**United States Government Accountability Office** 

**GAO** 

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

November 2009

# INFLUENZA PANDEMIC

Monitoring and Assessing the Status of the National Pandemic Implementation Plan Needs Improvement





Highlights of GAO-10-73, a report to the Chairman, Committee on Homeland Security, House of Representatives

#### Why GAO Did This Study

The current H1N1 pandemic highlights the threat posed to our nation by an influenza pandemic. The previous administration's Homeland Security Council (HSC) issued the Implementation Plan for the National Strategy for Pandemic Influenza (Plan) in May 2006 to help address a pandemic. GAO was asked to (1) determine how the HSC and responsible federal agencies monitor the progress and completion of the Plan's action items; and (2) assess the extent to which selected action items have been completed. To do this, GAO interviewed officials from the HSC and the six federal agencies responsible for implementing most of the Plan, and analyzed a random sample of 60 action items. While this report does not assess the response efforts for the H1N1 pandemic, GAO continues to monitor the outbreak and the federal response.

#### **What GAO Recommends**

GAO makes recommendations to the HSC related to the Plan and any future updates, including developing a monitoring and reporting process for action items intended for nonfederal entities, identifying the types of information needed to carry out the responserelated action items, and improving how completion is assessed. The Principal Deputy Counsel to the President stated that the administration will consider GAO's recommendations. The HSC also provided technical comments. Comments from other agencies are discussed in the report.

View GAO-10-73 or key components. For more information, contact Bernice Steinhardt at (202) 512-6543 or steinhardtb@gao.gov.

## **INFLUENZA PANDEMIC**

# Monitoring and Assessing the Status of the National Pandemic Implementation Plan Needs Improvement

#### What GAO Found

To oversee agencies' progress in implementing the Plan's action items, the HSC, which is supported by the White House National Security Staff in this administration, convenes regular interagency meetings, asks agencies for summaries of progress; and leads the interagency process that monitors the progress of the Plan. Officials from the six agencies stated that they monitor action items tasked to more than one agency by selecting one or two agencies to report a consolidated summary of progress, approved by each responsible agency, to the HSC. However, neither the HSC nor the agencies monitor or report on the 17 action items intended for nonfederal entities, including, for example, action items asking state, local, and tribal entities to ensure their preparedness plans address mass immunization, even though the information may have been available from other sources, such as the interagency review of state pandemic plans led by the Department of Health and Human Services. In addition, the Plan does not describe the types of information needed to carry out the Plan's response-related action items, although agencies may have operational plans or other existing guidance that would provide this information.

The HSC reported in October 2008 that the majority of the 324 action items were designated as complete. However, GAO's review of 60 action items found that it was difficult to determine the actual status of some of the 49 designated as complete. All of the action items reviewed have both a description of activities to be carried out and a measure of performance, which the HSC stated that it used to assess completion. However, for more than half of the action items considered complete, the measures of performance do not fully address all of the activities contained in their descriptions. While the HSC's progress summaries sometimes corrected for this by either referring to activities in the action item's description or some other information not reflected in either the measure of performance or description, future progress reports would benefit from using measures of performance that are more consistent with the action items' descriptions.

The Plan is predicated on a type of pandemic different in severity and origin than the current H1N1 pandemic, but it is serving as the foundation for the response to the outbreak, supplemented by an additional plan tailored specifically to the characteristics of the H1N1 pandemic. Nevertheless, the *National Strategy for Pandemic Influenza* and Plan will still be needed for future events as most of the action items in the Plan were to be completed by May 2009. As recommended in earlier GAO work, but not yet implemented, the Plan should be updated to take into account certain missing elements and lessons learned from the H1N1 pandemic; the update should also address the monitoring and assessment improvements GAO identified in this report.

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#### **Abbreviations**

DHS	Department of Homeland Security
DOC	Department of Commerce
DOD	Department of Defense
DOI	Department of the Interior
DOJ	Department of Justice
DOL	Department of Labor
DOS	Department of State
DOT	Department of Transportation
EMS	Emergency Medical Services
ESF	Emergency Support Function
FAO	Food and Agriculture Organization
HHS	Department of Health and Human Services
HSC	Homeland Security Council
NGO	nongovernmental organization
NSS	White House National Security Staff
NVS	National Veterinary Stockpile
OIE	World Organisation for Animal Health
Plan	Implementation Plan for the National Strategy for
	Pandemic Influenza
REDI	Regional Emerging Disease Intervention
Strategy	National Strategy for Pandemic Influenza
Treasury	Department of the Treasury
USAID	United States Agency for International Development
USDA	United States Department of Agriculture
USTR	United States Trade Representative
VA	Department of Veterans Affairs
WHO	World Health Organization
	-

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## United States Government Accountability Office Washington, DC 20548

November 24, 2009

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

Dear Mr. Chairman:

An influenza pandemic remains a real threat to our nation and to the world, as we are witnessing during the current H1N1 pandemic, which began in spring 2009 and continues today. The previous administration's Homeland Security Council (HSC) took an active approach to the potential disaster of an influenza pandemic by, among other things, issuing the National Strategy for Pandemic Influenza (Strategy) in November 2005, and the Implementation Plan for the National Strategy for Pandemic Influenza (Plan) in May 2006. The Strategy lays out high-level goals to prepare for and respond to an influenza pandemic, while 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 the goals. The Plan includes 324 action items, a majority of which have measures of performance and associated time frames. Both the Strategy and Plan are based on a scenario that assumes a severe pandemic originating outside the United States, spreading first among animal populations and then transmitted to humans. While the current pandemic does not share these characteristics, according to the Director of Medical Preparedness Policy for the White House National Security Staff (NSS), which supports the HSC in the current administration,<sup>2</sup> the Strategy and Plan provide the foundation for an additional planning document, the National Framework for 2009-H1N1

<sup>&</sup>lt;sup>1</sup>The HSC was established in 2001 pursuant to Executive Order 13228 to serve as a mechanism for ensuring coordination of homeland security—related activities of executive departments and agencies and effective development and implementation of homeland security policies. Congress subsequently established the HSC for the purpose of more effectively coordinating the policies and functions of the federal government relating to homeland security in the Homeland Security Act of 2002. Pub. L. No. 107-296 (Nov. 25, 2002).

<sup>&</sup>lt;sup>2</sup>On May 26, 2009, the President announced the full integration of White House staff supporting national security and homeland security. The HSC will be maintained as the principal venue for interagency deliberations on issues that affect the security of the homeland, such as influenza pandemic.

*Influenza Preparedness and Response*, that was developed this year to respond to the H1N1 pandemic. The framework for the 2009 H1N1 pandemic has not yet been made publicly available.

In August 2007, we reported that while the development of the Strategy and Plan were an important first step in guiding national preparedness, the Plan lacked a prescribed process for monitoring and reporting on progress, which is one element of the six desirable characteristics of a national strategy.<sup>3</sup> To address this and other areas that we had identified, we recommended that the HSC establish a specific process and time frame for updating the Plan, including lessons learned from exercises and other events, such as the 2009 H1N1 pandemic. For this report, you asked us to focus on the progress in implementing the action items in the Plan, specifically (1) determining how the HSC and the responsible federal agencies are monitoring the progress and completion of the Plan's action items; and (2) assessing the extent to which selected action items have been completed, whether activity has continued on the selected action items reported as complete, and the nature of that work. We did not assess the response to the 2009 H1N1 pandemic in this report, but we are continuing to monitor the outbreak and the federal government's response.

To address these objectives, we conducted an in-depth analysis of a random sample of 60 action items in the Plan. These 60 action items are listed in appendix II. We drew a random sample from the 286 action items involving six federal agencies with primary responsibility for ensuring completion of the large majority (88 percent) of the 324 action items. These six agencies include the Department of Defense (DOD), Department of Health and Human Services (HHS), Department of Homeland Security (DHS), Department of State (DOS), Department of Transportation (DOT), and the Department of Agriculture (USDA). We do not generalize the results of our analysis because the particular analytical steps we took

<sup>&</sup>lt;sup>3</sup>The six characteristics of an effective national strategy include: (1) purpose, scope, and methodology, (2) problem definition and risk assessment, (3) goals, subordinate objectives, activities, and performance measures, (4) resources, investments, and risk management, (5) organizational roles, responsibilities, and coordination, and (6) integration and implementation. GAO, *Influenza Pandemic: Further Efforts Are Needed to Ensure Clearer Federal Leadership Roles and an Effective National Strategy*, GAO-07-781 (Washington, D.C.: Aug. 14, 2007).

<sup>&</sup>lt;sup>4</sup>HHS, DHS, and USDA have primary responsibility in implementing a majority of the action items in the Plan.

across the selected action items varied, and as a result there was no common underlying measure on which to generalize the results to all of the action items in the Plan. In addition, we did not review all of the action items in the Plan in depth because our analyses involved multiple assessments for each action item, including the review of large volumes of agency documentation in determining the level of evidence for completion of the action item. See appendix I for a more detailed discussion of our scope and methodology.

For both objectives, we interviewed officials and obtained documentation from the six agencies. We also reviewed the HSC's 6-month, 1-year, and 2year progress reports, and the HSC's 1-year summary report on the implementation of the action items in the Plan. In addition, we interviewed a senior HSC official in the previous administration and the Director of Medical Preparedness Policy for the NSS in the current administration, who is responsible for overseeing the implementation of the Plan. We also relied on our prior pandemic work, including a review of whether the Strategy and Plan contained all the characteristics of an effective national strategy, to inform our analysis. To address the first objective, we assessed information from interviews and documentation on how the HSC and the selected agencies monitored the progress and completion of all action items. We also interviewed representatives from nonfederal entities that agency officials had identified as working on specific action items, such as the World Organisation for Animal Health (OIE) and the Denver Health Medical Center, to determine whether they had been consulted on the status of those action items. To address the second objective, we analyzed the 49 action items designated as complete in the HSC's 2-year progress report from the random sample of 60 action items, along with collected documentation and interviews with selected agency officials and a senior HSC official from the prior administration. To describe the extent to which action items had been completed, we analyzed information on the 49 selected action items in the Plan, the HSC progress reports, and documentation on each of the 49 action items. To evaluate the extent of work that has continued on the 49 action items in our sample designated as complete and the nature of that work, we asked all selected agencies with primary responsibility if they had performed additional work and, if so, to provide a brief description of the nature of that work. In addition, for the 34 selected action items designated as complete in the HSC's 1-year progress report, we analyzed each action item's summary in the HSC's 1-

<sup>&</sup>lt;sup>5</sup>GAO-07-781.

and 2-year progress reports for any new information on work conducted in that period.

We conducted this performance audit from July 2008 to November 2009 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives. Detailed information on our scope and methodology appears in appendix I. A list of related GAO products is also included at the end of this report.

