human Services should work together to develop and conduct rigorous testing, training, and exercises for an influenza pandemic to ensure that the federal leadership roles are clearly defined and understood and that leaders are able to effectively execute shared responsibilities to address emerging challenges. Once the leadership roles have been clarified through testing, training, and exercising, the Secretaries of Homeland Security and Health and Human Services should ensure that these roles are clearly understood by state, local, and tribal governments; the private and nonprofit sectors; and the international community.	(1) HHS and DHS officials stated that several influenza pandemic exercises had been conducted since November 2007 that involved both agencies and other federal officials, but it is unclear whether these exercises rigorously tested federal leadership roles in a pandemic.
	(2) The Homeland Security Council should establish a specific process and time frame for updating the National Pandemic Implementation Plan. The process should involve key nonfederal stakeholders and incorporate lessons learned from exercises and other sources. The National Pandemic Implementation Plan should also be improved by including the following information in the next update: (A) resources and investments needed to complete the action items and where they should be targeted, (B) a process and schedule for monitoring and publicly reporting on progress made on completing the action items, (C) clearer linkages with other strategies and plans, and (D) clearer descriptions of relationships or priorities among action items and greater use of outcome-focused performance measures.	(2) HSC did not comment on the recommendation and has not indicated if it plans to implement it.

Title and GAO product number	Summary of open recommendations	Status
Avian Influenza: USDA Has Taken Important Steps to Prepare for Outbreaks, but Better Planning Could Improve Response, GAO-07-652, June 11, 2007	(1) The Secretaries of Agriculture and Homeland Security should develop a memorandum of understanding that describes how USDA and DHS will work together in the event of a declared presidential emergency or major disaster, or an Incident of National Significance, and test the effectiveness of this coordination during exercises.	(1) Both USDA and DHS officials told us that they have taken preliminary steps to develop additional clarity and better define their coordination roles. For example the two agencies meet on a regular basis to discuss such coordination.
	(2) The Secretary of Agriculture should, in consultation with other federal agencies, states, and the poultry industry identify the capabilities necessary to respond to a probable scenario or scenarios for an outbreak of highly pathogenic avian influenza. The Secretary of Agriculture should also use this information to develop a response plan that identifies the critical tasks for responding to the selected outbreak scenario and, for each task, identifies the responsible entities, the location of resources needed, time frames, and completion status. Finally, the Secretary of Agriculture should test these capabilities in ongoing exercises to identify gaps and ways to overcome those gaps.	(2) USDA officials told us that it has created a draft preparedness and response plan that identifies federal, state, and local actions, timelines, and responsibilities for responding to highly pathogenic avian influenza, but the plan has not been issued yet.
	(3) The Secretary of Agriculture should develop standard criteria for the components of state response plans for highly pathogenic avian influenza, enabling states to develop more complete plans and enabling USDA officials to more effectively review them.	(3) USDA told us that it has drafted large volumes of guidance documents that are available on a secure Web site. However, the guidance is still under review and it is not clear what standard criteria from these documents USDA officials and states should apply when developing and reviewing plans.
	(4) The Secretary of Agriculture should focus additional work with states on how to overcome potential problems associated with unresolved issues, such as the difficulty in locating backyard birds and disposing of carcasses and materials.	(4) USDA officials have told us that the agency has developed online tools to help states make effective decisions about carcass disposal. In addition, USDA has created a secure Internet site that contains draft guidance for disease response, including highly pathogenic avian influenza, and it includes a discussion about many of the unresolved issues.

Title and GAO product number	Summary of open recommendations	Status
	(5) The Secretary of Agriculture should determine the amount of antiviral medication that USDA would need in order to protect animal health responders, given various highly pathogenic avian influenza scenarios. The Secretary of Agriculture should also determine how to obtain and provide supplies within 24 hours of an outbreak.	(5) USDA officials told us that the National Veterinary Stockpile now contains enough antiviral medication to protect 3,000 animal health responders for 40 days. However, USDA has yet to determine the number of individuals that would need medicine based on a calculation of those exposed to the virus under a specific scenario. Further, USDA officials told us that a contract for additional medication for the stockpile has not yet been secured, which would better ensure that medications are available in the event of an outbreak of highly pathogenic avian influenza.

