

August 2007

INFLUENZA PANDEMIC

Further Efforts Are Needed to Ensure Clearer Federal Leadership Roles and an Effective National Strategy





Highlights of [GAO-07-781](#), a report to congressional requesters

Why GAO Did This Study

An influenza pandemic is a real and significant potential threat facing the United States and the world. Pandemics occur when a novel virus emerges that can easily be transmitted among humans who have little immunity. In 2005, the Homeland Security Council (HSC) issued a *National Strategy for Pandemic Influenza* and, in 2006, an *Implementation Plan*.

Congress and others are concerned about the federal government's preparedness to lead a response to an influenza pandemic. This report assesses how clearly federal leadership roles and responsibilities are defined and the extent to which the Strategy and Plan address six characteristics of an effective national strategy. To do this, GAO analyzed key emergency and pandemic-specific plans, interviewed agency officials, and compared the Strategy and Plan with the six characteristics GAO identified.

What GAO Recommends

GAO recommends that (1) DHS and HHS develop rigorous testing, training, and exercises for pandemic influenza to ensure that federal leadership roles and responsibilities are clearly defined, understood, and work effectively and (2) the HSC set a time frame to update the Plan, involve key nonfederal stakeholders, and more fully address the characteristics of an effective national strategy. DHS and HHS concurred with the report. HSC did not comment.

www.gao.gov/cgi-bin/getrpt?GAO-07-781.

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

INFLUENZA PANDEMIC

Further Efforts Are Needed to Ensure Clearer Federal Leadership Roles and an Effective National Strategy

What GAO Found

The executive branch has taken an active approach to help address this potential threat, including establishing an online information clearinghouse, developing planning guidance and checklists, awarding grants to accelerate development and production of new technologies for influenza vaccines within the United States, and assisting state and local government pandemic planning efforts. 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. The Strategy and Plan do not specify how the leadership roles and responsibilities will work in addressing the unique characteristics of an influenza pandemic, which could occur simultaneously in multiple locations and over a long period. A pandemic could extend well beyond health and medical boundaries, affecting critical infrastructure, the movement of goods and services across the nation and the globe, the economy, and security. Although the Department of Health and Human Services' (HHS) Secretary is to lead the public health and medical response and the Department of Homeland Security's (DHS) Secretary is to lead overall nonmedical support and response actions, the Plan does not clearly address these simultaneous responsibilities or how these roles are to work together, particularly over an extended period and at multiple locations across the country. In addition, the Secretary of DHS has predesignated a national Principal Federal Official (PFO) to facilitate pandemic coordination as well as five regional PFOs and five regional Federal Coordinating Officers. Most of these leadership roles and responsibilities have not been tested under pandemic scenarios, leaving it unclear how they will work. Because initial actions may help limit the spread of an influenza virus, the effective exercise of shared leadership roles and responsibilities could have substantial consequences. However, only one national multisector pandemic-related exercise has been held and that was prior to the issuance of the Plan.

While the Strategy and Plan are an important first step in guiding national preparedness, they do not fully address all six characteristics of an effective national strategy. Specifically, they fully address only one of the six characteristics, by reflecting a clear description and understanding of problems to be addressed, and do not address one characteristic because the documents do not describe the financial resources needed to implement actions. Although the other characteristics are partially addressed, important gaps exist that could hinder the ability of key stakeholders to effectively execute their responsibilities, including state and local jurisdictions that will play crucial roles in preparing for and responding to a pandemic were not directly involved in developing the Plan, relationships and priorities among actions were not clearly described, performance measures focused on activities that are not always linked to results, insufficient information is provided about how the documents are integrated with other key related plans, and no process is provided for monitoring and reporting on progress.

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Abbreviations

CBO	Congressional Budget Office
COOP	Continuity of Operations
CRS	Congressional Research Service
DHS	Department of Homeland Security
DOD	Department of Defense
DOT	Department of Transportation
ESF	Emergency Support Function
FCO	Federal Coordinating Officer
FEMA	Federal Emergency Management Agency
HHS	Department of Health and Human Services
HSC	Homeland Security Council
NIMS	National Incident Management System
NRP	National Response Plan
PFO	Principal Federal Official
USDA	Department of Agriculture

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United States Government Accountability Office
Washington, DC 20548

August 14, 2007

The Honorable Judd Gregg
Ranking Member
Committee on the Budget
United States Senate

The Honorable Henry A. Waxman
Chairman
The Honorable Tom Davis
Ranking Member
Committee on Oversight and Government Reform
House of Representatives

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

An influenza pandemic is a real and significant threat facing the United States and the world. Pandemics occur when a novel virus emerges that infects and can be effectively transmitted between humans who have little immunity to it. Although the timing and severity of the next pandemic is unpredictable, there is widespread agreement that a pandemic will occur at some point. Three influenza pandemics occurred in the 20th century. Notable among these was the influenza pandemic of 1918, called the “Spanish flu,” which killed over 50 million people worldwide, including over 675,000 in the United States. Pandemics have spread worldwide within months, and a future pandemic is expected to spread even more quickly given modern travel patterns. While health experts cannot predict with certainty which strain of influenza virus will be involved in the next pandemic, the avian influenza virus that began in Hong Kong in 1997, known as H5N1, could lead to a pandemic if it acquires the genetic ability to spread efficiently from person to person.

Unlike incidents that are discretely bounded in space or time (e.g., most natural or man-made disasters), a 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. An influenza pandemic could result in 200,000 to 2 million deaths in the United States, depending on its severity. Further, an influenza pandemic

could have major impacts on society and the economy. According to a study by the Congressional Budget Office (CBO), a severe pandemic (similar to the 1918 pandemic) could result in a 5 percent reduction of the gross domestic product in the United States over the subsequent year. Further, an influenza pandemic could cause high rates of absences in schools and workplaces. According to the Centers for Disease Control and Prevention, in a severe pandemic, absences attributable to illness, the need to care for ill family members, and fear of infection may reach 40 percent during the peak weeks of a community outbreak, with lower rates of absence during the weeks before and after the peak.

To date, the H5N1 virus has been confirmed in birds in 60 nations, up from 16 nations reported in May 2005. There have been numerous cases where the virus has been transmitted from birds to humans, and although there have been isolated instances of human-to-human transmission, the virus has not yet transmitted efficiently from person to person. From January 2003 through July 25, 2007, the World Health Organization reported more than 300 confirmed human cases, and more than 190 of these people in 12 countries have died.

To address the potential threat of an influenza pandemic, the President and his Homeland Security Council (HSC) issued two planning documents. The first of these, the *National Strategy for Pandemic Influenza* (Strategy), was issued in November 2005 and 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 articulates expectations for nonfederal entities—including state, local, and tribal governments; the private sector; international partners; and individuals—to prepare themselves and their communities. The *Implementation Plan for the National Strategy for Pandemic Influenza* (Plan) was issued in May 2006. It is intended to lay out broad implementation requirements and responsibilities among the appropriate federal agencies and clearly define expectations for nonfederal entities. The Plan includes 324 action items related to these requirements, responsibilities, and expectations.

In light of the problems experienced during prior disasters, such as Hurricane Katrina, members of Congress and others have expressed concern about whether the federal government is adequately prepared to lead the nation in planning for and responding to an influenza pandemic. In response to your request, this report examines the clarity of federal leadership roles and responsibilities for preparing for and responding to a pandemic influenza and provides a detailed review of the Strategy and Plan.

The objectives of this report are to address the extent to which (1) federal leadership roles and responsibilities for preparing for and responding to a pandemic are clearly defined and documented and (2) the Strategy and the Plan address the characteristics of an effective national strategy. To address the first objective, we analyzed the Strategy and Plan and reviewed a variety of federal emergency documents, including the National Response Plan's (NRP) base plan and annexes, the draft implementation plan developed by the Department of Homeland Security (DHS), and the implementation plan developed by the Department of Health and Human Services (HHS). We interviewed officials from DHS (including the Federal Emergency Management Agency (FEMA)), HHS, and others with federal leadership roles in preparing for and responding to a pandemic, including the Departments of Agriculture (USDA), Defense (DOD), Transportation (DOT), and State. Some of these officials were involved in the development of the Plan. We also interviewed the Vice Commandant of the U.S. Coast Guard who has been pre-designated as the national Principal Federal Official for pandemic influenza. Additionally, we studied the findings in prior GAO products as well as reports issued by Congress, the Congressional Research Service (CRS), CBO, the HSC, DHS's Office of the Inspector General, and other experts.

For the second objective, we assessed the Strategy and Plan to determine how well they jointly addressed the six desirable characteristics of an effective national strategy that we developed in previous work, including reviewing several elements related to each characteristic. We have used this methodology to assess and report on the administration's strategies relating to combating terrorism, rebuilding Iraq, and improving citizens' financial literacy.¹ National strategies that address these characteristics offer policymakers and implementing agencies a management tool that can help ensure accountability and more effective results. Table 1 provides the desirable characteristics and a brief description of each characteristic.

¹ See GAO, *Combating Terrorism: Evaluation of Selected Characteristics in National Strategies Related to Terrorism*, [GAO-04-408T](#) (Washington, D.C.: Feb. 3, 2004); *Rebuilding Iraq: More Comprehensive National Strategy Needed to Help Achieve U.S. Goals*, [GAO-06-788](#) (Washington, D.C.: July 11, 2006); and *Financial Literacy and Education Commission: Further Progress Needed to Ensure an Effective National Strategy*, [GAO-07-100](#) (Washington, D.C.: Dec. 4, 2006).

Table 1: Summary of Desirable Characteristics for a National Strategy

Desirable characteristic	Brief description
Purpose, scope, and methodology	Addresses why the strategy was produced, the scope of its coverage, and the process by which it was developed.
Problem definition and risk assessment	Addresses the particular national problems and threats the strategy is directed toward.
Goals, subordinate objectives, activities, and performance measures	Addresses what the strategy is trying to achieve; steps to achieve those results; as well as the priorities, milestones, and performance measures to gauge results.
Resources, investments, and risk management	Addresses what the strategy will cost, the sources and types of resources and investments needed, and where resources and investments should be targeted by balancing risk reductions and costs.
Organizational roles, responsibilities, and coordination	Addresses who will be implementing the strategy, what their roles will be compared to others, and mechanisms for them to coordinate their efforts.
Integration and implementation	Addresses how a national strategy relates to other strategies' goals, objectives, and activities—and to subordinate levels of government and their plans to implement the strategy.

Source: GAO.

We rated the Strategy and Plan on each of the characteristics, giving a rating of “addresses,” “partially addresses,” or “does not address.” According to our methodology, a strategy “addresses” a characteristic when it explicitly cites all, or nearly all, elements of the characteristic, and has sufficient specificity and detail. A strategy “partially addresses” a characteristic when it explicitly cites one or a few of the elements of a characteristic, and the documents have sufficient specificity and detail. It should be noted that the “partially addresses” category includes a range that varies from explicitly citing most of the elements to citing as few as one of the elements of a characteristic. A strategy “does not address” a characteristic when it does not explicitly cite or discuss any elements of a characteristic, any references are either too vague or general to be useful, or both. The elements are provided in appendix I.

We conducted our review from May 2006 through June 2007 in accordance with generally accepted government auditing standards. Further details on our scope and methodology are in appendix I. A list of other related GAO

reports on pandemic preparedness, emergency preparedness, and other related topics is included at the end of this report.²

Results in Brief

While an influenza pandemic will most likely occur in the future, there is a high level of uncertainty about when a pandemic might occur and its level of severity. The administration has taken an active approach to this potential disaster by developing a Strategy and Plan and has taken a number of other actions. These include establishing an information clearinghouse for pandemic information; developing planning guidance and checklists for governments, businesses, nongovernmental organizations, and individuals; issuing the Strategy and Plan; and starting work on completing the action items contained in the Plan. In addition to these actions, HHS has awarded grants totaling \$350 million to state and local governments for pandemic planning and more than \$1 billion to accelerate development and production of new technologies for influenza vaccines within the United States. While these approaches have been significant, considerably more work needs to be done.