## Background

An influenza pandemic is caused by a novel strain of influenza virus for which there is little resistance and which therefore is highly transmissible among humans. Unlike incidents that are discretely bounded in space or time (e.g., most natural or man-made disasters), an influenza pandemic is not a singular event, but is likely to come in waves, each lasting weeks or months, and pass through communities of all sizes across the nation and the world simultaneously. While a pandemic will not directly damage physical infrastructure such as power lines or computer systems, it threatens the operation of critical systems by potentially removing the essential personnel needed to operate them from the workplace for weeks or months.

On June 11, 2009, the World Health Organization (WHO) declared a pandemic based on the novel influenza A (H1N1) virus currently in wide circulation by raising the worldwide pandemic alert level to Phase 6—the highest level. Figure 1 shows the WHO phases of a pandemic, characterizing Phase 6 as community-level outbreaks in at least one country in a different WHO region in addition to the criteria defined in Phase 5. This action was a reflection of the spread of the new H1N1 virus, not the severity of illness caused by the virus. At that time, more than 70

<sup>&</sup>lt;sup>6</sup>On April 25, 2009, WHO convened a meeting of the Emergency Committee, which is composed of international experts in a variety of disciplines, to assess the H1N1 influenza cases reported in Mexico and in the United States and declared the 2009 H1N1 a public health emergency of international concern.

 $<sup>^7</sup>$ Phase 5 is characterized by human-to-human spread of the virus into at least two countries in one WHO region.

countries had reported cases of 2009 H1N1 and there were ongoing community-level outbreaks in multiple parts of the world. As of November 8, 2009, WHO reported over 503,536 confirmed cases and at least 6,260 deaths, acknowledging, however, that the number of cases was actually understated since it is no longer requiring affected countries to count individual cases and confirm them through laboratory testing.

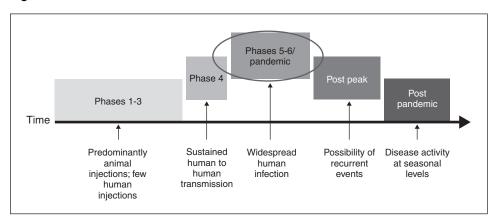


Figure 1: WHO Pandemic Influenza Phases

Source: WHO

Note: Circle indicates WHO assessment of current global phase.

Similar to the seasonal influenza, the 2009 H1N1 influenza can vary from mild to severe. Given ongoing H1N1 activity to date, the Centers for Disease Control and Prevention (CDC) stated that it anticipates that there will be more cases, more hospitalizations, and more deaths associated with this pandemic in the United States in the fall and winter. The novel H1N1 virus, in conjunction with regular seasonal influenza viruses, poses the potential to cause significant illness with associated hospitalizations and deaths during the U.S. influenza season. The United States continues to report the largest number of 2009 H1N1 cases of any country worldwide, although most people who have become ill have recovered without requiring medical treatment. The 2009 H1N1 influenza has been reported in all 50 states, the District of Columbia, Guam, American Samoa, the Commonwealth of the Northern Mariana Islands, Puerto Rico, and the U.S. Virgin Islands.

## National Planning Efforts for an Influenza Pandemic

As shown in figure 2, the Strategy lays out three high-level goals to prepare for and respond to an influenza: (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, including: (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. The Plan outlines steps for federal entities and also provides expectations for nonfederal entities—including state, local, and tribal governments; the private sector; international partners; and individuals—to prepare themselves and their communities.

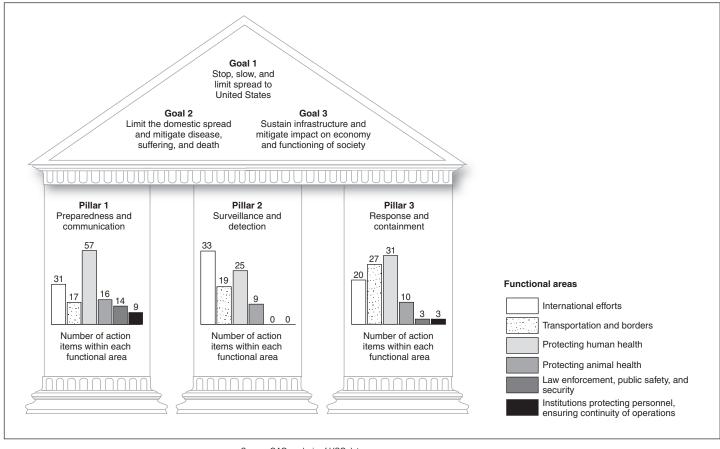


Figure 2: Elements of the Strategy and Plan

Source: GAO analysis of HSC data.

Note: Data are from the *National Strategy for Pandemic Influenza* and the *Implementation Plan for the National Strategy for Pandemic Influenza*.

Of the 324 action items in the Plan, 144 are related to pillar 1 on preparedness and communication; 86 are related to pillar 2 on surveillance and detection; and the remaining 94 are related to pillar 3 on response and containment. Nearly all of the action items (307 of 324) have a measure of performance, and most (287 of 324) of the action items have a time frame identified either in the action item's description, measure of performance, or both. Most of the action items in the Plan—those that were not tied to response—were expected to have been completed in 3 years, by May 2009. Since the issuance of the Plan in May 2006, the HSC publicly reported on the status of the action items at 6 months, 1 year, and 2 years in December 2006, July 2007, and October 2008, respectively. Although this

administration has not yet publicly reported on the 3-year status of implementing the Plan's action items, an NSS official stated that the 3-year progress report had been in development prior to the 2009 H1N1 pandemic, and may be released shortly.

## The HSC Monitors Agencies' Progress on Most Action Items

The HSC monitors the status of action items in the Plan tasked to federal agencies by convening regular interagency meetings and requesting summaries of progress from agencies.8 According to a former HSC official who was involved with monitoring the Plan in the prior administration and officials from all of the six agencies, following the development of the Plan, the HSC officials convened interagency meetings at the Sub-Policy Coordination Committee level (deputy assistant secretary or his or her representative) that included discussions on the implementation of action items. The former HSC official stated that these meetings are a forum for monitoring the status of the Plan's action items. These meetings were held weekly after the release of the Plan and biweekly after the spring of 2008, according to the former HSC official. Officials from several of the selected agencies stated that the interagency meetings facilitate interagency cooperation and coordination on the action items in the Plan. Officials also said that these meetings provide a venue to raise and address concerns relating to how to implement particular action items, and enable them to build relationships with their colleagues in other agencies. In addition, the HSC requested that agencies provide the Council with periodic summaries of their progress on the action items in preparation for the HSC's progress reports, according to officials from all of the selected agencies.

Officials from the six selected agencies informed us that, in this administration, the NSS continues to lead the interagency process used to monitor progress of the Plan. Officials from several of the selected agencies stated that the NSS continues to hold meetings at the Sub-Interagency Policy Committee level to monitor efforts related to influenza pandemic, with a primary focus on the 2009 H1N1 response. According to an NSS official, the NSS has also requested periodic summaries of progress from agencies on the action items.

<sup>&</sup>lt;sup>8</sup>As discussed later, the HSC does not monitor action items intended for nonfederal entities.

For action items that involve multiple federal agencies, the six agencies monitor the action items assigned to them by designating one or two agencies to report one consolidated summary of progress for each action item to the HSC, according to agency officials. Some action items task additional federal agencies with a support role as well. According to agency officials, all agencies tasked with responsibility for an action item have to approve its summary of progress before it is provided to the HSC. The HSC's 6-month, 1-year, and 2-year progress reports state that the action items' summaries in the reports were prepared by relevant agencies and departments. Officials from all six agencies said that the HSC does not always require them to submit supporting documentation along with their summary of progress to determine if an action item is complete. For instance, officials at three of the agencies said that the HSC does not require them to submit supporting documentation, while officials from two other agencies said that additional information is required by the HSC if it is not convinced about the completeness of an action item, or if it is unclear that the respective measure of performance was met based on the summary of progress.

For the 112 action items in the Plan that include both federal agencies and nonfederal entities, the responsible federal agencies determined how they would work with and monitor the nonfederal entities. According to the former HSC official, the responsible agencies determined how these action items would be implemented, including deciding which nonfederal entities they would work with and in what manner they would work with them. Among the six agencies we reviewed, five said that they worked with nonfederal entities to implement some of the action items in the Plan. For example, DOT officials stated that they worked with professional associations to develop guidelines and recommendations for Emergency Medical Services (EMS) and 9-1-1 call centers, and HHS officials told us that they worked with medical experts to develop guidance on mass casualty care. We interviewed representatives of nine of these nonfederal entities and all of them confirmed that the status of the action items with which they were associated had been accurately reported. However, they also told us that they had not been asked for input into the summaries of progress for the action items with which they were associated and had therefore been unable to check the accuracy of the summaries before they were reported.

The HSC Uses Information Provided by Agencies to Determine Action Item Status

The HSC makes the final determination as to whether the Plan's action items are completed, according to the former HSC official and officials from the selected agencies. The HSC bases its determination on information from federal agencies, and uses the measure of performance associated with the action items as criteria for completion, as stated in the HSC's 6-month, 1-year, and 2-year progress reports. Officials from three of the selected agencies stated that their agencies advise the HSC as to whether they believe an action item is complete when they provide summaries of progress to the HSC, while officials from two selected agencies stated that they provide summaries of progress to the HSC, and the HSC ultimately determines if an action item is complete. An interagency group led by the HSC reviews the agencies' summaries of progress to help determine if action items are complete. The former HSC official told us that the HSC's method of assessing whether an action item was complete depends on the specific action item. For some action items, the former HSC official stated that the summary of progress is reviewed by both an interagency group and a technical working group consisting of subject-matter experts.

Neither the HSC nor Agencies Monitor Action Items Intended for Nonfederal Entities

As we reported in August 2007, 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, even though it relies on these stakeholders' efforts. Stakeholder involvement during the planning process is important to ensure that the federal government's and nonfederal entities' responsibilities are clearly understood and agreed upon. Moreover, the Plan states that in the event of an influenza pandemic, the distributed nature and sheer burden of disease across the nation would mean that the federal government's support to any particular community is likely to be limited, with the primary response to a pandemic coming from state governments and local communities. In our June 2008 report on states' influenza pandemic planning and exercising, officials from selected states and localities confirmed that they were not directly involved in developing the Plan. Further, HHS officials confirmed that the Plan was developed by the federal government without any state input.

<sup>&</sup>lt;sup>9</sup>GAO-07-781.

<sup>&</sup>lt;sup>10</sup>GAO, Influenza Pandemic: Federal Agencies Should Continue to Assist States to Address Gaps in Pandemic Planning, GAO-08-539 (Washington, D.C.: June 19, 2008).