Source: GAO

Appendix II: Implemented Recommendations from GAO's Work on an Influenza Pandemic as of February 2009

GAO report	Recommendation	Actions taken
Influenza Pandemic: DOD Combatant Commands' Preparedness Efforts Could Benefit from More Clearly Defined Roles, Resources, and Risk Mitigation, GAO-07-696, June 20, 2007	(1) The Secretary of Defense should instruct the Assistant Secretary of Defense for Homeland Defense and Americas' Security Affairs to issue guidance that specifies which of the tasks assigned to DOD in the plan and other pandemic planning tasks apply to the individual combatant commands, military services, and other organizations within DOD, as well as what constitutes fulfillment of these actions.	(1) The 14 national implementation plan tasks assigned to the Joint Staff as the lead organization within DOD, which includes tasks to be performed by the combatant commands, have been completed. According to DOD, the department's Global Pandemic Influenza Planning Team developed recommendations for the division of responsibilities, which were included in U.S. Northern Command's global synchronization plan for pandemic influenza. Additionally, DOD assigned pandemic influenza-related tasks to the combatant commands in its 2008 Joint Strategic Capabilities Plan.
	(2) The Secretary of Defense should instruct the Assistant Secretary of Defense for Homeland Defense and Americas' Security Affairs to issue guidance that specifies U.S. Northern Command's roles and responsibilities as global synchronizer relative to the roles and responsibilities of the various organizations leading and supporting the department's influenza pandemic planning.	(2) Revisions to DOD's 2008 Joint Strategic Capabilities Plan, as well as guidance from the Secretary of Defense during a periodic review of U.S. Northern Command's pandemic influenza global synchronization plan, clarified and better defined U.S. Northern Command's role as global synchronizer.
	(3) The Secretary of Defense should instruct the Assistant Secretary of Defense for Homeland Defense and Americas' Security Affairs to work with the Under Secretary of Defense (Comptroller) to identify the sources and types of resources combatant commands need to accomplish their influenza pandemic planning and preparedness activities.	(3) DOD, through U.S. Northern Command as the global synchronizer for pandemic influenza planning, collected information from the combatant commands on funding requirements related to pandemic influenza preparedness and submitted this information through DOD's formal budget and funding process. Through this process, five of the combatant commands (U.S. Northern Command, U.S. European Command, U.S. Pacific Command, U.S. Central Command, and U.S. Transportation Command) obtained about $25 million for fiscal years 2009 through 2013 for pandemic influenza planning and exercises. Future pandemic influenza-related funding requirements will be addressed through DOD's established budget process.

GAO report	Recommendation	Actions taken
	(4) The Secretary of Defense should instruct the Joint Staff to work with the combatant commands to develop options to mitigate the effects of factors that are beyond the combatant commands' control.	(4) The combatant commands are increasingly inviting representatives from the United Nations, including the World Health Organization and the Food and Agriculture Organization; host and neighboring nations; and other federal government agencies to exercises and conferences to share information and fill information gaps. Additionally, U.S. Northern Command and U.S. Pacific Command, along with the military services and installations, are increasingly working and planning with state, local, and tribal representatives. DOD views updating and reviewing plans to ensure that they are current as a continuous process driven by changes in policy, science, and environmental factors.
Financial Market Preparedness: Significant Progress Has Been Made, but Pandemic Planning and Other Challenges Remain, GAO-07-399, March 29, 2007	The Chairman, Federal Reserve, the Comptroller of the Currency, and the Chairman, Securities and Exchange Commission, should consider taking additional actions to ensure that market participants adequately prepare for an outbreak, including issuing formal expectations that business continuity plans for a pandemic should include measures likely to be effective even during severe outbreaks, and setting a date by which market participants should have such plans.	In December 2007, the Federal Reserve, in conjunction with the Federal Financial Institutions Examination Council, issued an Interagency Statement on Pandemic Planning to each Federal Reserve Bank and to all banking organizations supervised by the Federal Reserve. The statement directed those banks to ensure the pandemic plans they have in place are adequate to maintain critical operations during a severe outbreak. In December 2007, the Office of the Comptroller of the Currency, in conjunction with the Federal Financial Institutions Examination Council, also issued an Interagency Statement on Pandemic Planning to the national banks, outlining the same requirements for pandemic plans as the guidance issued by the Federal Reserve. In July and August of 2007, the Securities and Exchange Commission's Market Regulation Division issued letters to the major clearing organizations and exchanges—those covered by the Commission's 2003 Policy Statement on Business Continuity Planning for Trading Markets—that directed these organizations to confirm by year-end 2007 that their pandemic plans are adequate to maintain critical operations during a severe outbreak.
The Federal Workforce: Additional Steps Needed to Take Advantage of Federal Executive Boards' Ability to Contribute to Emergency Operations, GAO-07-515, May 4, 2007	(1) OPM should initiate discussion with the Department of Homeland Security and other responsible stakeholders to consider the feasibility of integrating the federal executive board's (FEB) emergency support responsibilities into the established emergency response framework, such as the *National Response Plan*.	(1) In January 2008, the FEBs were included in the *National Response Framework* section on regional support structures that have the potential to contribute to development of situational awareness during an emergency. In addition, in August 2007, the FEBs were integrated into the National Continuity Policy Implementation Plan issued by the White House Homeland Security Council.