To begin with, 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. The Strategy and the Plan do not specify how the leadership roles and responsibilities would work in addressing the unique characteristics of a pandemic influenza, which could occur simultaneously in multiple locations and over a long period, coming in waves, each lasting weeks or months. A pandemic necessitates a strategy that extends well beyond health and medical boundaries, to include sustaining critical infrastructure, private sector activities, the movement of goods and services across the nation and the globe, and economic and security considerations. The Strategy and Plan indicate that both the Secretary of Health and Human Services and the Secretary of Homeland Security will have leadership responsibilities that are consistent with the NRP—the former for leading the federal medical response to a pandemic and the latter for overall domestic incident management and federal coordination. However, it is not clear how, in a pandemic, the Secretaries of Health and Human Services and Homeland Security would

² In addition to these published reports, GAO has engagements under way to examine other aspects of preparing for and responding to a pandemic, including efforts by DHS, HHS, and state and local governments.

share leadership responsibilities in practice. For example, a pandemic could threaten critical infrastructure, a DHS responsibility, by removing essential personnel from the workplace for weeks or months, requiring both a medical response as well as actions to protect and sustain critical infrastructure. Yet, the Plan does not clearly address these simultaneous responsibilities or how these roles are to work together, particularly over an extended period and at multiple locations across the country. Moreover, under recent legislation, the FEMA Administrator was designated 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.

In addition to these positions, the NRP includes leadership roles for Principal Federal Officials (PFO) and Federal Coordinating Officers (FCO). To assist in planning and coordinating efforts to respond to a pandemic, in December 2006 the Secretary predesignated a national PFO, and established five pandemic regions each with a regional PFO and FCO. PFOs are responsible for facilitating federal domestic incident planning and coordination, and FCOs are responsible for coordinating federal resource 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.

Most of these leadership roles and responsibilities have not been tested under pandemic scenarios, leaving unclear how all of these new and developing relationships would work. According to a 2007 CRS report, although pandemic influenza scenarios have been used to exercise specific response elements, such as the distribution of stockpiled medications at specific locations or jurisdictions, there have been no national exercises to test a multisector, multijurisdictional response or any exercises to test the new national leadership structure for pandemic influenza.³ The only national multisector pandemic exercise to date was a tabletop simulation conducted by members of the cabinet in December 2005—prior to the release of the Plan in May 2006 and the establishment of PFO and FCO positions for a pandemic.

The Strategy and Plan represent an important first step in guiding the nation's preparedness and response activities, calling for a series of

³ Congressional Research Service, *Pandemic Influenza: Domestic Preparedness Efforts*, RL 33145 (Washington, D.C.: Feb. 20, 2007).

actions by federal agencies and expectations for states and communities, the private sector, global partners, and individuals. However, when viewed together, the Strategy and Plan do not fully address the six characteristics of an effective national strategy. Gaps and deficiencies in these documents are particularly troubling because they can affect the usefulness of the planning documents to those with key roles to play and affect their ability to effectively carry out their responsibilities.

As shown in table 2, while the Strategy and Plan address one of the desirable characteristics of an effective national strategy, they do not address another characteristic and partially address the remaining four characteristics. For example, the documents address the problem definition and risk assessment characteristic by identifying the potential problems associated with a pandemic as well as potential threats, challenges, and vulnerabilities. However, they did not address the resources, investments, and risk management characteristic because they do not discuss the financial resources and investments needed to implement the actions called for. Therefore, they do not provide a picture of priorities or how adjustments might be made in view of resource constraints.

Table 2: Extent to Which the Strategy and Plan Address GAO’s Desirable Characteristics of an Effective National Strategy

Desirable characteristic	Addresses	Partially addresses	Does not address
Clear purpose, scope, and methodology		X	
Problem definition and risk assessment	X		
Goals, subordinate objectives, activities, and performance measures		X	
Resources, investments, and risk management			X
Organizational roles, responsibilities, and coordination		X	
Integration and implementation		X	

Source: GAO analysis of the *National Strategy for Pandemic Influenza* and *Implementation Plan for the National Strategy for Pandemic Influenza*.

The Strategy and Plan partially address the remaining four characteristics. Some of the gaps we found include the following:

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- Purpose, scope and methodology: Key stakeholders, such as state, local, and tribal governments, were not directly involved in developing actions and the performance measures that are to assess progress, even though the Strategy and Plan rely on these stakeholders' efforts. The Plan contains 17 actions in which state, local, and tribal governments should lead national and subnational efforts and identifies another 64 actions where their involvement is needed.
 - Integration and implementation: The Strategy and Plan provide little detail about how the set of pandemic plans they propose, such as the individual agencies' pandemic plans, are to be integrated with other existing national strategies that are to provide an overall all-hazards framework. For example, although the Strategy and Plan's leadership framework is consistent with provisions of the NRP, there are no linkages between the 39 response action items in the plan and the NRP or other response-related plans.
 - Goals, objectives, activities, and performance measures: Most of the Plan's performance measures are focused on activities, such as disseminating guidance, and are not always clearly linked to the goals and objectives described in the Strategy and Plan. This lack of a clear linkage between the performance measures and intended results makes it difficult to ascertain whether any progress beyond the completion of activities has in fact been made. Also, the Plan does not establish priorities among the 324 actions it calls for, and although the intent expressed in the Plan is that it will be updated, there are no mechanisms provided in the Plan to do so. Further, while officials told us they periodically report to the HSC the status of the action items for which their agencies have lead responsibility, there is no prescribed process for publicly reporting nor is there a process for monitoring actions led by other entities, such as states and local governments. In December 2006, the HSC publicly reported on the status of most of the actions that were to have been completed within 6 months of the Plan's release. However, some of the actions the HSC reported as complete are actually still under way, and other actions that were supposed to be completed were omitted from the report.
 - Organizational roles, responsibilities, and coordination: As noted earlier, the Strategy and Plan did not clarify how responsible officials will share leadership responsibilities.

This report contains two recommendations to enhance preparedness efforts for a possible pandemic. First, we recommend that the Secretaries of Homeland Security and Health and Human Services work together to develop and conduct rigorous testing, training, and exercises for pandemic influenza 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. The second

recommendation is that the HSC establish a specific process and time frame for updating the Plan. The process should involve key nonfederal stakeholders and incorporate lessons learned from exercises and other sources. The Plan can also be improved by including the following information in the next update: (1) resources and investments needed to complete the action items and where they should be targeted, (2) a process and schedule for monitoring and publicly reporting on progress made on completing the action items, (3) clearer linkages with other strategies and plans, and (4) clearer descriptions of relationships or priorities among actions items and greater use of outcome-focused performance measures.

DHS officials we met with said that they are developing a *Federal Concept Plan for Pandemic Influenza* that focuses on federal interagency tasks and is intended to help ensure coordinated federal preparation, response, and recovery operations if there is an outbreak. In May 2007, DHS provided a draft to federal agencies for review and comment, and officials think it may help address some of the gaps we identified in the Plan. DHS had not determined when the *Concept Plan* would be issued.

We provided a draft of this report to DHS, HHS, and the HSC for review and comment. DHS provided written comments which are reprinted in appendix II. In commenting on the draft report, DHS concurred with the first recommendation and stated that it is taking action on many of the shortfalls identified in the report. DHS also provided us with technical comments, which we incorporated in the report as appropriate.

HHS informed us that it had no comments and concurred with the draft report. The HSC did not comment on the draft report.

Background

The Strategy lays out three high-level goals to prepare for and respond to an influenza pandemic: (1) stop, slow, or otherwise limit the spread of a pandemic to the United States; (2) limit the domestic spread of a pandemic and mitigate disease, suffering, and death; and (3) sustain infrastructure and mitigate impact on the economy and the functioning of society. These goals are underpinned by three pillars that are intended to guide the federal government's approach to a pandemic threat: (1) preparedness and communication, (2) surveillance and detection, and (3) response and containment. Each pillar describes domestic and international efforts, animal and human health efforts, and efforts that would need to be undertaken at all levels of government and in communities to prepare for and respond to a pandemic.

The Plan is intended to support the broad framework and goals articulated in the Strategy by outlining specific steps that federal departments and agencies should take to achieve these goals. It also describes expectations regarding preparedness and response efforts of state and local governments and tribal entities and the private sector. The Plan's chapters cover categories of actions that are intended to address major considerations raised by a pandemic, including protecting human and animal health; transportation and borders; and international, security, and institutional considerations. The Plan is not intended to describe the operational details of how federal departments and agencies would accomplish their objectives to support the Strategy. Rather, these operational details are supposed to be included in the departments' and agencies' pandemic implementation plans along with additional considerations raised during a pandemic involving (1) protection of employees, (2) maintenance of essential functions and services, and (3) the manner in which departments and agencies would communicate messages about pandemic planning and respond to their stakeholders.

All-Hazards Emergency Management Policies Provide the Overarching Context for the Strategy and Plan

The Homeland Security Act of 2002 required the newly established DHS to develop a comprehensive National Incident Management System (NIMS) and a comprehensive NRP.⁴ NIMS and the NRP are intended to provide an integrated all-hazards approach to emergency incident management. As such, they are expected to form the basis of the federal response to a pandemic. NIMS defines "how" to manage an emergency incident. It defines roles and responsibilities of federal, state, and local responders for emergency incidents regardless of the cause, size, or complexity of the situation. Its intent is to establish a core set of concepts, principles, terminology, and organizational processes to enable effective, efficient, and collaborative emergency incident management at all levels. The NRP, on the other hand, defines "what" needs to be done to manage an emergency incident. It is designed to integrate federal government domestic prevention, protection, response, and recovery plans into a single operational plan for all hazards and all emergency response disciplines. Using the framework provided by NIMS, the NRP is intended to provide the structure and mechanisms for national-level policy and operational direction for domestic incident management where federal support is necessary.

⁴ Pub. L. No. 107-296, 116 Stat. 2135 (2002).

States may need federal assistance in the event of a pandemic to maintain essential services. Upon receiving such requests, the President may issue emergency or major disaster declarations pursuant to the Robert T. Stafford Disaster Relief and Emergency Assistance Act of 1974 (the Stafford Act).⁵ The Stafford Act primarily establishes the programs and processes for the federal government to provide major disaster and emergency assistance to state and local governments and tribal nations, individuals, and qualified private nonprofit organizations. Federal assistance may include technical assistance, the provision of goods and services, and financial assistance, including direct payments, grants, and loans. FEMA is responsible for carrying out the functions and authorities of the Stafford Act.

The Secretary of Health and Human Services also has authority, under the Public Health Service Act, to declare a public health emergency and to take actions necessary to respond to that emergency consistent with his/her authorities.⁶ These actions may include making grants, entering into contracts, and conducting and supporting investigations into the cause, treatment, or prevention of the disease or disorder that caused the emergency. The Secretary's declaration may also initiate the authorization of emergency use of unapproved products or approved products for unapproved uses as well as waiving of certain HHS regulatory requirements.