Although the Plan calls for 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. While the HSC reported on progress on all of the action items involving both federal and nonfederal entities that are included in the 2-year progress report, the 17 action items that are intended for nonfederal entities are not monitored or reported on by the HSC or the six federal agencies we reviewed. According to the former HSC official in the prior administration and an NSS official in the current administration, the HSC is not in a position to assess progress on these action items because the federal government cannot direct nonfederal entities to complete them. Therefore, these 17 action items do not contain measures of performance against which to measure progress. Although the HSC's 1- and 2-year progress reports stated that the HSC intended to continue and intensify its work with nonfederal entities, the 2-year progress report does not have any information on work conducted on these 17 action items nor is their status reported. Examples of the 17 action items intended for nonfederal entities include the following:

- State, local, and tribal pandemic preparedness plans should address the implementation and enforcement of isolation and quarantine, the conduct of mass immunization programs, and provisions for release or exception.<sup>11</sup>
- States should ensure that pandemic response plans adequately address law enforcement and public safety preparedness across the range of response actions that may be implemented, and that these plans are integrated with authorities that may be exercised by federal agencies and other state, local, and tribal governments.<sup>12</sup>

Although there is no information on these two action items in the HSC's 2-year progress report, we reported in June 2008 that HHS had led a multidepartment effort to review pertinent parts of states' influenza pandemic plans in 22 priority areas, <sup>13</sup> and had provided feedback to states in November 2007. <sup>14</sup> These priority areas included mass vaccination, law

<sup>&</sup>lt;sup>11</sup>Action item 6.3.1.1.

<sup>&</sup>lt;sup>12</sup>Action item 8.1.1.1.

 $<sup>^{13}\</sup>mathrm{Stage}\ 1$  of the HHS-led interagency review of state pandemic plans spanned from August 2006 to January 2007.

<sup>&</sup>lt;sup>14</sup>GAO-08-539.

enforcement, and community containment, which includes community-level interventions designed to limit the transmission of a pandemic virus with emphasis on isolation and quarantine, closing schools, and discouragement of large public gatherings, at a minimum. This HHS-led review found major gaps in these three areas, which are activities cited in the two action items noted above. Since our 2008 report, HHS led a second interagency assessment of state influenza pandemic plans, <sup>15</sup> which found that although states have made important progress toward preparing for combating an influenza pandemic, most states still have major gaps in their pandemic plans. <sup>16</sup> So, for these two action items, HHS had gathered information on their status for other purposes and made it publicly available on www.flu.gov, but this information was not reported in the HSC's progress reports.

The Plan Lacks a Description of the Information Needed to Carry Out Response-Related Action Items

The Plan includes response-related action items that have a measure of performance or time frame associated with a pandemic or animal outbreak. In a response-related section in the HSC's 2-year progress report, the report states that although neither a pandemic nor animal outbreak had occurred in the United States as of October 2008, the federal government had exercised many of the capabilities called for in these action items.

We found that the Plan does not describe the specific circumstances, such as the type or severity of an outbreak or pandemic, under which the response-related action items would be undertaken. In addition, for response-related action items in which the trigger is not an outbreak or pandemic, the Plan does not describe the types of information that would be needed in order to make a decision to implement the action items. For example, one of the action items, shown in table 1 below, calls for DOS and DHS to impose restrictions on travel into the United States as appropriate. <sup>17</sup> However, a senior DOS official told us that the agency does

 $<sup>^{15}</sup>$ Stage 2 of the HHS-led interagency review of state pandemic plans spanned from January 2007 to December 2008.

<sup>&</sup>lt;sup>16</sup>GAO, Influenza Pandemic: Sustaining Focus on the Nation's Planning and Preparedness Efforts, GAO-09-334 (Washington, D.C.: Feb. 26, 2009) and Departments of Health and Human Services and Homeland Security and other agencies, Assessment of States' Operating Plans to Combat Pandemic Influenza: Report to Homeland Security Council, (Washington, D.C.: January 2009).

<sup>&</sup>lt;sup>17</sup>Action item 5.3.1.1.

not have triggers for when these travel restrictions would be implemented. As we have previously reported, in preparing for, responding to, and recovering from any catastrophic disaster, roles and responsibilities must be clearly defined, effectively communicated, and well understood in order to facilitate rapid and effective decision making. In an August 2009 report on U.S. preparations for the 2009 H1N1 pandemic, the President's Council of Advisors on Science and Technology highlighted the need for quantitative triggers and recommended that federal agencies adopt structured frameworks for key decision making by incorporating scenarios and specific trigger points for action. In the control of the cont

Table 1: The 10 Response-Related Action Items in Our Sample

Action item number	Description	Measure of performance
4.3.6.3.	USDA, in coordination with DHS, the United States Trade Representative (USTR), and DOS, shall ensure that clear and coordinated messages are provided to international trading partners regarding animal disease outbreak response activities in the United States.	Within 24 hours of an outbreak, appropriate messages will be shared with key animal / animal product trading partners.
5.3.1.1.	DOS and DHS, in coordination with DOT, Department of Commerce (DOC), HHS, Department of the Treasury (Treasury), and USDA, shall work with foreign counterparts to limit or restrict travel from affected regions to the United States, as appropriate, and notify host government(s) and the traveling public.	Measures imposed within 24 hours of the decision to do so, after appropriate notifications made.
5.3.4.3.	DHS, if needed, will implement contingency plans to maintain border control during a period of pandemic influenza induced mass migration.	Contingency plan activated within 24 hours of notification.
5.3.4.5.	DOT shall issue safety-related waivers as needed, to facilitate efficient movement of goods and people during an emergency, balancing the need to expedite services with safety, and states should consider waiving state-specific regulatory requirements, such as size and weight limits and convoy registration.	All regulatory waivers as needed balance need to expedite services with safety.

<sup>&</sup>lt;sup>18</sup>GAO, Catastrophic Disasters: Enhanced Leadership, Capabilities, and Accountability Controls Will Improve the Effectiveness of the Nation's Preparedness, Response, and Recovery System, GAO-06-618 (Washington, D.C.: Sept. 6, 2006).

<sup>&</sup>lt;sup>19</sup>Executive Office of the President, President's Council of Advisors on Science and Technology, *Report to the President on U.S. Preparations for 2009-H1N1 Influenza* (Washington, D.C.: Aug. 7, 2009).

Action item number	Description	Measure of performance
5.3.5.3.	DOT, in coordination with DHS; state, local, and tribal governments; and the private sector, shall monitor system closures, assess effects on the transportation system, and implement contingency plans.	Timely reports transmitted to DHS and other appropriate entities, containing relevant, current, and accurate information on the status of the transportation sector and impacts resulting from the pandemic; when appropriate, contingency plans implemented within no more than 24 hours of a report of a transportation sector impact or issue.
5.3.5.4.	DOT, in support of DHS and in coordination with other emergency support function (ESF) #1 support agencies, shall work closely with the private sector and state, local, and tribal entities to restore the transportation system, including decontamination and reprioritization of essential commodity shipments.	Backlogs or shortages of essential commodities and goods quickly eliminated, returning production and consumption to prepandemic levels.
5.3.1.4.	DHS, in coordination with DOS, USDA, and the Department of the Interior (DOI), shall provide countries with guidance to increase scrutiny of cargo and other imported items through existing programs, such as the Container Security Initiative, and impose country-based restrictions or item-specific embargoes.	Guidance, which may include information on restrictions, is provided for increased scrutiny of cargo and other imported items, within 24 hours upon notification of an outbreak.
5.3.2.3.	DHS, in coordination with USDA, DOS, DOC, DOI, and shippers, shall rapidly implement and enforce cargo restrictions for export or import of potentially contaminated cargo, including embargo of live birds, and notify international partners/shippers.	Measures implemented within 6 hours of decision to do so.
7.3.1.2.	USDA shall coordinate with DHS and other federal, state, local, and tribal officials, animal industry, and other affected stakeholders during an outbreak in commercial or other domestic birds and animals to apply and enforce appropriate movement controls on animals and animal products to limit or prevent spread of influenza virus.	Initial movement controls in place within 24 hours of detection of an outbreak.
7.3.2.1.	USDA shall activate plans to distribute veterinary medical countermeasures and materiel from the National Veterinary Stockpile (NVS) to federal, state, local, and tribal influenza outbreak responders within 24 hours of confirmation of an outbreak in animals of influenza with human pandemic potential, within 9 months.	NVS materiel distributed within 24 hours of confirmation of an outbreak.

Source: HSC.

Note: Data are from the HSC's 2-year progress report.

As of late May 2009, an official from only one of the four selected agencies responsible for the 10 response-related action items in our sample, the Deputy Associate Director for Security Policy at DOT, stated that the 2009 H1N1 outbreak had triggered an action item from this group (5.3.5.3) for which the agency was responsible. For the remaining nine action items, officials from all four agencies noted that none of the action items for

which their agency had responsibility were relevant to the H1N1 outbreak at that time.

The Plan states that the operational details on how to carry out actions in support of the Strategy will be included in departmental pandemic plans. <sup>20</sup> Federal agencies may have operational plans or other existing guidance that would specify the information needed to determine whether to undertake the response-related action items during a pandemic. However, the Plan itself gives no indication of whether these plans or guidance actually contain such information, or whether the information that would be needed has been determined in advance.

## Status of Some Selected Action Items Considered Complete Was Difficult to Determine

The HSC reported in October 2008 that about 75 percent of the 324 action items in the Plan were designated as complete based on its criteria of whether the measures of performance were achieved. Among the 60 action items in our sample, 49 had been designated as complete, 3 designated as in-progress, and 8 had no reported status. For a number of reasons, as stated in the following sections, it was difficult to determine the actual status of some of the 49 selected action items that were designated complete.

Measures of Performance Used to Determine Status Do Not Always Fully Reflect the Descriptions of the Action Items As discussed earlier, according to the HSC's progress reports, a determination that an action item is complete is based on whether the action item's measure of performance is achieved. Our review found, however, that for more than half of the action items considered complete, the measures of performance did not fully address all the activities contained in their descriptions. In some instances, the HSC used information other than the measures of performance to report progress.

<sup>&</sup>lt;sup>20</sup>HSC, Implementation Plan for the National Strategy for Pandemic Influenza, (Washington, D.C.: May 2006).

<sup>&</sup>lt;sup>21</sup>As of October 2008, the HSC reported that of the 324 action items, 245 were complete, 21 were in progress, and 58 had no status reported. Of the 58 action items that had no status reported, 34 had measures of performance and time frames associated with a pandemic or animal outbreak in the United States, 17 were intended for nonfederal entities, 3 were directed to the federal government or to agencies and nonfederal entities, 2 had deadlines beyond the 2-year reporting time frame, and the remaining 2—action items 5.2.4.10. and 6.1.6.3.— were not included in the report.

 $<sup>^{22}\!\</sup>mathrm{Action}$  items with no reported status were either response-related or had time frames greater than 24 months.