GAO report	Recommendation	Actions taken
	(2) OPM should continue its efforts to establish performance measures and accountability for the emergency support responsibilities of the FEBs before, during, and after an emergency event that affects the federal workforce outside Washington, D.C.	(2) The FEB strategic plan for fiscal years 2008 through 2012 includes operational goals with associated measures for its emergency preparedness, security, and employee safety line of business. The data intended to support these measures includes methods such as stakeholder and participant surveys, participant lists, and emergency preparedness test results.
	(3) OPM, as part of its strategic planning process for the FEBs, should develop a proposal for an alternative to the current voluntary contribution mechanism that would address the uncertainty of funding sources for the boards.	(3) In November 2008, OPM submitted a legislative proposal to provide for interagency funding of FEB operations nationwide.
	(4) OPM should work with FEMA to develop a memorandum of understanding, or some similar mechanism that formally defines the FEB role in emergency planning and response.	(4) In addition to integrating the FEBs into national emergency plans, FEMA and OPM signed a memorandum of agreement on August 1, 2008. Among other things, the memorandum states that the federal executive boards and FEMA will work together in carrying out their respective roles in the promotion of the National Incident Management System and the *National Response Framework*.
Influenza Pandemic: DOD Has Taken Important Actions to Prepare, but Accountability, Funding, and Communications Need to be Clearer and Focused Departmentwide, GAO-06-1042, September 21, 2006	(1) The Secretary of Defense should instruct the Assistant Secretary of Defense for Homeland Defense, as the individual accountable for DOD's influenza pandemic planning and preparedness efforts, to clearly and fully define and communicate departmentwide the roles and responsibilities of the organizations that will be involved in DOD's efforts, with clear lines of authority; the oversight mechanisms, including reporting requirements, for all aspects of DOD's influenza pandemic planning efforts, to include those tasks that are outside of the national implementation plan; and the goals and performance measures for DOD's planning and preparedness efforts.	(1) The Deputy Secretary of Defense verbally designated the Assistant Secretary of Defense for Homeland Defense, working with the Assistant Secretary of Defense for Health Affairs, to lead DOD's pandemic influenza efforts and established a Pandemic Influenza Task Force. This information was communicated throughout the department when the Principal Deputy to the Assistant Secretary of Defense for Homeland Defense and Americas' Security Affairs issued DOD's Implementation Plan for Pandemic Influenza within the department in a July 2006 memo. Additionally, U.S. Northern Command was designated as the lead combatant command for directing, planning, and synchronizing DOD's global response to an influenza pandemic; this information was disseminated throughout the department in November 2006.
	(2) The Secretary of Defense should instruct the Assistant Secretary of Defense for Homeland Defense to work with the Under Secretary of Defense (Comptroller) to establish a framework for requesting funding for the department's preparedness efforts. The framework should include the appropriate funding mechanism and controls to ensure that needed funding for DOD's influenza pandemic preparedness efforts is tied to the department's goals.	(2) The Office of the Under Secretary of Defense (Comptroller) is utilizing established protocols for programming funds related to pandemic influenza preparedness for DOD. Funding requests for preparedness efforts were submitted as part of the department's fiscal year 2009 integrated program and budget review, and long-term funding requests will be included in future budget requests.

GAO report	Recommendation	Actions taken
	(3) The Secretary of Defense should instruct the Assistant Secretary of Defense for Health Affairs to clarify DOD's guidance to explicitly define whether or how all types of personnel—including DOD's military and civilian personnel, contractors, dependents, and beneficiaries—would be included in DOD's distribution of vaccines and antivirals, and communicate this information departmentwide.	(3) In August 2007, DOD issued additional guidance related to the distribution of its vaccine and antiviral stockpiles in the event of an influenza pandemic.
	(4) The Secretary of Defense should instruct the Assistant Secretary of Defense for Public Affairs to implement a comprehensive and effective communications strategy departmentwide that is transparent as to what actions each group of personnel should take and the limitations of the efficacy, risks, and potential side effects of vaccines and antivirals.	(4) DOD has updated its publicly available pandemic influenza Web site, to include links to the Military Vaccine Agency, which provides information on the risks and side effects of vaccines.

Source: GAO

Appendix III: GAO Contact and Staff Acknowledgments

GAO Contact

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Staff Acknowledgments

In addition to the contact named above, major contributors to this report include Sarah Veale, Assistant Director; Maya Chakko; Susan Sato; Mark Ryan; Kara Marshall; and members of GAO's Pandemic Working Group.

Related GAO Products

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