The NRP, as revised in May 2006, applies to all incidents requiring a coordinated federal response. The most severe of these incidents, termed Incidents of National Significance, must be personally declared and managed by the Secretary of Homeland Security. According to the Plan, the Secretary of Homeland Security may declare a pandemic an Incident of National Significance, perhaps as early as when an outbreak occurs in foreign countries but before the disease reaches the United States. In addition to the base response plan, the NRP has 31 annexes consisting of 15 Emergency Support Function (ESF) annexes, 9 support annexes, and 7 incident annexes. The ESFs are the primary means through which the federal government provides support to state, local, and tribal governments, and the ESF structure provides a mechanism for interagency coordination during all phases of an incident—some departments and

⁵ The Robert T. Stafford Disaster Relief and Emergency Assistance Act of 1974 is codified, as amended, at 42 U.S.C. § 5121-5207.

⁶ The Public Health Service Act is codified, as amended, at 42 U.S.C. § 201-300ii-4.

agencies may provide resources during the early stages, while others would be more prominent in supporting recovery efforts. The ESFs group capabilities and resources into the functions that are most likely needed during actual or potential incidents where coordinated federal response is required.

Of the 15 ESF annexes, ESF-8, the public health and medical services ESF, would be the primary ESF used for the public health and medical care aspects of a pandemic involving humans.⁷ Although HHS is the lead agency for ESF-8, the ESFs are carried out through a “unified command” approach and several other federal agencies, including the Departments of Agriculture, Defense, Energy, Homeland Security (and the U.S. Coast Guard), Justice, and Labor, are specifically supporting agencies.

ESF-11 pertains to agriculture and natural resources, and its purpose includes control and eradication of an outbreak of a highly contagious or economically devastating animal/zoonotic disease including avian influenza. The purpose of ESF-11 is to ensure, in coordination with ESF-8, that animal/veterinary/wildlife issues in natural disasters are supported. The Departments of Agriculture and the Interior share responsibilities as primary agencies for this ESF.⁸

FEMA has or shares lead responsibility for several of the ESFs, including those that would be applicable during a pandemic. For example, FEMA is the lead agency for ESF-5 (emergency management), ESF-6 (mass care, housing, and human services), and ESF-14 (long-term community recovery and mitigation) and is the primary agency for ESF-15 (external affairs). Additionally, FEMA is responsible for carrying out the functions and authorities of the Stafford Act.

The incident annexes describe the policies, situations, concept of operations, and responsibilities pertinent to the type of incident in question. Included among the seven incident annexes within the NRP is

⁷ The 15 ESF annexes are in (1) transportation; (2) communications; (3) public works and engineering; (4) firefighting; (5) emergency management; (6) mass care, housing, and human services; (7) resource support; (8) public health and medical services; (9) urban search and rescue; (10) oil and hazardous materials response; (11) agriculture and natural resources; (12) energy; (13) public safety and security; (14) long-term community recovery and mitigation; and (15) external affairs.

⁸ ESF-11 supporting agencies include the Departments of Commerce, Defense, Energy, Justice, and Labor.

the Catastrophic Incident Annex.⁹ The Catastrophic Incident Annex could be applicable to a pandemic influenza as it applies to any incident that results in extraordinary levels of mass casualties, damage, or disruption severely affecting the population, infrastructure, environment, economy, national morale, and/or government functions.

The NRP also addresses two key leadership positions in the event of a Stafford Act emergency or major disaster. One official, the FCO, who can be appointed by the Secretary of Homeland Security on behalf of the President, manages and coordinates federal resource support activities related to Stafford Act disasters and emergencies.¹⁰ The other official, the PFO, is designated by the Secretary of Homeland Security to facilitate federal support to established incident command structures and to coordinate overall federal incident management and assistance activities across the spectrum of prevention, preparedness, response, and recovery. The PFO is to provide a primary point of contact and situational awareness for the Secretary of Homeland Security. While the PFO is supposed to work closely with the FCO during an incident, the PFO has no operational authority over the FCO.

The Executive Branch Has Taken Other Steps to Prepare for a Pandemic

The executive branch has also developed tools and guidance to aid in preparing for and responding to a pandemic influenza. Among these are the following:

- A Web site, www.pandemicflu.gov, to provide one-stop access to U.S. government avian and pandemic influenza information. This site is managed by HHS.
- Planning checklists for state and local governments, businesses, schools, community organizations, health care providers, and individuals and

⁹ The NRP includes the seven incident annexes: biological, catastrophic, cyber, food and agriculture, nuclear/radiological, oil and hazardous materials, and terrorism incident law enforcement and investigation.

¹⁰ For non-Stafford Act incidents, the NRP refers to Federal Resource Coordinators.

families. As of July 2007, there were 16 checklists included on the Web site.¹¹

- Interim planning guidance for state, local, tribal, and territorial communities on nonpharmaceutical interventions (i.e., other than vaccines and drug treatment) to mitigate an influenza pandemic. This guidance, called the *Interim Pre-pandemic Planning Guidance: Community Strategy for Pandemic Influenza Mitigation in the United States*, includes a Pandemic Severity Index to characterize the severity of a pandemic, provides planning recommendations for specific interventions for a given level of pandemic severity, and suggests when those interventions should be started and how long they should be used.
- In March 2006, FEMA issued guidance for federal agencies to revise their Continuity of Operations (COOP) Plans to address pandemic threats. COOP plans are intended to ensure that essential government services are available in emergencies. We testified in May 2006, on the need for agencies to adequately prepare their telework capabilities for use during a COOP event.¹²
- In September 2006, DHS issued guidance to assist owners and operators of critical infrastructure and key resources to prepare for a localized outbreak, as well as a broader influenza pandemic.¹³

In addition to these tools and guidance, other actions included HHS grant awards totaling \$350 million to state and local governments for pandemic planning and more than \$1 billion to accelerate development and production of new technologies for influenza vaccines within the United States.

¹¹ As of July 25, 2007, the checklists included State and Local Pandemic Influenza Planning Checklist, Pandemic Preparedness Planning for United States Businesses with Overseas Operations, Business Pandemic Influenza Planning Checklist, Health Insurer Pandemic Influenza Planning Checklist, Travel Industry Pandemic Influenza Planning Checklist, Child Care and Preschool Pandemic Influenza Planning Checklist, School District (K-12) Pandemic Influenza Planning Checklist, Colleges and Universities Pandemic Influenza Planning Checklist, Faith-Based and Community Organizations Pandemic Influenza Planning Checklist, Home Health Care Services Pandemic Influenza Planning Checklist, Medical Offices and Clinics Checklist, Emergency Medical Services and Medical Transport Checklist, Hospital Preparedness Checklist, Long-term Care and Other Residential Facilities Pandemic Influenza Planning Checklist, and Pandemic Flu Planning Checklist for Individuals and Families.

¹² GAO, *Continuity of Operations: Agencies Could Improve Planning for Telework during Disruptions*, [GAO-06-740T](#) (Washington, D.C.: May 11, 2006).

¹³ Department of Homeland Security, *Pandemic Influenza Preparedness, Response, and Recovery Guide for Critical Infrastructure and Key Resources*, (Washington, D.C.: Sept. 19, 2006).

Federal Government Leadership Roles and Responsibilities Need Clarification and Testing

While the Strategy and Plan describe the broad roles and responsibilities for preparing for and responding to a pandemic influenza, they do little to clarify existing emergency response roles and responsibilities. Instead, the documents restate the shared roles and responsibilities of the Secretaries of Health and Human Services and Homeland Security already prescribed by the NRP and related annexes and plans. These and other leadership roles and responsibilities continue to evolve, such as with the establishment of a national PFO and regional PFOs and FCOs and potential changes from ongoing efforts to revise the NRP. Congress has also passed legislation to address prior problems that emerged regarding federal leadership roles and responsibilities for emergency management that have ramifications for pandemic influenza. Although pandemic influenza scenarios have been used to exercise specific response elements, such as the distribution of stockpiled medications at specific locations or jurisdictions, no national exercises have tested the new federal leadership structure for pandemic influenza.¹⁴ The only national multisector pandemic exercise to date was a tabletop simulation conducted by members of the cabinet in December 2005, which was prior to the release of the Plan and the establishment of the PFO and FCO positions for a pandemic.

The Strategy and Plan Do Not Clarify Leadership Roles and Responsibilities

The Strategy and Plan do not clarify the specific leadership roles and responsibilities for a pandemic. Instead, they restate the existing leadership roles and responsibilities, particularly for the Secretaries of Homeland Security and Health and Human Services, prescribed in the NRP—an all-hazards plan for emergencies ranging from hurricanes to wildfires to terrorist attacks. However, the leadership roles and responsibilities prescribed under the NRP may need to operate somewhat differently because of the characteristics of a pandemic that distinguish it from other emergency incidents. For example, because a pandemic influenza is likely to occur in successive waves, planning has to consider how to sustain response mechanisms for several months to over a year—issues that are not clearly addressed in the Plan. In addition, the distributed nature of a pandemic, as well as the sheer burden of disease across the nation, means that the support states, localities, and tribal entities can expect from the federal government would be limited in comparison to the aid it mobilizes for geographically and temporarily bounded disasters like earthquakes and hurricanes. Consequently, legal authorities, roles and responsibilities, and lines of authority at all levels of

¹⁴ Congressional Research Service, *Pandemic Influenza*.

government must be clearly defined, effectively communicated, and well-understood to facilitate rapid and effective decision making. This is also important for public and private sector organizations and international partners so everyone can better understand what is expected of them before and during a pandemic.

The Strategy and Plan describe the Secretary of Health and Human Services as being responsible for leading the medical response in a pandemic, while the Secretary of Homeland Security is responsible for overall domestic incident management and federal coordination. However, since a pandemic extends well beyond health and medical boundaries, to include sustaining critical infrastructure, private sector activities, the movement of goods and services across the nation and the globe, and economic and security considerations, it is not clear when, in a pandemic, the Secretary of Health and Human Services would be in the lead and when the Secretary of Homeland Security would lead.

Specifically, the Plan states that the Secretary of Health and Human Services, consistent with his/her role under the NRP as the coordinator for ESF-8, would be responsible for the overall coordination of the public health and medical emergency response during a pandemic, including coordinating all federal medical support to communities; providing guidance on infection control and treatment strategies to state, local, and tribal entities and the public; maintaining, prioritizing, and distributing countermeasures in the Strategic National Stockpile; conducting ongoing epidemiologic assessment and modeling of the outbreak; and researching the influenza virus, novel countermeasures, and rapid diagnostics. The Plan calls for the Secretary to be the principal federal spokesperson for public health issues, coordinating closely with DHS on public messaging pertaining to the pandemic.

Also similar to the NRP, the Plan states that the Secretary of Homeland Security, as the principal federal official for domestic incident management, would be responsible for coordinating federal operations and resources; establishing reporting requirements; and conducting ongoing communications with federal, state, local, and tribal governments, the private sector, and nongovernmental organizations. It also states that in the context of response to a pandemic, the Secretary of Homeland Security would coordinate overall nonmedical support and response actions, sustain critical infrastructure, and ensure necessary support to the Secretary of Health and Human Services' coordination of public health and medical emergency response efforts. Additionally, the Plan states that the Secretary of Homeland Security would be responsible for coordinating the

overall response to the pandemic; implementing policies that facilitate compliance with recommended social distancing measures; providing for a common operating picture for all departments and agencies of the federal government; and ensuring the integrity of the nation's infrastructure, domestic security, and entry and exit screening for influenza at the borders.¹⁵

Other DHS responsibilities include operating and maintaining the National Biosurveillance Integration System, which is intended to provide an all-source biosurveillance common operating picture to improve early warning capabilities and facilitate national response activities through better situational awareness. This responsibility, however, appears to be both a public health issue and an overall incident management issue, raising similar issues about the interrelationship of DHS and HHS roles and responsibilities. In addition, a pandemic could threaten our critical infrastructure, such as the capability to deliver electricity or food, by removing essential personnel from the workplace for weeks or months.¹⁶ The extent to which this would be considered a medical response with the Secretary of Health and Human Services in the lead, or when it would be under the Secretary of Homeland Security's leadership as part of his/her responsibility for ensuring that critical infrastructure is protected, is unclear. According to HHS officials we interviewed, resolving this ambiguity will depend on several factors, including how the outbreak occurs and the severity of the pandemic.