All of the 49 action items designated as complete that we reviewed have both a description of activities to be carried out, and a measure of performance, which generally is used as an indicator to measure progress of completion by responsible parties in carrying out what is specified in its respective description. We found that the types of performance measures for selected action items varied widely. For instance, measures of performance may call for processes to be developed and implemented, changes to be effected in foreign countries, or products such as guidance or a vaccine to be developed.

As we reported in 2007, most of the Plan's measures of performance for action items 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. In these cases, it is difficult to determine whether the goals and objectives have been achieved. We found that the selected action items' measures of performance addressed the descriptions of their respective action items to varying degrees. Examples can be seen in table 2.

<sup>&</sup>lt;sup>23</sup>GAO-07-781.

<sup>&</sup>lt;sup>24</sup>For this analysis, we reviewed the action item's measure of performance relative to the respective description as written in the Plan, and therefore we could not determine the intent of the measure or of the description.

Table 2: Examples of Selected Action Items Where Measures of Performance Fully or Partially Addressed the Plan's Respective Descriptions

Action item number	Plan's description	Plan's measure of performance	GAO analysis of relationship between Plan's description and measure of performance
4.2.3.9.	DOD, in coordination with HHS, shall prioritize international DOD laboratory research efforts to develop, refine, and validate diagnostic methods to rapidly identify pathogens, within 18 months.	Completion of prioritized research plan, resources identified, and tasks assigned across DOD medical research facilities.	Fully addressed—measure of performance includes all components specified in its respective description.
6.1.13.6.	DOT, in coordination with HHS; DHS; state, local, and tribal officials; and other EMS stakeholders, shall develop suggested EMS pandemic influenza guidelines for statewide adoption that address: clinical standards, education, treatment protocols, decontamination procedures, medical direction, scope of practice, legal parameters, and other issues, within 12 months.	EMS pandemic influenza guidelines completed.	Fully addressed—measure of performance includes all components specified in its respective description.
5.1.1.5.	DOD, in coordination with DHS, DOT, the Department of Justice (DOJ), and DOS, shall conduct an assessment of military support related to transportation and borders that may be requested during a pandemic and develop a comprehensive contingency plan for Defense Support to Civil Authorities, within 18 months.	Defense Support to Civil Authorities plan in place that addresses emergency transportation and border support.	Partially addressed—measure of performance excludes a reference to an assessment of military support related to transportation and borders, as specified in its respective description.
9.1.2.2.ª	DHS, in coordination with states, localities, and tribal entities, shall support private sector preparedness with education, exercise, training, and information-sharing outreach programs, within 6 months.	Preparedness exercises established with private sector partners in all states and U.S. territories.	Partially addressed—measure of performance excludes a reference to education, training, and information-sharing outreach programs for private sector preparedness, as specified in its respective description.

Source: GAO analysis of HSC data.

Data are from the Implementation Plan for the National Strategy for Pandemic Influenza.

Notes: "Fully addressed" means that the measure of performance contained all of the activities specified in the respective description. "Partially addressed" means that the measure of performance contained some of the activities specified in the respective description. "Did not address" means that the measure of performance did not contain any of the activities specified in the respective description.

<sup>a</sup>For action item 9.1.2.2., although the measure of performance partially addressed the respective description, the HSC's 2-year progress summary addressed all of the components identified in the description. However, the progress summary did not fully address the measure of performance as it excluded a reference to whether the preparedness exercises were established with private sector partners in all states and U.S. territories.

All of the 49 selected action items' measures of performance either fully or partially addressed their respective descriptions. In 23 of the 49 selected action items that were designated as complete in the HSC's 2-year progress report, we found that the measures of performance fully

addressed the respective descriptions for the action items. For the remaining 26 action items, the measures of performance partially addressed their respective descriptions. For example, as noted in table 2, the description for one of the action items calls for DOD to conduct an assessment of military support related to transportation and borders that could be requested during a pandemic. While the measure of performance did not include this activity, the HSC nevertheless designated the action item as complete.

Our review also found that for 22 of the 49 selected action items designated as complete in the HSC's 2-year progress report, the progress summaries fully addressed how the measures of performance were achieved, thereby supporting the HSC's designation of complete for these action items. However, for the other 27 selected action items designated as complete, the progress summaries did not fully address how the measures of performance were achieved. 25 Specifically, in 18 of the 27 selected action items, the HSC's summaries addressed some but not all of the activities specified in the respective measures of performance, and for the remaining 9 action items, the summaries did not address at all how the measures of performance were achieved.<sup>26</sup> In these instances, we found that the HSC either used the action item's description, or used information that was not reflected in either the description or measure of performance, to assess completion. Table 3 below includes two examples where the HSC summaries partially addressed or did not address the action item's measure of performance.

 $<sup>^{25}</sup>$ For this analysis, we reviewed the summaries of the status of selected action items in the HSC's 2-year progress report and the action item's measure of performance in the Plan as written.

<sup>&</sup>lt;sup>26</sup>For these nine action items, we analyzed the HSC's summaries from its 2-year progress report to determine whether the HSC used the action item's descriptions to make its determination that they were complete. Our analysis found that the HSC's summaries from its 2-year progress report fully or partially addressed five of the respective action item's descriptions and did not address the four remaining action items' descriptions. In these four cases, it is unclear on what basis the HSC made its determination since the summaries did not address either the respective measures of performance or their descriptions.

Table 3: Examples of Selected Action Items Where the HSC's 2-Year Progress Report Summaries Partially Addressed or Did Not Address the Plan's Respective Measures of Performance

Action item number	Plan's description	Plan's measure of performance	Summaries of status of action items in the HSC's 2-year progress report (as of October 2008)	GAO analysis of relationship between the HSC's summary and Plan's measure of performance
4.2.3.10.	DOD shall work with priority nations' military forces to assess existing laboratory capacity, rapid response teams, and portable field assay testing equipment, and fund essential commodities and training necessary to achieve an effective national military diagnostic capability, within 18 months.	Assessments completed, proposals accepted, and funding made available to priority countries.	The Department of Defense performed assessments in all priority countries with the exception of those where the nations' Ministry of Defense, Ministry of Health, or political limitations would not allow. DOD has worked with and conducted training with other nations to enhance their lab capability. Combatant commands have worked with our partners to develop and improve infection control programs and develop training and exercise programs. In addition, the military laboratories assist regional partner nations with testing and diagnosis.	Partially addressed— The HSC's summary partially addressed the measure of performance for this action item as it did not explicitly state that proposals were accepted, and funding was made available to priority countries.
8.1.1.2.	DHS, in coordination with DOJ, HHS, the Department of Labor (DOL), and DOD, shall develop a pandemic influenza tabletop exercise for state, local, and tribal law enforcement / public safety officials that they can conduct in concert with public health and medical partners, and ensure it is distributed nationwide within 4 months.	Percent of state, local, and tribal law enforcement / public safety agencies that have received the pandemic influenza tabletop exercise.	A tabletop exercise template has been developed for use by public health authorities. DHS is continuing to work with federal partners to develop pandemic influenza tabletop exercises for state, local, and tribal law enforcement / public safety officials that can be conducted in concert with medical and public health entities.	Did not address—The HSC's summary did not address how the measure of performance was achieved because it did not include information on the percentage of various law enforcement and public safety agencies that received the tabletop exercises.

Source: GAO analysis of HSC data.

Data are from the *Implementation Plan for the National Strategy for Pandemic Influenza* and HSC's Two-Year Progress Report.

Notes: "Fully addressed" means that the HSC's progress summary contained all of the activities specified in the action item's measure of performance. "Partially addressed" means that the HSC's progress summary contained some of the activities specified in the action item's measure of performance. "Did not address" means that the HSC's progress summary did not contain any of the activities specified in action item's measure of performance.

Some Selected Action Items Were Designated as Complete Despite Requiring Actions outside the Authority of the Responsible Entities

Of the 49 selected action items designated as complete, 11 have measures of performance that cannot be accomplished solely by responsible entities tasked to work on these action items. Five of these require other countries' assistance while the remaining six require nondesignated entities' participation in order for the action items to be completed. For these 11 action items, the responsible federal agencies are not able to achieve the measures of performance for these action items on their own, but can provide assistance, such as funding and guidance, to encourage completion of these action items by others. For example, one of the action items below calls for DOS to promote, among other things, rapid reporting of influenza cases by other nations; the measure of performance is that all high-risk countries improve their capacity for rapid reporting. Even though this outcome is beyond DOS's ability to achieve on its own, the action item was considered complete, and no explanation was provided.

Some examples of the measures of performance that cannot be entirely fulfilled by the agencies and organizations in the United States include the following:

- DOS, in coordination with other agencies, shall work on a continuing basis through the Partnership and through bilateral and multilateral diplomatic contacts to promote transparency, scientific cooperation, and rapid reporting of avian and human influenza cases by other nations within 12 months. Measure of performance: All high-risk countries actively cooperating in improving capacity for transparent, rapid reporting of outbreaks.<sup>28</sup>
- USDA shall provide technical assistance to priority countries to increase safety of animal products by identifying potentially contaminated animal products, developing screening protocols, regulations, and enforcement capacities that conform to the World Organisation for Animal Health (OIE) avian influenza standards for transboundary movement of animal products, within 36 months. Measure of performance: All priority countries have protocols and regulations in place or in process.<sup>29</sup>

<sup>&</sup>lt;sup>27</sup>Action item 4.2.1.1.

<sup>&</sup>lt;sup>28</sup>Action item 4.2.1.1.

<sup>&</sup>lt;sup>29</sup>Action item 4.2.7.2.

We previously reported in June 2007 that DOS officials confirmed that the following action item, which was designated as complete in the HSC's 2-year progress report, had a measure of performance that was difficult to address because the agency did not have the means to accurately estimate the effective reach or impact of their efforts on target audiences.<sup>30</sup> As a result, this action item could only be achieved with the participation from nondesignated entities.

• DOS, in coordination with HHS, the United States Agency for International Development (USAID), USDA, DOD, and DHS, shall lead an interagency public diplomacy group to develop a coordinated, integrated, and prioritized plan to communicate U.S. foreign policy objectives relating to our international engagement on avian and pandemic influenza to key stakeholders (e.g., the American people, the foreign public, nongovernmental organizations, international businesses), within 3 months. Measure of performance: Number and range of target audiences reached with core public affairs and public diplomacy messages, and impact of these messages on public responses to avian and pandemic influenza.<sup>31</sup>

Additional Work Was Conducted on Some Selected Action Items Designated as Complete We found that work has continued on some of the selected action items the HSC designated as complete, including providing additional guidance, training and exercises. In some instances, continued efforts may be warranted—for example, when new information or circumstances might require an update of guidance. In addition, according to the HSC's progress reports, a determination of "complete" indicates that the measure of performance has been achieved but does not necessarily mean that work on the action items has ended; the work is ongoing in many cases.