Officials from other agencies also need greater clarity about these roles and responsibilities. For example, USDA is not planning for DHS to assume the lead coordinating role if an outbreak of avian flu among poultry occurs sufficient in scope to warrant a presidential declaration of an emergency or major disaster.¹⁷ The federal response may be slowed as agencies resolve their roles and responsibilities following the onset of a

¹⁵ Social distancing includes measures such as limiting public gatherings or closing buildings to help people avoid exposure to infectious diseases.

¹⁶ Critical infrastructure and key resource sectors include agriculture and food; banking and finance; chemical; commercial facilities; dams; defense industrial base; drinking water and water treatment systems; emergency services; energy; government facilities; information technology; national monuments and icons; nuclear reactors, materials, and waste; postal and shipping; public health and health care; telecommunications; and transportation systems.

¹⁷ 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).

significant outbreak. In addition, although DHS and HHS officials emphasize that they are working together on a frequent basis, these roles and responsibilities have not been thoroughly tested and exercised.

Additional Key Leadership Roles and Responsibilities Are Evolving and Untested

The executive branch has several efforts, some completed and others under way, to strengthen and clarify leadership roles and responsibilities for preparing for and responding to a pandemic influenza. However, many of these efforts are new, untested through exercises, or both. For example, on December 11, 2006, the Secretary of Homeland Security predesignated the Vice Commandant of the U.S. Coast Guard as the national PFO for pandemic influenza, and also established five pandemic regions, each with a regional PFO.¹⁸ Also, FCOs were predesignated for each of the regions. In addition to the five regional FCOs, a FEMA official with significant FCO experience has been selected to serve as the senior advisor to the national PFO. DOD has selected Defense Coordination Officers and HHS has selected senior health officials to work together within this national pandemic influenza preparedness and response structure.

DHS is taking steps to further clarify federal leadership roles and responsibilities. Specifically, it is developing a *Federal Concept Plan for Pandemic Influenza*, which is intended to identify specific federal response roles and responsibilities for each stage of an outbreak. According to DHS, the *Concept Plan*, which is based on the *Implementation Plan* and other related documents, would also identify “seams and gaps that must be addressed to ensure integration of all federal departments and agencies prior to, during, and after a pandemic outbreak in the U.S.” According to DHS officials, they sent a draft to federal agencies in May for comment and have not yet determined when the *Concept Plan* will be issued.

U.S. Coast Guard and FEMA officials we met with recognized that planning for and responding to a pandemic would require different operational leadership roles and responsibilities than for most other emergencies. For example, a FEMA official said that given the number of people who would be involved in responding to a pandemic, collaboration between HHS, DHS, and FEMA would need to be greater than for any other past emergencies. Officials are starting to build relationships among

¹⁸ The Secretary of Homeland Security combined the jurisdictions covered by FEMA’s 10 regional offices into 5 pandemic regions.

the federal actors for a pandemic. For example, some of the federal officials with leadership roles for an influenza pandemic met during the week of March 19, 2007, to continue to identify issues and begin developing solutions. One of the participants, however, told us that although additional coordination meetings are needed, it may be challenging since there is no dedicated funding for the staff working on pandemic issues to participate in these and other related meetings.

The national PFO for pandemic influenza said that a draft charter has also been developed to establish a Pandemic Influenza PFO Working Group to help identify and address many policy and operational issues before a pandemic. According to a FEMA official, some of these issues include staff availability, protective measures for staff, and how to ensure that the assistance to be provided under the Stafford Act is implemented and coordinated in a unified and consistent manner across the country during a pandemic. As of June 7, 2007, the draft charter was undergoing some revisions and was expected to be sent to the Secretary of Homeland Security for review and approval around the end of June. Additionally, there are plans to identify related exercises, within and outside of the federal government, to create a consolidated schedule of exercises for the national PFO for pandemic influenza and regional PFOs and FCOs to participate in by leveraging existing exercise plans. DHS officials said that they expect FEMA would retain responsibility for maintaining this consolidated schedule.

It is unclear whether the newly established national and regional positions for a pandemic will further clarify leadership roles. For example, in 2006, DHS made revisions to the NRP and released a Supplement to the Catastrophic Incident Annex—both designed to further clarify federal roles and responsibilities and relationships among federal, state, and local governments and responders. However, we reported in February 2007 that these revisions had not been tested and there was little information available on the extent to which these and other actions DHS was taking to improve readiness were operational.¹⁹ Additionally, DHS is currently coordinating a comprehensive review of the NRP and NIMS to assess their effectiveness, identify improvements, and recommend modifications. One of the issues expected to be addressed during this review is clarifying of roles and responsibilities of key structures, positions, and levels of

¹⁹ GAO, *Homeland Security: Management and Programmatic Challenges Facing the Department of Homeland Security*, [GAO-07-398T](#) (Washington, D.C.: Feb. 6, 2007).

government, including the role of the PFO and that position's current lack of operational authority during an emergency. The review is expected to be done, and a revised NRP and NIMS issued, by the summer of 2007.

Recent Congressional Actions Addressed Leadership Roles and Responsibilities

Pandemic and All-Hazards Preparedness Act and Its Implementation

In 2006, Congress passed two acts addressing leadership roles and responsibilities for emergency management—the Pandemic and All-Hazards Preparedness Act²⁰ and the Post-Katrina Emergency Management Reform Act of 2006²¹—which were enacted into law on December 19, 2006 and October 4, 2006, respectively.

The Pandemic and All-Hazards Preparedness Act codifies preparedness and response federal leadership roles and responsibilities for public health and medical emergencies that are now in the NRP by designating the Secretary of Health and Human Services as the lead federal official for public health and medical preparedness and response, consistent with the NRP. The act also requires the Secretary to establish an interagency agreement, in collaboration with DOD, DHS, DOT, the Department of Veterans Affairs, and other relevant federal agencies, prescribing that consistent with the NRP, HHS would assume operational control of emergency public health and medical response assets in the event of a public health emergency. Further, the act requires that the Secretary develop a coordinated National Health Security Strategy and accompanying implementation plan for public health emergency preparedness and response. This health security strategy and accompanying implementation plan are to be completed by 2009 and updated every 4 years.

The act also prescribes several new preparedness responsibilities for HHS. For example, the Secretary must develop and disseminate criteria for an effective state plan for responding to a pandemic influenza. Additionally, the Secretary is required to develop and require the application of measurable evidence-based benchmarks and objective standards that measure the levels of preparedness in such areas as hospitals and state and local public health security.

The act seeks to further strengthen HHS's public health leadership role by transferring the National Disaster Medical System from DHS back to HHS,

²⁰ Pub. L. No. 109-417.

²¹ Pub. L. No. 109-295, Title VI.

Post-Katrina Reform Act and
Its Implementation

thus placing these public health resources within HHS.²² It also creates the Office of the Assistant Secretary for Preparedness and Response (replacing the Office of the Assistant Secretary for Public Health Emergency Preparedness) and consolidates other preparedness and response functions within HHS in the new Assistant Secretary's office.

HHS has set up an implementation team involving over 200 HHS staff to implement the provisions of this act. According to a HHS official, an interim implementation plan is expected to be made available for public comment sometime during the summer of 2007.

In response to the findings and recommendations from several reports, the Post-Katrina Emergency Management Reform Act (referred to as the Post-Katrina Reform Act in this report) designated the FEMA Administrator as the principal domestic emergency management advisor to the President, the HSC, and the Secretary of Homeland Security. Therefore, the FEMA Administrator also has a leadership role in preparing for and responding to an influenza pandemic, including key areas such as planning and exercising. For example, under the Post-Katrina Reform Act, the FEMA Administrator is responsible for carrying out a national exercise program to test and evaluate preparedness for a national response to natural and man-made disasters.

The act made FEMA a distinct entity within DHS for leading and supporting the nation in a risk-based, comprehensive emergency management system of preparedness, protection, response, recovery, and mitigation. As part of the reorganization, DHS transferred several offices and divisions of its National Preparedness Directorate to FEMA, including the Offices of Grants and Training and National Capital Region Coordination.²³ FEMA's National Preparedness Directorate contains functions related to preparedness doctrine, policy, and contingency planning and includes DHS's exercise coordination and evaluation program and emergency management training. Other transfers included the Chemical Stockpile Emergency Preparedness Division, Radiological Emergency Preparedness Program, and the United States Fire

²² The National Disaster Medical System was transferred to DHS from HHS as part of the Homeland Security Act of 2002 establishing DHS.

²³ On January 18, 2007, DHS provided Congress with a notice of implementation of the Post-Katrina Reform Act reorganization requirements and additional organizational changes made under the Homeland Security Act of 2002.

Administration. The reorganization took effect on March 31, 2007, and it will likely take some time before it is fully implemented and key leadership positions within FEMA are filled.

Rigorous and Robust Exercises Are Important for Testing Federal Leadership for a Pandemic

Disaster planning, including for a pandemic influenza, needs to be tested and refined with a rigorous and robust exercise program to expose weaknesses in plans and allow planners to refine them. Exercises—particularly for the type and magnitude of emergency incidents such as a severe influenza pandemic for which there is little actual experience—are essential for developing skills and identifying what works well and what needs further improvement. Our prior work examining the preparation for and response to Hurricane Katrina highlighted the importance of realistic exercises to test and refine assumptions, capabilities, and operational procedures; and build upon strengths.²⁴ In response to the experiences during Hurricane Katrina, the Post-Katrina Reform Act called for a national exercise program to evaluate preparedness of a national response to natural and man-made disasters.

While pandemic influenza scenarios have been used to exercise specific response elements and locations, such as for distributing stockpiled medications, there has been no national exercise to test a multisector, multijurisdictional response or any exercises to test the working and operational relationships of the national PFO and the five regional PFOs and FCOs for pandemic influenza. According to a CRS report, the only national multisector pandemic exercise to date was a tabletop simulation involving members of the federal cabinet in December 2005.²⁵ This tabletop exercise was prior to the release of the Plan in May 2006, the establishment of a national PFO and regional PFO and FCO positions for a pandemic, and enactment of the Pandemic and All-Hazards Preparedness Act in December 2006 and the Post-Katrina Reform Act in October 2006.

²⁴ GAO, *Hurricane Katrina: GAO's Preliminary Observations Regarding Preparedness, Response, and Recovery*, [GAO-06-442T](#) (Washington, D.C.: Mar. 8, 2006).

²⁵ Congressional Research Service, *Pandemic Influenza*.

The National Strategy and Its Implementation Plan Do Not Address All the Characteristics of an Effective Strategy, Thus Limiting Their Usefulness as Planning Tools

The Strategy and Plan represent important efforts to guide the nation's preparedness and response activities, setting forth actions to be taken by federal agencies and expectations for a wide range of actors, including states and communities, the private sector, global partners, and individuals. However, the Strategy and Plan do not address all of the characteristics of an effective national strategy as we identified in our prior work. While national strategies necessarily vary in content, the six characteristics we identified apply to all such planning documents and can help ensure that they are effective management tools. Gaps and deficiencies in these documents are particularly troubling in that a pandemic represents a complex challenge that will require the full understanding and collaboration of a multitude of entities and individuals. The extent to which these documents, that are to provide an overall framework to ensure preparedness and response to a pandemic influenza, fail to adequately address key areas, could have critical impact on whether the public and key stakeholders have a clear understanding and can effectively execute their roles and responsibilities.

As shown in table 3, the Strategy and its Plan address one of the six characteristics of an effective national strategy. However, they only partially address four and do not address one of the characteristics at all. As a result, the Strategy and Plan fall short as an effective national strategy in important areas.

Table 3: Extent to Which the Strategy and Plan Address GAO's Desirable Characteristics of an Effective National Strategy

Desirable characteristic	Addresses	Partially addresses	Does not address
Clear purpose, scope, and methodology		X	
Problem definition and risk assessment	X		
Goals, subordinate objectives, activities, and performance measures		X	
Resources, investments, and risk management			X
Organizational roles, responsibilities, and coordination		X	
Integration and implementation		X	

Source: GAO analysis of the *National Strategy for Pandemic Influenza* and *Implementation Plan for the National Strategy for Pandemic Influenza*.

The Strategy and Plan Partially Address Purpose, Scope, and Methodology

A national strategy should address its purpose, scope, and methodology, including the process by which it was developed, stakeholder involvement, and how it compares and contrasts with other national strategies. Addressing this characteristic helps make a strategy more useful to organizations responsible for implementing the strategy, as well as those responsible for oversight. We found that the Strategy and Plan partially address this characteristic by describing their purpose and scope. However, neither document described in adequate detail their methodology for involving key stakeholders, how they relate to other national strategies, or a process for updating the Plan.

In describing its purpose, the Strategy states that it was developed to provide strategic direction for the departments and agencies of the U.S. government and guide the U.S. preparedness and response activities to mitigate the impact of a pandemic. In support of the Strategy, the Plan states that its purpose is to translate the Strategy into tangible action and direct federal departments and agencies to take specific, coordinated steps to achieve the goals of the Strategy and outline expectations for state, local, and tribal entities; businesses; schools and universities; communities; nongovernmental organizations; and international partners.

As a part of its scope, the Plan identifies six major functions: (1) protecting human health, (2) protecting animal health, (3) international considerations, (4) transportation and borders, (5) security considerations, and (6) institutional considerations. The Plan proposes that departments and agencies undertake a series of actions in support of these functional areas with operational details on how departments would accomplish these objectives to be provided by separate departmental plans. Additionally, the Strategy and Plan describe the principles and planning assumptions that guided their development. The Strategy's guiding principles include recognition of the private sector's integral role and leveraging global partnerships. The Plan's principles are more expansive, listing 12 planning assumptions that it identifies as facilitating its planning efforts. For example, 1 of the assumptions is that illness rates would be highest among school-aged children (about 40 percent).

Another element under this characteristic is the involvement of key stakeholders in the development of the strategy. Neither the Strategy nor Plan described the involvement of key stakeholders, such as state, local, and tribal entities, in the development of the Strategy or Plan, even though they would be on the front lines in a pandemic and the Plan identifies actions they should complete. The Plan contains 17 actions calling for state, local, and tribal governments to lead national and subnational

efforts, and identifies another 64 actions where their involvement is needed. Officials told us that federal stakeholders had opportunities to review and comment on the Plan but that state, local, and tribal entities were not directly involved, although the drafters of the Plan were generally aware of their concerns. Stakeholder involvement during the planning process is important to ensure that the federal government's and nonfederal entities' responsibilities and resource requirements are clearly understood and agreed upon. Therefore, the Strategy and Plan may not fully reflect a national perspective on this critical national issue since nonfederal stakeholders were not involved in the process to develop the actions where their leadership, support, or both would be needed. Further, these nonfederal stakeholders need to understand their critical roles in order to be prepared to work effectively under difficult and challenging circumstances.

Both documents address the scope of their coverage and include several important elements in their discussions, but do not address how they compare and contrast to other national strategies. The Strategy recognizes that preparing for a pandemic is more than a purely federal responsibility, and that the nation must have a system of plans at all levels of government and in all sectors outside of government that can be integrated to address the pandemic threat. It also extends its scope to include the development of an international effort as a central component of overall capacity. The Strategy lays out the major functions, mission areas, and activities considered under the extent of its coverage. For example, the Strategy's scope is defined as extending well beyond health and medical boundaries, to include sustaining critical infrastructure, private sector activities, the movement of goods and services across the nation and the globe, and economic and security considerations. Although the Strategy states that it will be consistent with the National Security Strategy and the Strategy for Homeland Security, it does not specify how they are related. The Plan mentions the NRP and states that it will guide the federal pandemic response. Because a pandemic would affect all facets of our society, including the nation's security, it is important to recognize and reflect an understanding of how these national strategies relate to one another.

The Plan does not describe a mechanism for updating it to reflect policy decisions, such as clarifications in leadership roles and responsibilities and other lessons learned from exercising and testing or other changes. Although the Plan was developed with the intent of being initial guidance and being updated and expanded over time, officials in several agencies told us that specific processes or time frames for updating and revising it have not been established. In addition to incorporating lessons learned,

such updates are important in ensuring that the Plan accurately reflects entities' capabilities and a clear understanding of roles and responsibilities. Additionally, an update would also provide the opportunity for input from nonfederal entities that have not had an opportunity to directly provide input to the Strategy and Plan.

Strategy and Plan Address Problem Definition and Risk Assessment

National strategies need to reflect a clear description and understanding of the problems to be addressed, their causes, and operating environment. In addition, the strategy should include a risk assessment, including an analysis of the threats to and vulnerabilities of critical assets and operations. We found that the Strategy and Plan address this characteristic by describing the potential problems associated with a pandemic as well as potential threats and vulnerabilities.

In defining the problem, both documents provide information on what a pandemic is and how influenza viruses are transmitted, and explain that a threat stems from an unprecedented outbreak of avian influenza in Asia and Europe, caused by the H5N1 strain of the influenza A virus. The President, in releasing the Strategy, stated that it presented an approach to address the threat of pandemic influenza, whether it results from the strain currently in birds in Asia or another influenza virus. Additionally, the problem definition includes a historical perspective of other pandemics in the United States.

The Plan used the severity of the 1918 influenza pandemic as the basis for its risk assessment. A CBO study²⁶ was used to describe the possible economic consequences of such a severe pandemic on the U.S. economy today. While the Plan did not discuss the likelihood of a severe pandemic or analyze the possibility of whether the H5N1 strain would be the specific virus strain to cause a pandemic, it stated that history suggests that a pandemic would occur some time in the future. As a result, it recognizes the importance of preparing for an outbreak.

The Strategy and Plan included discussions of the constraints and challenges involved in a pandemic. For example, the Plan included challenges such as severe shortfalls in surge capacity in the nation's health care facilities, limited vaccine production capabilities, the lack of real-time

²⁶ Congressional Budget Office, *A Potential Influenza Pandemic: Possible Macroeconomic Effects and Policy Issues* (Washington, D.C.: Dec. 8, 2005).

surveillance among most of the systems, and the inability to quantify the value of many infection control strategies.

In acknowledging the challenges involved in pandemic preparedness, the Plan also describes a series of circumstances to enable preparedness, such as viewing pandemic preparedness as a national security issue, connectivity between communities, and communicating risk and responsibility. In this regard, the Plan recognizes that one of the nation's greatest vulnerabilities is the lack of connectivity between communities responsible for pandemic preparedness. The Plan specifically cites vulnerabilities in coordination of efforts between the animal and human health communities, as well as between the public health and medical communities. In the case of public health and medical communities, the public health community has responsibility for communitywide health promotion and disease prevention and mitigation efforts, and the medical community is largely focused on actions at the individual level.

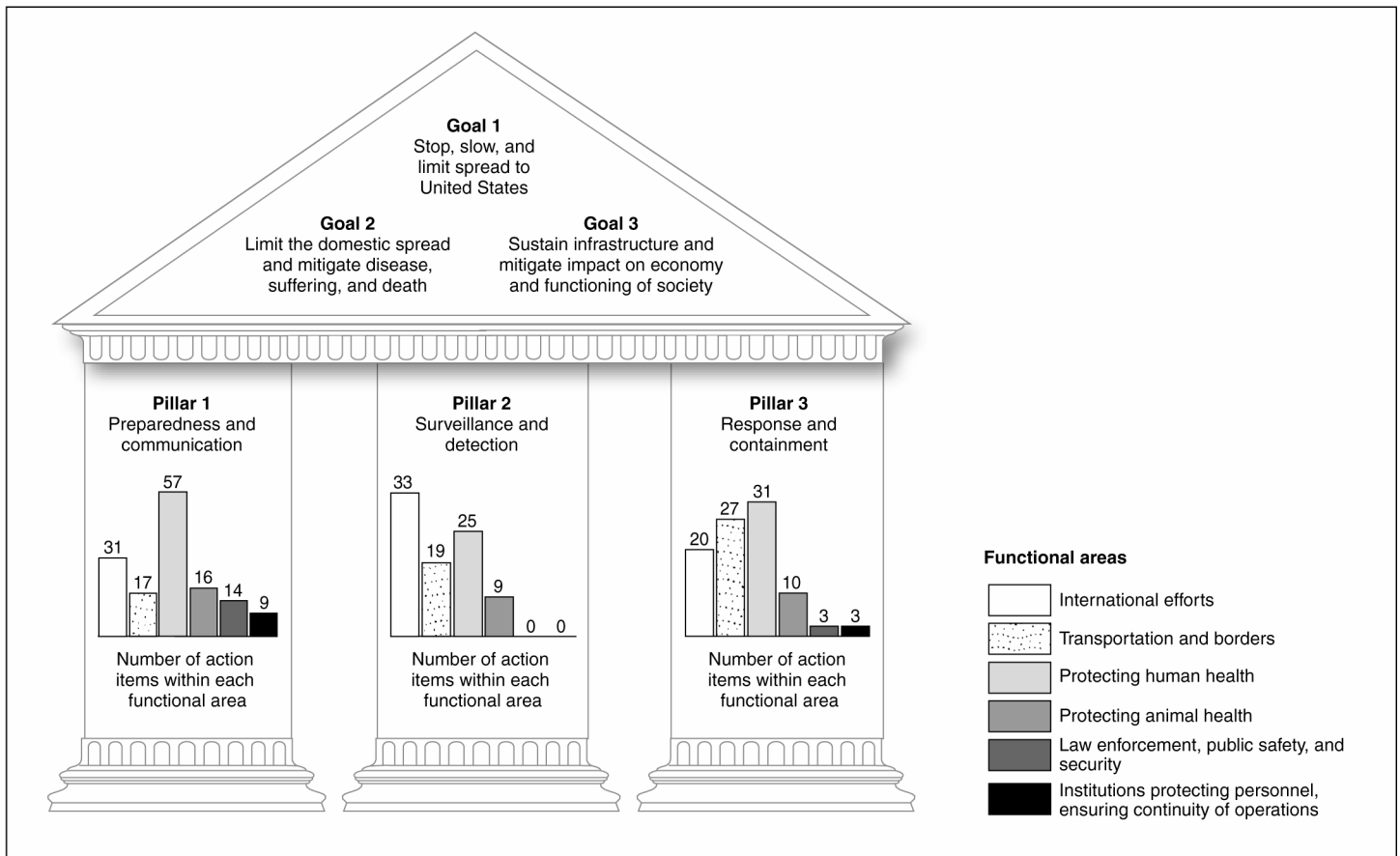
The Strategy and Plan Partially Address Goals, Objectives, Activities, and Performance Measures

A national strategy should describe its goals and the steps needed to achieve those results, as well as the priorities, milestones, and outcome-related performance measures to gauge results. Identifying goals, objectives, and outcome-related performance measures aids implementing parties in achieving results and enables more effective oversight and accountability. We found that the Strategy and Plan partially address this characteristic by identifying the overarching goals and objectives for pandemic planning. However, the documents did not describe relationships or priorities among the action items, and some of the action items lacked a responsible entity for ensuring their completion. The Plan also did not describe a process for monitoring and reporting on the action items. Further, many of the performance measures associated with action items were not clearly linked with results nor assigned clear priorities.²⁷

The Strategy and Plan identify a hierarchy of major goals, pillars, functional areas, and specific activities (i.e., action items), as shown in figure 1. The Plan includes and expands upon the Strategy's framework by including 324 action items.