Our analysis of the 1-year and 2-year progress reports confirmed that there was additional work conducted for 20 of the 34 selected action items initially designated complete as of the 1-year report. <sup>32</sup> For example, one of

<sup>&</sup>lt;sup>30</sup>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).

<sup>&</sup>lt;sup>31</sup>Action item 4.3.6.1.

 $<sup>^{32}</sup>$ Our sample included 49 action items designated as complete as of the HSC's 2-year report. However, we only reviewed the 34 of 49 action items designated as complete as of the HSC's 1-year report. The remaining 15 of the 49 action items were not reviewed as they had time frames beyond 12 months.

the action items called for national spokespersons to coordinate and communicate messages to the public. 33 The HSC's 1-year report stated that for this action item, which was designated as complete, the federal government had engaged various spokespersons by providing training for risk communications and supporting community and individual actions to reduce illness and death. In the HSC's 2-year report, the HSC provided new information on an influenza pandemic communications plan, which included messaging and spokesperson development components and numerous regional and local crisis and emergency risk communications trainings. In another example, an action item required all hospitals and health facilities funded by HHS, DOD, and the Department of Veterans Affairs (VA) to develop and publicly disseminate guidance materials on infection control.<sup>34</sup> In its 1-year report, the HSC provided information on guidance documents issued by HHS on hospital infection control and VA's national infection prevention campaign, whereas in its 2-year report, the HSC reported on new information related to two DOD guidance documents on preparation and response health policy and clinical and public health guidelines for the military health system.

In addition to the supplementary information provided in the HSC's 2-year progress report, the selected agencies informed us that they had conducted additional work for 27 of the 49 selected action items that had earlier been designated as complete, which included providing additional guidance, training, and exercises for an influenza pandemic.<sup>35</sup> For example, the selected agencies that had primary responsibility for three different action items reported that they were continuing to either provide funding or conduct additional influenza pandemic exercises with states and local governments and the private sector to help them better prepare for an outbreak.<sup>36</sup> Officials from HHS also informed us that they were conducting additional training to help improve surveillance and laboratory diagnostics in priority countries.<sup>37</sup> Further, USDA officials stated that they continued to provide guidance and training materials to countries in the

<sup>&</sup>lt;sup>33</sup>Action item 6.1.3.3.

<sup>&</sup>lt;sup>34</sup>Action item 6.3.2.5.

<sup>&</sup>lt;sup>35</sup>Fifteen of these 27 action items were designated complete as of the HSC's 1-year report and also contained new information that was not highlighted in the HSC's 2-year report.

<sup>&</sup>lt;sup>36</sup>Action items 6.1.1.3., 7.3.2.1., and 9.1.2.2.

<sup>&</sup>lt;sup>37</sup>Action items 4.2.2.4., 4.2.3.1., and 4.2.3.5.

implementation of a national animal vaccination program.<sup>38</sup> An official from the Food and Agriculture Organization (FAO) also confirmed that additional work had continued for this action item in conjunction with the World Organisation for Animal Health (OIE) in developing joint strategies for highly pathogenic avian influenza.

## Conclusions

In 2007, we recommended that the HSC establish a specific process and time frame for updating the Plan to include a number of features we identified as important elements of a national strategy, including a process for monitoring and reporting on progress. While the Plan's assumptions are not matched to the 2009 H1N1 pandemic, making some of the action items less relevant to current circumstances, the process for monitoring and reporting on the status of pandemic plans is not particular to any one type of pandemic scenario. The lessons learned from developing and monitoring the 2006 Plan should be relevant to all future pandemic planning efforts.

In particular, although the HSC, which is supported by the NSS, has monitored progress on the Plan, it has not yet established a process for updating the Plan, as previously reported, and we have found additional areas for improvement in how the Plan has been monitored and the status of action items assessed. For one thing, the NSS and the responsible federal agencies have not been monitoring or reporting on action items in the Plan intended for state and local governments and other nonfederal entities, even though, in some instances, they have information available that would allow them to do so, such as the interagency assessment of state pandemic plans led by HHS. Given that the Plan states that in a pandemic the primary response will come from states and communities, this information should be in the progress reports, notwithstanding that it may be available in other sources. Similarly, while agency operational plans or guidance may provide the information under which the responserelated action items would be undertaken, the Plan itself contains no such information. As a result, it is unclear whether the information that would be needed to activate the response-related action items in the Plan has been identified or worked out in advance.

 $<sup>^{38}</sup>$ Action item 4.1.7.3.

The HSC designated about 75 percent of the action items in the Plan as completed, as of October 2008. However, based on our review of 49 of the 245 action items designated as complete, it is difficult to determine the actual status of some of the selected action items designated as complete. The HSC and the responsible federal agencies generally relied on the measures of performance to assess progress in completing the selected action items. However, for more than half of the selected action items, we found that the measures of performance did not fully reflect all of the activities called for in the action items' descriptions. While the HSC's progress summaries sometimes corrected for this by referring to activities in the action item's description omitted from the measures of performance, future progress reports would benefit from using measures of performance that are more consistent with the action items' descriptions. This would, in turn, provide a more consistent and complete basis for describing progress in implementing the Plan.

Finally, although the administration has prepared an additional planning document tailored specifically to the 2009 H1N1 pandemic, the Strategy and Plan will still be needed for future events. Because most of the action items were to be completed by May 2009, the Plan should be updated, as we earlier recommended, to include all the elements identified in our 2007 report and to take into account the lessons learned from the 2009 H1N1 pandemic. As part of the process for monitoring the progress made in preparing the nation for an influenza pandemic, the Plan should address the monitoring and assessment improvements we identified in this report.

# Recommendations for Executive Action

To improve how progress is monitored and completion is assessed under the Plan and in future updates of the Plan, the HSC should instruct the NSS to work with responsible federal agencies to

- develop a monitoring and reporting process for action items that are intended for nonfederal entities, such as state and local governments;
- identify the types of information needed to decide whether to carry out the response-related action items; and
- develop measures of performance that are more consistent with the descriptions of the action items.

# Agency Comments and Our Evaluation

We provided a draft of this report to the Homeland Security Council (HSC), and to the Secretaries of Agriculture, Defense, Health and Human Services, Homeland Security, State, and Transportation for their review and comment.

In written comments on our draft report, the Principal Deputy Counsel to the President, on behalf of the administration, stated that our report is one notable source of suggestions for improving national pandemic planning, and that the administration would give consideration to our findings and recommendations as it continues its work in this area. The HSC also provided us with technical comments, which we incorporated as appropriate.

HHS noted in its comments that important questions and analysis that underpin our findings and recommendations were not presented or addressed in this report, including whether (1) the original Plan was adequate, (2) the priorities selected were appropriate, (3) the measures selected for monitoring progress were appropriate, and (4) the monitoring parameters selected were measurable or even achievable. We agree that these are important questions. However, the objectives of this report were to (1) determine how the HSC and responsible federal agencies monitor the progress and completion of the Plan's action items and (2) assess the extent to which selected action items have been completed. As such, we believe that we have in fact addressed the issues raised by HHS in this report in our examination of action items and related measures of performance, as well as in our prior recommendation that has not yet been implemented to incorporate into future updates of the Plan the lessons learned from exercises and other events, such as the H1N1 pandemic.

HHS also provided two other general comments. First, regarding our discussion related to the lack of details in the Plan on the information that would be used to activate the response-related action items, HHS stated that it would be inappropriate to set specific trigger points to activate specific responses because an influenza virus has an infinite range of potential characteristics, which are not predictable, and that flexibility is necessary. HHS further stated that it would be more appropriate to discuss the "types" of circumstances and responses that should be planned for. We agree that flexibility is necessary to assess the specific circumstances under which to implement the response-related action items in the Plan, given the changing nature of an influenza virus. We agree with HHS that the Plan should discuss the types of circumstances that should be planned for in a pandemic. We have made changes to the report to clarify this point.

Second, with respect to our discussion of additional work conducted on selected action items designated as complete, HHS noted that preparedness is a continuous and iterative improvement process based on lessons learned, and that ongoing training and exercises should be iterative and adapt to lessons learned. We agree. As we noted in this

report, in some instances, continued efforts on action items may be warranted—for example, when new information or circumstances might require an update of guidance. Our concern, however, is that it is unclear what additional work or progress had been made on these action items, since the HSC had designated them as complete.

DHS stated that the information in our report is generally accurate and had no substantive comments on the content of the report. DHS further stated that while improvements can be made in the Plan as we outlined in our report, there has been significant work accomplished in pandemic preparedness as a direct result of the Plan. For example, DHS noted that significant collaboration at all levels of government and the private sector has occurred, which enabled a more efficient and coordinated response for the 2009 H1N1 pandemic.

DOT provided us with technical comments, which we incorporated. DOD, DOS, and USDA informed us that they did not have any comments on the draft report. The White House, HHS, and DHS provided written comments on a draft of this report, which are reprinted in appendixes III, IV, and V, respectively.

As agreed with your office, we plan no further distribution of this report until 30 days from its date, unless you publicly announce its contents earlier. At that time we will send copies to the HSC, Secretary of Agriculture, Secretary of Defense, Secretary of Health and Human Services, Secretary of Homeland Security, Secretary of State, Secretary of Transportation, and other interested parties. In addition, this report will be available at no charge on GAO's Web site at http://www.gao.gov.

If you or your staff have any further questions about this report, please contact me at (202) 512-6543 or steinhardtb@gao.gov. 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 VI.

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Sincerely yours,

Bernice Steinhardt

Director, Strategic Issues

# Appendix I: Objectives, Scope, and Methodology

The objectives of this study were to (1) determine how the Homeland Security Council (HSC) and the responsible federal agencies are monitoring the progress and completion of the *Implementation Plan for the National Strategy for Pandemic Influenza* (Plan) action items, and (2) assess the extent to which selected action items have been completed, whether activity has continued on the selected action items reported as complete, and the nature of that work. We did not assess the response efforts for the 2009 H1N1 pandemic in this report, but we continue to monitor the outbreak and the federal government's response.

To address these objectives, we conducted an in-depth analysis of a random sample of 60 action items in the Plan. We drew a random sample from the 286 action items involving six federal agencies with primary responsibility for ensuring completion of the large majority (88 percent) of the 324 action items. These six agencies are the Department of Defense (DOD), Department of Health and Human Services (HHS), Department of Homeland Security (DHS), Department of State (DOS), Department of Transportation (DOT), and the Department of Agriculture (USDA). Of the 60 action items selected for our sample, the HSC reported that 49 were completed, 3 were in progress, and 8 had no status updates in its 2-year progress report. The purpose of this random sampling was not to be able to generalize our findings to the entire population of 286; rather, it was to produce a sample that had a distribution of items generally mirroring that of the overall population of 286 using the following variables so that the sample would include action items that represented (1) the six agencies with primary responsibility for implementing the Plan, (2) the three pillars in the Plan,<sup>2</sup> (3) the presence of collaboration between federal agencies and nonfederal entities (i.e. state, local, and tribal entities, the private sector, international organizations, and nongovernmental organizations), and (4) various time frames of when they should be completed, which range from within 24 hours of an outbreak to 60 months from the release of the Plan in May 2006, among other time frames. We do not generalize the results of our analysis because the particular analytical steps we took across the selected action items varied and as a result there was no

 $<sup>^{\</sup>rm 1}\!$  The Plan includes a total of 324 action items. As noted, we drew a random sample using 286 of the 324 action items.