²⁷ Of the 324 action items, 39 were response related with performance measures requiring certain efforts within a prescribed time frame after an outbreak and thus not included in the universe of action items assessed for this purpose. Additionally, there were no performance measures associated with 18 action items.

Figure 1: National Strategy and Implementation Plan's Goals, Pillars, Functional Areas, and Action Items



Source: GAO analysis of the *National Strategy for Pandemic Influenza* and the *Implementation Plan for the National Strategy for Pandemic Influenza*.

The Plan uses the Strategy's three major goals that are underpinned by three pillars as its framework and expands on this organizing structure by presenting chapters on six functional areas with various objectives, action items, and performance measures. For example, pillar 2, surveillance and detection, under the transportation and borders functional area, includes an objective to develop and exercise mechanisms to provide active and passive surveillance during an outbreak, both within and outside our borders. Under this objective is an action item for HHS, in coordination with other specific federal agencies, to develop policy recommendations for transportation and borders entry and exit protocols, screening, or both and to review the need to develop domestic response protocols and screening within 6 months. The item's performance measure is policy recommendations for response protocols, screening, or both.

While some action items depend on other action items, these linkages are not always apparent in the Plan. For example, one action item, concerning the development of a joint strategy for deploying federal health care and public health assets and personnel, is under the preparedness and communication pillar. However, another action item concerning the development of strategic principles for deployment of federal medical assets is under the response and containment pillar within the same chapter. While these two action items are clearly related, the plan does not make a connection between the two or discuss their relationship. An HHS official who helped draft the Plan acknowledged that while an effort was made to ensure linkages among action items, there may be gaps in the linkages among interdependent action items within and across the Plan's chapters on the six functional areas (i.e., the chapters that contain action items).

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 and how their completion will be ensured. For example, one such action item states that "all health care facilities should develop and test infectious disease surge capacity plans that address challenges including: increased demand for services, staff shortages, infectious disease isolation protocols, supply shortages, and security." Similarly, another action item states that "all Federal, State, local, tribal, and private sector medical facilities should ensure that protocols for transporting influenza specimens to appropriate reference laboratories are in place within 3 months." Yet the plan does not make clear who will be responsible for making sure that these actions are completed.

While most of the action items have deadlines for completion, ranging from 3 months to 3 years, the Plan does not identify a process to monitor and report on the progress of the action items nor does it include a schedule for reporting progress. Agency officials told us that they had identified individuals to act as overall coordinators to monitor the action items for which their agencies have lead responsibility and provide periodic progress reports to the HSC. However, we could not identify a similar mechanism to monitor the progress of the action items that fall to state and local governments or the private sector. The first public reporting on the status of the action items occurred in December 2006 when the HSC reported on the status of the action items that were to have been completed by November 3, 2006—6 months after the release of the

Plan. Of the 119 action items that were to be completed by that time, we found that the HSC omitted the status of 16 action items. Two of the action items that were omitted from the report were to (1) establish an interagency transportation and border preparedness working group and (2) engage in contingency planning and related exercises to ensure preparedness to maintain essential operations and conduct missions.

Additionally, we found that several of the action items that were reported by the HSC as being completed were still in progress. For example, DHS, in coordination with the Department of State (State), HHS, the Department of the Treasury (Treasury), and the travel and trade industry, was to tailor existing automated screening programs and extended border programs to increase scrutiny of travelers and cargo based on potential risk factors within 6 months. The measure of performance was to implement enhanced risk-based screening protocols. Although this action item was reported as complete, the HSC reported that DHS was still developing risk-based screening protocols, a major component of this action. A DHS official, responsible for coordinating the completion of DHS-led action items, acknowledged that all action items are a work in progress and that they would continue to be improved, including those items that were listed as completed in the report. The HSC's report included a statement that a determination of "complete" does not necessarily mean that work has ended; in many cases work is ongoing. Instead, the complete determination means that the measure of performance associated with an action item was met. It appears that this determination has not been consistently or accurately applied for all items. Our recent report on U.S. agencies' international efforts to forestall a pandemic influenza also reported that eight of the Plan's international-related action items included in the HSC's report either did not directly address the associated performance measure or did not indicate that the completion deadline had been met.²⁸

Most of the Plan's performance measures are focused on activities 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 Strategy and Plan. Most of

²⁸ 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).

the Plan's performance measures consist of actions to be completed, such as guidance developed and disseminated. 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. Further, 18 of the action items have no measure of performance associated with them. In addition, the 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.

The Strategy and Plan Do Not Address Resources, Investments, and Risk Management

A national strategy needs to describe what the strategy will cost; identify where resources will be targeted to achieve the maximum results; and describe how the strategy balances benefits, risks, and costs. Guidance on costs and resources needed using a risk management approach helps implementing parties allocate resources according to priorities, track costs and performance, and shift resources, as appropriate. We found that neither the Strategy nor Plan contain these elements.

While neither document addresses the overall cost to implement the Plan, the Plan refers to the administration's budget request of \$7.1 billion and a congressional appropriation of \$3.8 billion to support the objectives of the Strategy. In November 2005, the administration requested \$7.1 billion in emergency supplemental funding over 3 years to support the implementation of the Strategy. In December 2005, Congress appropriated \$3.8 billion to support budget requirements to help address pandemic influenza issues.²⁹ The Plan states that much of this funding would be directed toward domestic preparedness and the establishment of countermeasure stockpile and production capacity, with \$400 million directed to bilateral and multilateral international efforts. However, the 3-year \$7.1 billion budget proposal does not coincide with the period of the Plan. Additionally, whereas the Plan does not allocate funds to specific action items, our analysis of budget documents indicates that the funds were allocated primarily toward those action items related to vaccines and antivirals.

Developing and sustaining the capabilities stipulated in the Plan would require the effective use of federal, state, and local funds. Given that funding needs may not be readily addressed through existing mechanisms

²⁹ Emergency Supplemental Appropriations to Address Hurricanes in the Gulf of Mexico and Pandemic Influenza Act of 2006, Division B of Pub.L. No. 109-148 (2005).

and could stress existing government and private resources, it is critical for the Plan to lay out funding requirements. For example, the Plan states that one of the primary objectives of domestic vaccine production capacity would be for domestic manufacturers to produce enough vaccine for the entire U.S. population within 6 months. However, it states that production capacity would depend on the availability of future appropriations. Despite the fact that the production of enough vaccine for the population would be critical if a pandemic were to occur, the Plan does not provide even a rough estimate of how much the vaccine could cost for consideration in future appropriations.

Despite the numerous action items and specific implementing directives and guidance directed toward federal agencies, states, organizations, and businesses, neither document addresses what it would cost to complete the actions that are stipulated. Rather, the Plan states that the local communities would have to address the medical and nonmedical effects of the pandemic with available resources, and also that pandemic influenza response activities may exceed the budgetary resources of responding federal and state government agencies.

The overall uncertainty of funding to complete action items stipulated in the Plan has been problematic. For example, there were more than 50 actions in the Plan that were to be completed before the end of 2006 for which DOD was either a lead or support agency. We reported that because DOD had not yet requested funding, it was unclear whether DOD could address the tasks assigned to it in the Plan and pursue its own preparedness efforts for its workforce departmentwide within current resources.³⁰

The Strategy and Plan Partially Address Organizational Roles, Responsibilities, and Coordination

A national strategy should address which organizations would implement the strategy, their roles and responsibilities, and mechanisms for coordinating their efforts. It helps to answer the fundamental question about who is in charge, not only during times of crisis, but also during all phases of emergency management, as well as the organizations that will provide the overall framework for accountability and oversight. This characteristic entails identifying the specific federal departments,

³⁰ 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).

agencies, and offices involved and, where appropriate, the different sectors, such as state, local, private, and international sectors. We found that the Strategy and Plan partially address this characteristic by containing broad information on roles and responsibilities. But, as we noted earlier, while the Plan describes coordination mechanisms for responding to a pandemic, it does not clarify how responsible officials would share leadership responsibilities. In addition, it does not describe mechanisms for coordinating preparations and completing the action items, nor does it describe an overall accountability and oversight framework.

The Strategy identifies lead agencies for preparedness and response. Specifically, HHS is the lead agency for medical response; USDA for veterinary response; State for international activities; and DHS for overall domestic incident management, sustainment of critical infrastructure and key resources, and federal coordination. The Plan also briefly describes the preparedness and response roles and responsibilities of DOD, the Department of Labor, DOT, and Treasury. The Plan states that these and all federal cabinet agencies are responsible for their respective sectors and developing pandemic response plans. In addition, the Strategy and Plan broadly describe the expected roles and responsibilities of state, local, and tribal governments; international partners; the private and nonprofit sectors; and individuals and families. For example, in the functional area of transportation and borders, the Plan states that it expects state and local communities to involve transportation and health professionals to identify transportation options, consequences, and implications in the event of a pandemic.

The Plan states that the primary mechanism for coordinating the federal government's response to a pandemic is the NRP. In this regard, the Plan acknowledges that sustaining mechanisms for several months to over a year will present unique challenges, and thus day-to-day monitoring of the response to a pandemic influenza would occur through the national operations center with an interagency body composed of senior decision makers from across the government and chaired by the White House. Additionally, the Plan states that policy issues that cannot be resolved at the department level would be addressed through the HSC-National Security Council policy coordination process. As stipulated in the Plan, the specifics of this policy coordination mechanism were included in the May 2006 revisions to the NRP.

The Plan also generally identifies lead and support roles for the action items federal agencies are responsible for completing, but it is not explicit

in defining these roles or processes for coordination and collaboration. While it identifies which federal agencies have lead and support roles for completing 305 action items, the Plan does not define the roles of the lead and support agencies. Rather, it leaves it to the agencies to interpret and negotiate their roles. According to DOT officials we met with, this lack of clarity, coupled with staff turnover, left them unclear about their roles and responsibilities in completing action items. Thus, they had to seek clarification from DHS and HHS officials to assist them in defining what it meant to be the lead agency for an action item. Additionally, the Plan does not describe specific processes for coordination and collaboration between federal and nonfederal organizations and sectors for completing the action items.

Related to this issue, we recently reported that some of DOD's combatant commands, tasked with providing support in the event of a pandemic, had received limited detailed guidance from the lead agencies about what support they may be asked to provide during a pandemic.³¹ This has hindered these commands' ability to plan to provide support to lead federal agencies domestically and abroad during a pandemic.

The Plan also does not describe the role played by organizations that are to provide the overall framework for accountability and oversight, such as the HSC. According to agency officials, the HSC is monitoring executive branch agencies' efforts to complete the action items. However, there is no specific documentation describing this process or institutionalizing it. This is important since some of the action items are not expected to be completed during this administration. Also, a similar oversight process for those actions items for which nonfederal entities have the lead responsibility does not appear to exist.

The Strategy and Plan Partially Address Integration and Implementation

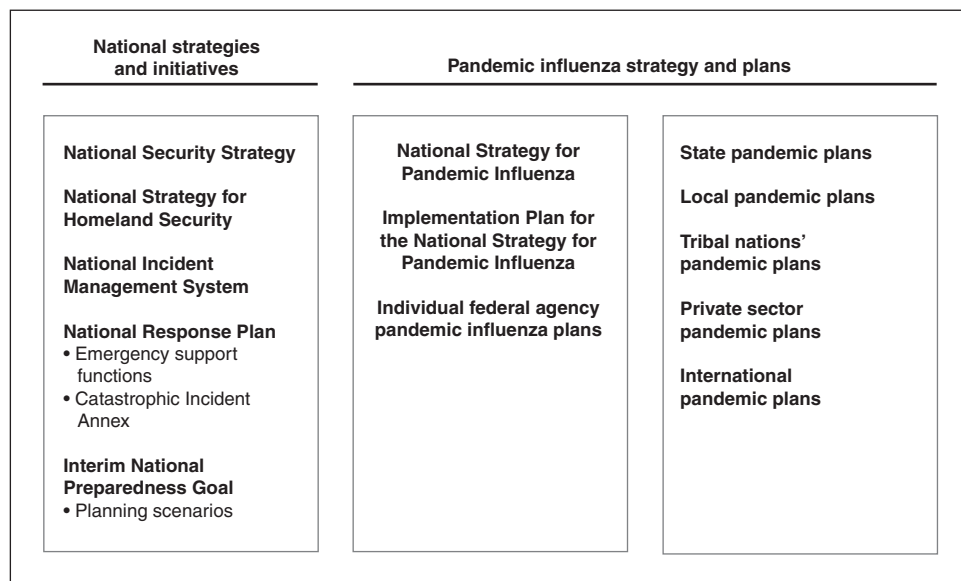
A national strategy should make clear how it relates to the goals, objectives, and activities of other strategies and to subordinate levels of government and their plans to implement the strategy. A strategy might also discuss, as appropriate, various strategies and plans produced by state, local, private, and international sectors. A clear relationship between the strategy and other critical implementing documents helps agencies and

³¹ GAO, *Influenza Pandemic: DOD Combatant Commands' Preparedness Efforts Could Benefit from More Clearly Defined Roles, Resources, and Risk Mitigation*, [GAO-07-696](#) (Washington, D.C.: June 20, 2007).

other entities understand their roles and responsibilities, foster effective implementation, and promote accountability. We found that the Strategy and Plan partially address this characteristic. Although the documents mention other related national strategies and plans, they do not provide sufficient detail describing the relationships among these strategies and plans nor do they describe how subordinate levels of government and independent plans proposed by the Plan would be integrated to implement the Strategy.

Since September 11, 2001, various national strategies, presidential directives, and national initiatives have been developed to better prepare the nation to respond to incidents of national significance, such as a pandemic influenza. As noted in figure 2, these include the National Security Strategy and the NRP. However, although the Strategy states that it is consistent with the National Security Strategy and the National Strategy for Homeland Security, it does not state how it is consistent or describe its relationship with these two strategies. In addition, the Plan does not specifically address how the Strategy or other related pandemic plans should be integrated with the goals, objectives, and activities of the national initiatives already in place.

Figure 2: Related National Preparedness Strategies, Initiatives, and Plans



Source: GAO.

Whereas the Plan states that it supports Homeland Security Presidential Directive 8, which required the development of a domestic all-hazards

preparedness goal—the National Preparedness Goal (Goal)—it does not describe how it supports the directive or its relationship to the Goal.³² The current interim Goal is particularly important for determining what capabilities are needed for a catastrophic disaster. It defines 36 major capabilities that first responders should possess to prevent, protect from, respond to, and recover from a wide range of incidents and the most critical tasks associated with these capabilities. An inability to effectively perform these critical tasks would, by definition, have a detrimental effect on protection, prevention, response, and recovery capabilities. The interim Goal also includes 15 planning scenarios, including one for pandemic influenza that outlines universal and critical tasks to be undertaken for planning for an influenza pandemic and target capabilities, such as search and rescue and economic and community recovery. Yet, the Strategy and Plan do not integrate this already-developed planning scenario and related tasks and capabilities. One federal agency official who assisted in drafting the Plan told us that the Goal and its pandemic influenza scenario had been considered but omitted because the Goal’s pandemic influenza scenario is geared to a less severe pandemic—such as those that occurred in 1957 and 1968—while the Plan is based on the more severe 1918-level mortality and morbidity rates.

Further, the Strategy and Plan do not provide sufficient detail about how the Strategy, action items, and proposed set of independent plans are to be integrated with other national strategies and framework. Without clearly providing this linkage, the Plan may limit a common understanding of the overarching framework, thereby hindering the nation’s ability to effectively prepare for, respond to, and recover from a pandemic. For example, the Plan contains 39 action items that are response related (i.e., specific actions are to be taken within a prescribed number of hours or days after an outbreak). However, these action items are interspersed among the 324 action items, and the Plan does not describe the linkages of these response-related action items with the NRP or other response related plans. Further, DHS officials have recognized the need for a common understanding across federal agencies and better integration of agencies plans to prepare for and respond to a pandemic. DHS officials are developing a *Federal Concept Plan for Pandemic Influenza* to enhance interagency preparedness, response, and recovery efforts.

³² The Goal establishes the national vision and priorities to guide the nation’s efforts to set measurable readiness benchmarks and targets to strengthen the nation’s preparedness, and attempts to provide a comprehensive preparedness effort.

The Plan also requires the federal departments and agencies to develop their own pandemic plans that describe the operational details related to the respective action items and cover the following areas: (1) protection of their employees; (2) maintenance of their essential functions and services; (3) how they would support both the federal response to a pandemic and those of states, localities, and tribal entities; and (4) the manner in which they would communicate messages about pandemic planning and response to their stakeholders. Further, it is unclear whether all the departments will share some or all of the information in their plans with nonfederal entities. While some agencies—such as HHS, DOD, and the Department of Veterans Affairs—have publicly released their pandemic plans, at least one agency, DHS, has indicated that it does not intend to publicly release its plan. Since DHS is a lead agency for planning for and responding to a pandemic, this gap may make it more challenging to fully advance joint and integrated planning across all levels of government and the private sector.

The Plan recognizes and discusses the need for integrating planning across all levels of government and the private sector to ensure that the plans and response actions are complementary, compatible, and coordinated. In this regard, the Plan provides initial planning guidance for state, local, and tribal entities; businesses; schools and universities; and nongovernmental organizations for a pandemic. It also includes various action items that when completed, would produce additional planning guidance and materials for these entities. However, the Plan is unclear as to how the existing guidance relates to broad federal and specific departmental and agency plans as well as how the additional guidance would be integrated and how any gaps or conflicts that exist would be identified and addressed.

Conclusions

Although it is likely that an influenza pandemic will occur in the future, there is a high level of uncertainty about when a pandemic might occur and its level of severity. The administration has taken an active approach to this potential disaster by establishing an information clearinghouse for pandemic information; developing numerous planning guidelines for governments, businesses, nongovernmental organizations, and individuals; issuing the Strategy and Plan; completing many action items contained in the Plan; and continuing efforts to complete the remaining action items.

A pandemic poses some unique challenges. Other disasters, such as hurricanes, earthquakes, or terrorist attacks, generally occur within a short period and the immediate effects are experienced in specific

locations. By contrast, a pandemic would likely occur in multiple waves, each lasting weeks or months and affecting communities across the nation. Initial actions may help limit the spread of an influenza virus, reflecting the importance of a swift and effective response. Therefore, the effective exercise of shared leadership roles and responsibilities could have substantial consequences, both in the short and long term. However, these roles and responsibilities continue to evolve, leaving uncertainty about how the federal government would lead preparations for and response to a pandemic. Since the release of the Plan in May 2006, no national pandemic exercises of federal leadership roles and responsibilities have been conducted. Without rigorous testing, training, and exercising, the administration lacks information to determine whether current and evolving leadership roles and responsibilities are clear and clearly understood or if more changes are needed to ensure clarity.

The Strategy and Plan are important because they broadly describe the federal government's approach and planned actions to prepare for and respond to a pandemic, as well as expectations for states and communities, the private sector, and global partners. Although they contain a number of important characteristics, the documents lack several key elements. As a result, their usefulness as a management tool for ensuring accountability and achieving results is limited. For example, because the Strategy and Plan do not address the resources and investments needed to implement the actions called for, it is unclear what resources are needed to build capacity and whether they would be available. Further, because they did not include stakeholders that are expected to be the primary responders to a pandemic in the development of the Strategy and Plan, these documents may not fully reflect a national perspective on this critical national issue, and stakeholders and the public may not have a full understanding of their critical roles. In addition, the linkages among pandemic planning efforts and with all-hazards plans and initiatives need to be clear so that the numerous parties involved can operate in an integrated manner. Finally, because many of the performance measures do not provide information about the impacts of proposed actions, it will be difficult to assess the extent to which we are better prepared or to identify areas needing additional attention. Opportunities exist to improve the usefulness of the Plan because it is viewed as an evolving document and is intended to be updated on a regular basis to reflect ongoing policy decisions, as well as improvements in domestic preparedness. Currently, however, time frames or mechanisms for updating the Plan are undefined.

While the HSC publicly reported on the status of approximately 100 action items that were to have been completed by November 2006, the Plan lacks a prescribed process for monitoring and reporting on the progress of the action items or what has been accomplished as a result. Therefore, it is unclear when the next report will be issued or how much information will be released. In addition, some of the information reported was incorrect. This lack of transparency makes it difficult to inform a national dialogue on the progress made to date or what further steps are needed. It also inhibits congressional oversight of strategies, funding priorities, and critical efforts to enhance the nation's level of preparedness.

DHS officials believe that their efforts to develop a *Federal Concept Plan for Pandemic Influenza* may help to more fully address some of the characteristics that we found the Strategy and Plan lack. According to those officials, the proposed *Concept Plan* may help, for example, better integrate the organizational roles, responsibilities, and coordination of interagency partners. They recognized, however, that the *Concept Plan* would not fully address all of the gaps we have identified. For example, they told us that the *Concept Plan* may not address actual or estimated costs or investments of the resources that will be required. Overall, they agreed that more needs to be done, especially in view of the long time requirements and challenging issues presented by a potential pandemic influenza.

Recommendations for Executive Action

To enhance preparedness efforts for a possible pandemic, we are making the following two recommendations:

We recommend that the Secretaries of Homeland Security and Health and Human Services work together to develop and conduct rigorous testing, training, and exercises for pandemic influenza to ensure that 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.

We also recommend that the Homeland Security Council establish a specific process and time frame for updating the *Implementation Plan for the National Strategy for Pandemic Influenza*. The process for updating the Plan should involve key nonfederal stakeholders and incorporate

lessons learned from exercises and other sources. The Plan should also be improved by including the following information in the next update:

- the cost, sources, and types of resources and investments needed to complete the action items and where they should be targeted;
- a process and schedule for monitoring and publicly reporting on progress made on completing the actions;
- clearer linkages with other strategies and plans; and
- clearer descriptions of relationships or priorities among action items and greater use of outcome-focused performance measures.

Agency Comments and Our Evaluation

We provided a draft of this report to DHS, HHS, and the HSC for review and comment. DHS provided written comments, which are reprinted in appendix II. In commenting on the draft report, DHS concurred with the first recommendation and stated that DHS is taking action on many of the shortfalls identified in the report. For example, DHS stated that it is working closely with HHS and other interagency partners to develop and implement a series of coordinated interagency pandemic exercises and will include all levels of government as well as the international community and the private and nonprofit sectors. Additionally, DHS stated that its Incident Management Planning Team intends to use our list of desirable characteristics of an effective national strategy as one of the review metrics for all future plans. DHS also provided us with technical comments, which we incorporated in the report as appropriate.