<sup>&</sup>lt;sup>2</sup>As noted earlier, the *National Strategy for Pandemic Influenza* has three high-level goals, which are underpinned by three pillars that are intended to guide the federal government's approach to a pandemic threat, including: (1) preparedness and communication, (2) surveillance and detection, and (3) response and containment.

common underlying measure on which to generalize results to all of the action items in the Plan. In addition, we did not review all of the action items in the Plan in depth because our analyses involved multiple assessments for each action item, including the review of large volumes of agency documentation in determining the level of evidence for completion of the action item.<sup>3</sup>

For both objectives, we interviewed officials and obtained documentation from the six federal agencies. We reviewed the HSC's 6-month, 1-year, and 2-year progress reports and the HSC's 1-year summary report on the implementation of the action items in the Plan. In addition, we interviewed a senior HSC official from the previous administration and the Director of Medical Preparedness Policy for the White House National Security Staff (NSS) in the current administration responsible for overseeing the implementation of the Plan. <sup>4</sup> We also relied on our prior pandemic work to inform our analysis.

To address the first objective on how the HSC and responsible federal agencies are monitoring the progress and completion of the Plan's action items, we assessed information from interviews and documentation, such as the HSC's progress reports, on how the HSC and the selected agencies monitored the progress and completion of all action items. We also requested information from the six agencies on how the NSS is currently overseeing the interagency process used for monitoring the implementation of action items in the Plan. We also interviewed representatives from nine nonfederal entities, such as the World Organisation for Animal Health (OIE) and the Denver Health Medical Center, which agency officials had identified as working collaboratively with them on four action items in our sample, and asked these representatives whether the agencies asked for information on the progress of implementing these action items. In addition, we reviewed the

<sup>&</sup>lt;sup>3</sup>In addition, we randomly sampled 11 action items from our sample of 60 that called for joint collaboration with nonfederal entities. We interviewed nonfederal entities that federal agencies told us they had worked with for 4 of the 11 action items. However, we only report this information anecdotally in the report. Additionally, we did not request documentation attesting to the presence of collaboration with the federal agencies with primary responsibility or the completion of the action item with the nonfederal entities.

<sup>&</sup>lt;sup>4</sup>As noted earlier in the report, on May 26, 2009, the President announced the full integration of White House staff supporting national security and homeland security. The HSC will be maintained as the principal venue for interagency deliberations on issues that affect the security of the homeland, such as influenza pandemic.

Plan and the HSC's 2-year progress report to identify specific circumstances that would trigger the response-related action items that are activated by an animal outbreak or pandemic. We also collected information from the four selected agencies that had primary responsibility for the 10 response-related action items in our sample regarding criteria that would trigger these action items.<sup>5</sup>

To address the second objective, we analyzed the 49 action items in our random sample that the HSC's 2-year progress report designated as complete. We also collected documentation and conducted interviews with selected agency officials from the six agencies and a senior HSC official from the prior administration. To describe the extent to which action items had been completed, we analyzed information on the 49 selected action items in the Plan, the HSC progress reports, and supporting documentation provided by the six agencies with primary responsibility for each of the 49 action items to demonstrate how the measures of performance were achieved based on the HSC's criteria for completion. Specifically, we analyzed the 49 selected action items designated as complete to assess whether

- 1. the measures of performance fully addressed, partially addressed, or did not address their respective action item description;<sup>6</sup>
- 2. the summaries contained in the HSC's 2-year progress report fully addressed, partially addressed, or did not address how the measures of performance were achieved;<sup>7</sup> and
- 3. the measures of performance could be accomplished solely by responsible entities that are tasked to work on the action items.<sup>8</sup>

<sup>&</sup>lt;sup>5</sup>Of the 10 response-related action items, the HSC designated 4 as complete and 6 had no status reported. As stated earlier in the report, according to the HSC's 2-year progress report, 4 action items were designated as complete because the agencies with primary responsibility had previously responded to animal outbreaks in other countries and within the United States.

<sup>&</sup>lt;sup>6</sup>"Fully addressed" means that the measure of performance contained all of the activities specified in the respective description. "Partially addressed" means that the measure of performance contained some of the activities specified in the respective description. "Did not address" means that the measure of performance did not contain any of the activities specified in the respective description.

<sup>&</sup>lt;sup>7</sup>"Fully addressed" means that the HSC's progress summary contained all of the activities specified in the action item's measure of performance. "Partially addressed" means that the HSC's progress summary contained some of the activities specified in the action item's measure of performance. "Did not address" means that the HSC's progress summary did not contain any of the activities specified in action item's measure of performance.

To evaluate the extent of work that has continued on the 49 action items in our sample that were designated as complete, and the nature of that work, we gathered information in two ways. First, we compared the HSC's 1-year and 2-year progress reports for 34 selected action items initially designated as complete as of the 1-year report by analyzing each action item's summary in the HSC's 1- and 2-year progress reports for any new information on work conducted. Second, we asked the six agencies with primary responsibility if they had performed additional work after action items were designated as complete and, if so, to provide a brief description of the nature of that work. For 27 of the 49 action items designated as complete, the agencies indicated that they had performed additional work after the action items were designated as complete. For 22 of those 27 action items, the agencies also specified the nature of the additional work. To ensure consistency and accuracy of our analysis, at least two GAO analysts independently analyzed the data we received for the 49 selected action items in our sample designated as complete and then compared their results. In cases where there were discrepancies, the two analysts reconciled their differences for a final response. Additionally, methodologists in GAO's Applied Research and Methods team conducted an independent analysis and verification of our assessment by reviewing whether the measures of performance addressed its respective description and whether the HSC summaries addressed how the measures of performance were achieved for all 49 action items designated as complete. In cases where there were discrepancies between the analysts' and methodologists' teams, a joint reconciliation was conducted for a final response.

We conducted this performance audit from July 2008 to November 2009 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

<sup>&</sup>lt;sup>8</sup>We conducted this analysis by reviewing whether the responsible entities, such as federal agencies, tasked to the 49 action items designated as complete could achieve the respective measures of performance without the assistance of nondesignated entities, such as other countries.

# Appendix II: Sample of 60 Selected Action Items in the Implementation Plan for the National Strategy for Pandemic Influenza

Action item		
number	Actions and expectations	Measure of performance
4.1.2.1.	The Department of State (DOS) shall ensure strong U.S. government engagement in and follow-up on bilateral and multilateral initiatives to build cooperation and capacity to fight pandemic influenza internationally, including the Asia-Pacific Economic Cooperation initiatives (inventory of resources and regional expertise to fight pandemic influenza, a regionwide tabletop exercise, a Symposium on Emerging Infectious Diseases to be held in Beijing in April 2006 and the Regional Emerging Disease Intervention (REDI) Center in Singapore), the U.SChina Joint Initiative on Avian Influenza, and the U.SIndonesia-Singapore Joint Avian Influenza Demonstration Project; and should develop a strategy to expand the number of countries fully cooperating with U.S. and/or international technical agencies in the fight against pandemic influenza, within 6 months.	Finalized action plans that outline goals to be achieved and timeframes in which they will be achieved.
4.1.2.2.	The Department of Health and Human Services (HHS) shall staff the REDI Center in Singapore within 3 months.	U.S. government staff provided to REDI Center.
4.1.2.3.	The United States Department of Agriculture (USDA), working with the United States Agency for International Development (USAID) and the Partnership, shall support the Food and Agriculture Organization (FAO) and the World Organisation for Animal Health (OIE) to implement an instrument to assess priority countries' veterinary infrastructure for prevention, surveillance, and control of animal influenza and increase veterinary rapid response capacity by supporting national capacities for animal surveillance, diagnostics, training, and containment in at-risk countries, within 9 months.	Per the OIE's Performance, Vision and Strategy Instrument, assessment tools exercised and results communicated to the Partnership, and priority countries are developing, or have in place, an infrastructure capable of supporting their national prevention and response plans for avian or other animal influenza.
4.1.4.2.	DOS and HHS, in coordination with other agencies, shall implement programs within 3 months to inform U.S. citizens, including businesses, nongovernmental organization (NGO) personnel, the Department of Defense (DOD) personnel, and military family members residing and traveling abroad, where they may obtain accurate, timely information, including risk level assessments, to enable them to make informed decisions and take appropriate personal measures.	Majority of registered U.S. citizens abroad have access to accurate and current information on influenza.
4.1.4.3.	DOS and HHS shall ensure that adequate guidance is provided to federal, state, tribal, and local authorities regarding the inviolability of diplomatic personnel and facilities and shall work with such authorities to develop methods of obtaining voluntary cooperation from the foreign diplomatic community within the United States consistent with U.S. government treaty obligations within 6 months.	Briefing materials and an action plan in place for engaging with relevant federal, state, tribal, and local authorities.
4.1.5.3.	HHS shall provide technical expertise, information, and guidelines for stockpiling and use of pandemic influenza vaccines within 6 months.	All priority countries and partner organizations have received relevant information on influenza vaccines and application strategies.
4.1.7.2.	The Department of Justice (DOJ) and DOS, in coordination with HHS, shall consider whether the U.S. Government, in order to benefit from the protections of the Defense Appropriations Act, should seek to negotiate liability-limiting treaties or arrangements covering U.S. contributions to an international stockpile of vaccine and other medical countermeasures, within 6 months.	Review initiated and decision rendered.

Action item number	Actions and expectations	Measure of performance		
4.1.7.3.	USDA, in collaboration with FAO and OIE, shall develop and provide best-practice guidelines and technical expertise to countries that express interest in obtaining aid in the implementation of a national animal vaccination program, within 4 months.	Interested countries receive guidelines and other assistance within 3 months of their request.		
4.2.1.1.	DOS, in coordination with other agencies, shall work on a continuing basis through the Partnership and through bilateral and multilateral diplomatic contacts to promote transparency, scientific cooperation, and rapid reporting of avian and human influenza cases by other nations within 12 months.	All high-risk countries actively cooperating in improving capacity for transparent, rapid reporting of outbreaks.		
4.2.1.5.	HHS shall support the World Health Organization (WHO) Secretariat to enhance the early detection, identification and reporting of infectious disease outbreaks through the WHO's Influenza Network and Global Outbreak and Alert Response Network within 12 months.			
4.2.2.4.	HHS shall enhance surveillance and response to high priority infectious disease, including influenza with pandemic potential, by training physicians and public health workers in disease surveillance, applied epidemiology and outbreak response at its Global Disease Detection Response Centers in Thailand and China and at the U.SChina Collaborative Program on Emerging and Re-Emerging Infectious Diseases, within 12 months.			
4.2.2.7.	DOD, in coordination with DOS and with the cooperation of the host nation, shall assist with influenza surveillance of host nation populations in accordance with existing treaties and international agreements, within 24 months.  Medical surveillance "watchbo expanded to include host national agreements, within agreements, within agreements."			
4.2.3.1.	HHS shall develop and implement laboratory diagnostics training programs in basic laboratory techniques related to influenza sample influenza sample preparation and diagnostics in priority countries within 9 months.			
4.2.3.5.	HHS and USAID shall work with the WHO Secretariat and private sector partners, through existing bilateral agreements, to provide support for human health diagnostic laboratories by developing and giving capacity. assistance in implementing rapid international laboratory diagnostics protocols and standards in priority countries, within 12 months.			
4.2.3.9.	DOD, in coordination with HHS, shall prioritize international DOD laboratory research efforts to develop, refine, and validate diagnostic methods to rapidly identify pathogens, within 18 months.  Completion of prioritized research resources identified, and tasks as across DOD medical research face.			
4.2.3.10.	DOD shall work with priority nations' military forces to assess existing laboratory capacity, rapid response teams, and portable field assay testing equipment, and fund essential commodities and training priority countries.  Assessments completed, proposal accepted, and funding made availate priority countries.  priority countries.			
4.2.5.1.	HHS and USAID shall develop, in coordination with the WHO Secretariat and other donor countries, rapid response protocols for use in responding quickly to credible reports of human-to-human transmission that may indicate the beginnings of an influenza pandemic, within 12 months.	Adoption of protocols by WHO and other stakeholders.		

Action item number	Actions and expectations	Measure of performance	
4.2.7.2.	USDA shall provide technical assistance to priority countries to increase safety of animal products by identifying potentially contaminated animal products, developing screening protocols, regulations, and enforcement capacities that conform to OIE avian influenza standards for transboundary movement of animal products, within 36 months.	regulations in place or in process.	
4.3.6.1.	DOS, in coordination with HHS, USAID, USDA, DOD, and the Department of Homeland Security (DHS), shall lead an interagency public diplomacy group to develop a coordinated, integrated, and prioritized plan to communicate U.S. foreign policy objectives relating to our international engagement on avian and pandemic influenza to key stakeholders (e.g., the American people, the foreign public, NGOs, international businesses),within 3 months.	Number and range of target audiences reached with core public affairs and public diplomacy messages, and impact of these messages on public responses to avian and pandemic influenza.	
4.3.6.3.	USDA, in coordination with DHS, the United States Trade Representative (USTR), and DOS, shall ensure that clear and coordinated messages are provided to international trading partners regarding animal disease outbreak response activities in the United States.	Within 24 hours of an outbreak, appropriate messages will be shared with key animal/animal product trading partners.	
5.1.1.5.	DOD, in coordination with DHS, the Department of Transportation (DOT), DOJ, and DOS, shall conduct an assessment of military support related to transportation and borders that may be requested during a pandemic and develop a comprehensive contingency plan for Defense Support to Civil Authorities, within 18 months.		
5.1.4.2.	DHS, in coordination with DOT, the Department of Labor (DOL), the Office of Personnel Management, and DOS, shall disseminate workforce protection information to stakeholders, conduct outreach with stakeholders, and implement a comprehensive program for all Federal transportation and border staff within 12 months.  100 percent of workforce has of access to information on pander influenza risk and appropriate program for all Federal		
5.2.4.7.	DHS, DOT, and HHS, in coordination with transportation and border stakeholders, and appropriate state and local health authorities, shall develop aviation, land border, and maritime entry and exit protocols and/or screening protocols, and education materials for non-medical, front-line screeners and officers to identify potentially infected persons or cargo, within 10 months.		
5.2.4.8.	DHS and HHS, in coordination with DOT, DOJ, and appropriate State and local health authorities, shall develop detection, diagnosis, quarantine, isolation, emergency medical services (EMS) transport, reporting, and enforcement protocols and education materials for travelers, and undocumented aliens apprehended at and between ports of entry, who have signs or symptoms of pandemic influenza or who may have been exposed to influenza, within 10 months.		
5.2.5.2.	USDA, in coordination with DHS, the Department of the Interior (DOI), and HHS, shall review the process for withdrawing permits for of high-risk importers.  importation of live avian species or products and identify ways to increase timeliness, improve detection of high-risk importers, and increase outreach to importers and their distributors, within 6 months.		
5.2.5.3.	USDA, in coordination with DOI, DHS, shall enhance protocols at air, land, and sea ports of entry to identify and contain animals, animal products, and/or cargo that may harbor viruses with pandemic potential and review procedures to quickly impose restrictions, within 6 months.	Risk based protocols established and in use.	

Action item number	Actions and expectations	Measure of performance	
5.2.5.6.	USDA, DHS, and DOI, in coordination with DOS, HHS, and the Department of Commerce (DOC), shall conduct outreach and expand education campaigns for the public, agricultural stakeholders, wildlife trade community, and cargo and animal importers/exporters on import and export regulations and influenza disease risks, within 12 months.	100 percent of key stakeholders are aware of current import and export regulations and penalties for noncompliance.	
5.3.1.1.	DOS and DHS, in coordination with DOT, DOC, HHS, the Department of the Treasury (Treasury), and USDA, shall work with foreign counterparts to limit or restrict travel from affected regions to the United States, as appropriate, and notify host government(s) and the traveling public.	Measures imposed within 24 hours of the decision to do so, after appropriate notifications made.	
5.3.1.4.	DHS, in coordination with DOS, USDA and DOI, shall provide countries with guidance to increase scrutiny of cargo and other imported items through existing programs, such as the Container Security Initiative, and impose country-based restrictions or item-specific embargoes.  Guidance, which may include on restrictions, is provided for scrutiny of cargo and other in items, within 24 hours upon an outbreak.		
5.3.2.3.	DHS, in coordination with USDA, DOS, DOC, DOI, and shippers, shall rapidly implement and enforce cargo restrictions for export or import of potentially contaminated cargo, including embargo of live birds, and notify international partners/shippers.  Measures implemented within 6 decision to do so.		
5.3.4.3.	DHS, if needed, will implement contingency plans to maintain border control during a period of pandemic influenza induced mass migration.	Contingency plan activated within 24 hours of notification.	
5.3.4.5.	DOT shall issue safety-related waivers as needed, to facilitate efficient movement of goods and people during an emergency, balancing the need to expedite services with safety, and states should consider waiving state-specific regulatory requirements, such as size and weight limits and convoy registration.	All regulatory waivers as needed balance need to expedite services with safety.	
5.3.5.3.	DOT, in coordination with DHS, state, local, and tribal governments, and the private sector, shall monitor system closures, assess effects on the transportation system, and implement contingency plans.	Timely reports transmitted to DHS and other appropriate entities, containing relevant, current, and accurate information on the status of the transportation sector and impacts resulting from the pandemic; when appropriate, contingency plans implemented within no more than 24 hours of a report of a transportation sector impact or issue.	
5.3.5.4.	DOT, in support of DHS and in coordination with other emergency support function (ESF) #1 support agencies, shall work closely with the private sector and state, local, and tribal entities to restore the transportation system, including decontamination and reprioritization of essential commodity shipments.  Backlogs or shortages of essentia commodities and goods quickly eliminated, returning production are consumption to prepandemic level essential commodity shipments.		
6.1.1.3.	DHS, in coordination with HHS, DOJ, DOT, and DOD, shall be prepared to provide emergency response element training (e.g., incident management, triage, security, and communications) and exercise assistance upon request of state, local, and tribal communities and public health entities within 6 months.	Percentage of requests for training and assistance fulfilled.	

Appendix II: Sample of 60 Selected Action Items in the Implementation Plan for the National Strategy for Pandemic Influenza

Action item number	Actions and expectations	Measure of performance	
6.1.2.2.	HHS, in coordination with DHS, DOD, and the Department of Veterans Affairs (VA), shall develop a joint strategy defining the objectives, conditions, and mechanisms for deployment under which the National Disaster Medical System assets, U.S. Public Health Service Commissioned Corps, Epidemic Intelligence Service officers, and DOD/VA health care personnel and public health officers would be deployed during a pandemic, within 9 months.	Interagency strategy completed and tested for the deployment of federal medical personnel during a pandemic.	
6.1.3.1.	HHS, in coordination with DHS, DOS, DOD, VA, and other federal partners, shall develop, test, and implement a federal government public health emergency communications plan (describing the government's strategy for responding to a pandemic, outlining U.S. international commitments and intentions, and reviewing containment measures that the government believes will be effective as well as those it regards as likely to be ineffective, excessively costly, or harmful) within 6 months.	Containment strategy and emergency response materials completed and published on www.pandemicflu.gov; communications plan implemented.	
6.1.3.3.	HHS, in coordination with DHS, DOD, and the VA, and in collaboration with state, local, and tribal health agencies and the academic community, shall select and retain opinion leaders and medical experts to serve as credible spokespersons to coordinate and effectively communicate important and informative messages to the public, within 6 months.		
6.1.4.2.	DOT, in cooperation with HHS, DHS, and DOC, shall develop model protocols for 9-1-1 call centers and public safety answering points that address the provision of information to the public, facilitate caller screening, and assist with priority dispatch of limited emergency medical services, within 12 months.	Model protocols developed and disseminated to 9-1-1call centers and public safety answering points.	
6.1.8.1.	HHS shall work with the pharmaceutical industry toward the goal of developing, within 60 months, domestic vaccine production capacity sufficient to provide vaccine for the entire U.S. population within 6 months after the development of a vaccine reference strain.  Domestic vaccine manufactur in place to produce 300 million vaccine within 6 of a vaccine within 6 of a vaccine reference strain of pandemic.		
6.1.13.6.	DOT, in coordination with HHS, DHS, state, local, and tribal officials and other EMS stakeholders, shall develop suggested EMS pandemic completed. influenza guidelines for statewide adoption that address: clinical standards, education, treatment protocols, decontamination procedures, medical direction, scope of practice, legal parameters, and other issues, within 12 months.		
6.1.13.9.	HHS, in coordination with DOD, VA, and in collaboration with state, territorial, tribal, and local partners, shall develop/refine mechanisms to: (1) track adverse events following vaccine and antiviral administration; (2) ensure that individuals obtain additional doses of vaccine, if antiviral-effectiveness study proto antiviral-effectiveness studies during a pandemic, within 18 months.		
6.1.14.3.	HHS, in coordination with DHS and sector-specific agencies, DOS, DOD, DOL, and VA, shall establish a strategy for shifting priorities based on at-risk populations, supplies and efficacy of countermeasures against the circulating pandemic strain, and characteristics of the virus within 9 months.	Clearly articulated process in place for evaluating and adjusting prepandemic recommendations of groups receiving priority access to medical countermeasures.	