HHS informed us that it had no comments and concurred with the draft report. The HSC did not comment on the draft report.

As agreed with your offices, unless you publicly announce the contents of this report earlier, we plan no further distribution of it until 30 days from its date. We will then send copies of this report to the appropriate congressional committees and to the Assistant to the President for Homeland Security; the Secretaries of HHS, DHS, USDA, DOD, State, and DOT; and other interested parties. We will also make copies available to others upon request. In addition, this report will be available at no charge on the GAO Web site at <http://www.gao.gov>.

If you or your staff have any questions regarding this report, please contact me at (202) 512-6543 or steinhardt@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on

the last page of this report. GAO staff who made major contributions to this report are listed in appendix III.

A handwritten signature in black ink that reads "Bernice Steinhardt". The signature is written in a cursive, flowing style.

Bernice Steinhardt
Director
Strategic Issues

Appendix I: Scope and Methodology

Our reporting objectives were to review the extent to which (1) federal leadership roles and responsibilities for preparing for and responding to a pandemic are clearly defined and (2) the *National Strategy for Pandemic Influenza* (Strategy) and the *Implementation Plan for the National Strategy for Pandemic Influenza* (Plan) address the characteristics of an effective national strategy.

To determine to what extent federal leadership roles and responsibilities for preparing for and responding to a pandemic are clearly defined, we drew upon our extensive body of work on the federal government's response to hurricanes Katrina and Rita as well as our prior work on pandemic influenza. We also studied the findings in reports issued by Congress, the Department of Homeland Security's Office of the Inspector General, the Homeland Security Council (HSC), and the Congressional Research Service. Additionally, we reviewed the Strategy and Plan and a variety of federal emergency documents, including the National Response Plan's base plan and supporting annexes and the implementation plans developed by the Departments of Homeland Security and Health and Human Services. HSC officials declined to meet with us, stating that we should rely upon information provided by agency officials. We interviewed officials in the departments of Agriculture, Defense, Health and Human Services, Homeland Security, Transportation, and State and the Federal Emergency Management Agency and the U.S. Coast Guard. Some of these officials were involved in the development of the Plan.

To review the extent to which the Strategy and Plan address the characteristics of an effective national strategy, we analyzed the Strategy and Plan; reviewed key relevant sections of major statutes, regulations, directives, national strategies, and plans discussed in the Plan; and interviewed officials in agencies that the Strategy and Plan identified as lead agencies in preparing for and responding to a pandemic.

We assessed the extent to which the Strategy and Plan jointly addressed the six desirable characteristics, and the related elements under each characteristic, of an effective national strategy by using the six characteristics developed in previous GAO work.¹ Table 4 provides the desirable characteristics and examples of their elements.

¹ [GAO-04-408T](#).

Table 4: GAO Desirable Characteristics for a National Strategy

Desirable characteristic	Brief description	Examples of elements
Purpose, scope, and methodology	Addresses why the strategy was produced, the scope of its coverage, and the process by which it was developed.	<ul style="list-style-type: none"> • Statement of broad or narrow purpose, as appropriate. • How it compares and contrasts with other national strategies. • What major functions, mission areas, or activities it covers. • Principles or theories that guided its development. • Impetus for strategy, for example, statutory requirement or event. • Process to produce strategy, for example, interagency task force or state, local, or private input. • Definition of key terms.
Problem definition and risk assessment	Addresses the particular national problems and threats the strategy is directed toward.	<ul style="list-style-type: none"> • Discussion or definition of problems, their causes, and operating environment. • Risk assessment, including an analysis of threats and vulnerabilities. • Quality of data available, for example, constraints, deficiencies, and “unknowns.”
Goals, subordinate objectives, activities, and performance measures	Addresses what the strategy is trying to achieve; steps to achieve those results; as well as the priorities, milestones, and performance measures to gauge results.	<ul style="list-style-type: none"> • Overall results desired, that is, “end state.” • Hierarchy of strategic goals and subordinate objectives. • Specific activities to achieve results. • Priorities, milestones, and outcome-related performance measures. • Specific performance measures. • Process for monitoring and reporting on progress. • Limitations on progress indicators.
Resources, investments, and risk management	Addresses what the strategy will cost, the sources and types of resources and investments needed, and where resources and investments should be targeted by balancing risk reductions and costs.	<ul style="list-style-type: none"> • Resources and investments associated with the strategy. • Types of resources required, such as budgetary, human capital, information technology, research and development, and contracts. • Sources of resources, for example, federal, state, local, and private. • Economic principles, such as balancing benefits and costs. • Resource allocation mechanisms, such as grants, in-kind services, loans, or user fees. • “Tools of government,” for example, mandates or incentives to spur action. • Importance of fiscal discipline. • Linkage to other resource documents, for example, federal budget. • Risk management principles.

Desirable characteristic	Brief description	Examples of elements
Organizational roles, responsibilities, and coordination	Addresses who will be implementing the strategy, what their roles will be compared to others, and mechanisms for them to coordinate their efforts.	<ul style="list-style-type: none"> • Roles and responsibilities of specific federal agencies, departments, or offices. • Roles and responsibilities of state, local, private, and international sectors. • Lead, support, and partner roles and responsibilities. • Accountability and oversight framework. • Potential changes to current organizational structure. • Specific processes for coordination and collaboration. • How conflicts will be resolved.
Integration and implementation	Addresses how a national strategy relates to other strategies' goals, objectives, and activities—and to subordinate levels of government and their plans to implement the strategy.	<ul style="list-style-type: none"> • Integration with other national strategies (horizontal). • Integration with relevant documents from implementing organizations (vertical). • Details on specific federal, state, local, or private strategies and plans. • Implementation guidance. • Details on subordinate strategies and plans for implementation, for example, human capital and enterprise architecture.

Source: GAO.

National strategies with these characteristics offer policymakers and implementing agencies a management tool that can help ensure accountability and more effective results. We have used this methodology to assess and report on the administration’s strategies relating to terrorism, rebuilding of Iraq, and financial literacy.²

To assess whether the documents addressed these desirable characteristics, two analysts independently assessed both documents against each of the elements of a characteristic. If the analysts did not agree, a third party reviewed, discussed, and made the final determination to rate that element. Each characteristic was given a rating of either “addresses,” “partially addresses,” or “does not address.” According to our methodology, a strategy “addresses” a characteristic when it explicitly cites all, or nearly all, elements of the characteristic and has sufficient specificity and detail. A strategy “partially addresses” a characteristic when it explicitly cites one or a few of the elements of a characteristic and has sufficient specificity and detail. It should be noted that the “partially addresses” category includes a range that varies from explicitly citing most of the elements to citing as few as one of the elements of a characteristic.

² [GAO-04-408T](#), [GAO-06-788](#), and [GAO-07-100](#).

A strategy “does not address” a characteristic when it does not explicitly cite or discuss any elements of a characteristic, any references are either too vague or general to be useful, or both.

We reviewed relevant sections of major statutes, regulations, directives, and plans discussed in the Plan to better understand if and how they were related. Specifically, our review included Homeland Security Presidential Directive 5 on the Management of Domestic Incidents; the National Response Plan; and the Robert T. Stafford Disaster Relief and Emergency Assistance Act of 1974 (as amended) as well as other national strategies.

We conducted our review from May 2006 through June 2007 in accordance with generally accepted government auditing standards.

Appendix II: Comments from the Department of Homeland Security

U.S. Department of Homeland Security
Washington, DC 20528



**Homeland
Security**

July 10, 2007

Mr. Norman J. Rabkin
Managing Director
Homeland Security and Justice Issues
U.S. Government Accountability Office
441 G Street, NW
Washington, DC 20548

Dear Mr. Rabkin:

The Department of Homeland Security (DHS) appreciates the opportunity to review and respond to the Government Accountability Office's (GAO) draft report entitled, "INFLUENZA PANDEMIC: Further Efforts Are Needed to Ensure Clearer Federal Leadership Roles and Effective National Strategy," (GAO-07-81).

The Department appreciates the work done in this engagement to identify any issues that hinder the effectiveness of the National Strategy for Pandemic Influenza and Implementation Plan, both designed to minimize the negative effects of pandemic influenza. Although we feel the report offers an accurate depiction of the current pandemic preparedness issues from a broad and strategic perspective, the scope of the report does not address the significant planning efforts occurring at the operational and tactical levels among Federal, State, Tribal, Local, and private sector stakeholders. Over the last year, the Federal Government has conducted an extensive outreach effort to the private sector, particularly critical infrastructure businesses. In the last year, over 150 presentations, workshops, and forums have been conducted and have been attended by thousands of key stakeholders from critical infrastructure entities (e.g., healthcare operations, banking and finance entities, operations centers, retail operations, transportation and trucking operations, supply warehousing operations, grocery and food suppliers, and supply distributors) as well as businesses of all types. These information sharing sessions have provided practical action-oriented information to identify essential functions and critical planning elements, and to assist businesses in protecting the health of employees and in maintaining continuity of business operations during a pandemic.

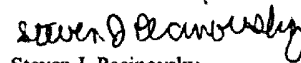
We concur with the recommendation that the Secretaries of the DHS and Health and Human Services (HHS) work together to develop and conduct rigorous testing, training, and exercises for pandemic influenza, ensuring that not only federal leadership roles, but the roles of all involved parties are clearly defined and understood, and that leaders are able to effectively execute shared responsibilities to address emerging challenges. DHS has identified and through the Incident Management Planning Team (IMPT), is already taking action on many of the shortfalls identified in this report. The IMPT now intends to use the GAO planning review methodology as one of our review metrics for all future

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IMPT plans. DHS is also working closely with the Department of Health and Human Services (HHS) and other interagency partners to develop and implement a series of coordinated interagency pandemic exercises that will include all levels of the Federal, State, Local, Tribal and Territorial governments. These exercises will include the private sector, volunteer, faith based organizations, and the international community. The Planning, Training, Exercises and Evaluations (PTEE-PCC) will coordinate these efforts to ensure interagency collaboration.

Thank you again for the opportunity to provide comments on this draft report and we look forward to working with you again on future homeland security and justice issues. Technical comments will be provided under a separate cover.

Sincerely,



Steven J. Pecinovsky
Director
Departmental GAO/OIG Liaison Office

Appendix III: GAO Contact and Staff Acknowledgments

GAO Contact

Bernice Steinhardt, (202) 512-6543 or steinhardtb@gao.gov

Acknowledgments

In addition to the contact named above, Susan Ragland, Assistant Director; Allen Lomax; David Dornisch; Donna Miller; Catherine Myrick; and members of GAO's Pandemic Working Group made key contributions to this report.

Related GAO Products

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.

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.

Influenza Pandemic: DOD Combatant Commands' Preparedness Efforts Could Benefit from More Clearly Defined Roles, Resources, and Risk Mitigation. [GAO-07-696](#). Washington, D.C.: June 20, 2007.

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.

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.

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.

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

Public Health and Hospital Emergency Preparedness Programs: Evolution of Performance Measurement Systems to Measure Progress. [GAO-07-485R](#). Washington, D.C.: March 23, 2007.

Homeland Security: Preparing for and Responding to Disasters. [GAO-07-395T](#). Washington, D.C.: March 9, 2007.

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.: September 21, 2006.

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

Emergency Preparedness and Response: Some Issues and Challenges Associated with Major Emergency Incidents. [GAO-06-467T](#). Washington, D.C.: February 23, 2006.

Statement by Comptroller General David M. Walker on GAO's Preliminary Observations Regarding Preparedness and Response to Hurricanes Katrina and Rita. [GAO-06-365R](#). Washington, D.C.: February 1, 2006.

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