Action item number	Actions and expectations	Measure of performance	
6.1.16.2.	HHS shall support the renovation of existing U.S. manufacturing facilities that produce other Food and Drug Administration licensed cell-based vaccines or biologics and the establishment of new domestic cell-based influenza vaccine manufacturing facilities, within 36 months.	Contracts awarded for renovation or establishment of domestic cell-based influenza vaccine manufacturing capacity.	
6.1.17.3.	HHS, in coordination with DHS, shall develop and test new point-of-care and laboratory-based rapid influenza diagnostics for screening and surveillance, within 18 months.  New grants and contracts awar researchers to develop and evaluation diagnostics.		
6.2.1.1.	HHS shall provide guidance to public health and clinical laboratories on the different types of diagnostic tests and the case definitions to use for influenza at the time of each pandemic phase. Guidelines for the current pandemic alert phase will be disseminated within 3 months.	and through other channels of guidance	
6.2.2.8.	HHS, in coordination with DHS, DOD, and VA, and in collaboration with state, local, and tribal authorities, shall be prepared to collect, analyze, integrate, and report information about the status of hospitals and health care systems, healthcare critical infrastructure, and medical materiel requirements, within 12 months.  Guidance provided to states an entities on the use and modification components of the National Hospitals and health available Beds for Emergencies Disasters system for implement the local level.		
6.3.2.5.	All HHS-, DOD-, and VA-funded hospitals and health facilities shall develop, test, and be prepared to implement infection control campaigns for pandemic influenza, within 3 months.  Guidance materials on infection control campaigns developed and disseminate www.pandemicflu.gov and channels.		
6.3.3.1.	HHS, in coordination with DHS, VA, and DOD, shall develop and disseminate guidance that explains steps individuals can take to decrease their risk of acquiring or transmitting influenza infection during a pandemic, within 3 months.	Guidance disseminated onwww.pandemicflu.gov and through VA and DOD channels.	
7.1.5.1.	USDA and DOI shall perform research to understand better how avian influenza viruses circulate and are transmitted in nature, in order to improve information on biosecurity distributed to local animal owners, producers, processors, markets, auctions, wholesalers, distributors, retailers, and dealers, as well as wildlife management agencies, rehabilitators, and zoos, within 18 months.  Completed research studies pro information, or validate current information, on the most useful biosecurity measures to be take effectively prevent introduction, a or prevent spread, of avian influenza viruses in domestic and captive populations.		
7.1.5.4.	USDA shall perform research to improve vaccines and mass immunization techniques for use against influenza in domestic birds within 36 months.  An effective avian influenza vaccines and mass can be delivered simultaneously multiple birds ready for commercial development.		
7.2.1.1.	DOI and USDA shall collaborate with state wildlife agencies, universities, and others to increase surveillance of wild birds, particularly migratory water birds and shore birds, in Alaska and other appropriate locations elsewhere in the United States and its territories, to detect influenza viruses with pandemic potential, including highly pathogenic avian influenza H5N1, and establish baseline data for wild birds, within 12 months.		
7.2.1.2.	I.2. USDA and DOI shall collaborate to develop and distribute information to state and tribal entities on the detection, identification, and reporting of influenza viruses in wild bird populations, within 6 months.		

Action item number	Actions and expectations	Measure of performance	
7.2.1.3.	USDA shall work with state and tribal entities, and industry groups, to perform surveys of game birds and waterfowl raised in captivity, and implement surveillance of birds at auctions, swap meets, flea markets, and public exhibitions, within 12 months.	Samples collected at 50 percent of the largest auctions, swap meets, flea markets, and public exhibitions held in at least five states or tribal entities believed to be at highest risk for an avian influenza introduction.	
7.3.1.2.	USDA shall coordinate with DHS and other federal, state, local, and tribal officials, animal industry, and other affected stakeholders during an outbreak in commercial or other domestic birds and animals to apply and enforce appropriate movement controls on animals and animal products to limit or prevent spread of influenza virus.		
7.3.2.1.	USDA shall activate plans to distribute veterinary medical countermeasures and materiel from the National Veterinary Stockpile (NVS) to federal, state, local, and tribal influenza outbreak responders within 24 hours of confirmation of an outbreak in animals of influenza with human pandemic potential, within 9 months.		
8.1.1.2.	DHS, in coordination with DOJ, HHS, DOL, and DOD, shall develop a pandemic influenza tabletop exercise for state, local, and tribal law enforcement/public safety officials that they can conduct in concert with public health and medical partners, and ensure it is distributed have received the pandemic in tabletop exercise.		
8.3.2.2.	DHS, in coordination with DOJ, DOD, DOT, HHS, and other appropriate federal sector-specific agencies, shall engage in contingency planning and related exercises to ensure they are prepared to sustain EMS, fire, emergency management, public works, and other emergency response functions during a pandemic, within 6 months.  Completed plans (validated by exercise(s)) for supporting EMS, fire, emergency management, public works, and other emergency response functions during a pandemic, within 6 months.		
9.1.2.2.	DHS, in coordination with states, localities and tribal entities, shall support private sector preparedness with education, exercise, training, and information sharing outreach programs, within 6 months.  Preparedness exercises established private sector partners in all states U.S. territories.		
9.3.1.2.	DHS shall develop and operate a national-level monitoring and information sharing system for core essential services to provide status updates to critical infrastructure dependent on these essential services, and aid in sharing real-time impact information, monitoring actions, and prioritizing national support efforts for preparedness, response, and recovery of critical infrastructure sectors within 12 months.		

Source: HSC.

Data are from the Implementation Plan for the National Strategy for Pandemic Influenza.

Notes: As stated earlier, we reviewed 60 of the 324 action items, of which the Homeland Security Council (HSC) designated 49 as complete, 3 as in progress, and 8 with no reported status. As we pointed out, our analysis highlighted a number of reasons why it was difficult to determine the actual status for some of the 49 selected action items that were designated as complete.

### Appendix III: Comments from the White House

### THE WHITE HOUSE

WASHINGTON

November 18, 2009

Ms. Bernice Steinhardt Director, Strategic Issues Government Accountability Office 441 G Street, N.W. Washington, DC 20548-0001

Dear Ms. Steinhardt:

Thank you for providing the White House National Security Staff, which supports the Homeland Security Council, the opportunity to comment on the Government Accountability Office's report entitled, "Influenza Pandemic: Monitoring and Assessing Status of the National Pandemic Plan Needs Improvement" (GAO-10-73).

We appreciate GAO's attention to the important and timely area of pandemic influenza planning. As the report notes, the previous Administration issued the *National Strategy for Pandemic Influenza* in 2005 and the *Implementation Plan for the National Strategy for Pandemic Influenza* in 2006; it also issued progress reports on the *Implementation Plan* in 2006, 2007, and 2008. Through these efforts, the Federal government has made important strides in improving its ability to respond to a pandemic, and it has formed crucial lines of collaboration and cooperation with state, local, and non-governmental entities on pandemic issues.

This Administration is committed to building on this prior work in order to improve national pandemic preparedness and to further strengthen cooperation with our non-federal partners. Your report is one notable source of suggestions for improving national pandemic planning. The Administration will give consideration to GAO's findings and recommendations as it continues its work in this important area.

Thank you for your work on this set of issues.

Daniel Meltzer

Principal Deputy Counsel to the President

### Appendix IV: Comments from the Department of Health and Human Services

Note: Page numbers in the draft report may differ from those in this report.



DEPARTMENT OF HEALTH & HUMAN SERVICES

OFFICE OF THE SECRETARY

Assistant Secretary for Legislation Washington, DC 20201

OCT 3 0 2009

Bernice Steinhardt Director, Strategic Issues U.S. Government Accountability Office 441 G Street N.W. Washington, DC 20548

Dear Ms. Steinhardt:

Enclosed are comments on the U.S. Government Accountability Office's (GAO) report entitled: Influenza Pandemic: Gaps in Monitoring and Assessing Status of the National Pandemic Implementation Plan Need to be Addressed (GAO-10-73).

The Department appreciates the opportunity to review this report before its publication.

Sincerely,

Andrea Palm

Acting Assistant Secretary for Legislation

Enclosure

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO) DRAFT REPORT ENTITLED: PANDEMIC INFLUENZA: GAPS IN MONITORING AND ASSESSING STATUS OF THE NATIONAL PANDEMIC IMPLEMENTATION PLAN NEEDS TO BE ADDRESSED (GAO-10-73)

GAO was asked to examine (1) how implementation of the HSC items is monitored and (2) whether selected HSC items have been completed and whether activity has continued on items reported as complete. The GAO report identifies difficulties in the HSC monitoring process and confirms that many activities continue, despite being considered as "complete" in terms of the HSC reporting requirements.

To resolve these issues, GAO makes three recommendations to HSC to improve use of the 324 HSC items as a monitoring tool:

- Developing a monitoring and reporting process for actions tasked exclusively to nonfederal
  entities such as state and local governments
- Defining information and circumstances that would trigger response-related action items
- Improving how completion of individual HSC items is assessed.

There are several scientific and technical inaccuracies in the statements and text that could affect the interpretation of the findings and recommendations in the Report. Important questions and analysis are not presented or addressed in the Report, that underpin GAO's findings and recommendations. For example: Was the original National Pandemic Implementation Plan adequate? Were the priorities selected appropriate? Were the measures selected for monitoring progress appropriate? Were the monitoring parameters selected measurable or even achievable? We believe that these predicate questions need to be addressed as part of any evaluation of the reports of progress and/or completion on the planned action items.

Two conclusions of the Report do not adequately take into account the realities of an influenza pandemic or important concepts of pandemic preparedness:

1) Page 15 - Discussion of lack of specific triggers and criteria to activate responses.

From a scientific and epidemiology perspective, setting of specific trigger points to activate specific responses is inappropriate because the influenza virus has an infinite range of potential behaviors, transmissibility, virulence, severity, attack rates, etc. that are defined by its genetic makeup. It is not possible, nor realistic to attempt to predict all the possible permutations and combinations of circumstances and appropriate responses. It is more appropriate to speak in terms of the "types" of circumstances and "types" of responses that should be planned for. Flexibility is necessary to assess the specific circumstances that arise and apply the specific and most appropriate response from the various available of options.

2) Page 26 – Discussion of additional work conducted on selected items designated as complete.

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SÉRVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO) DRAFT REPORT ENTITLED: PANDEMIC INFLUENZA: GAPS IN MONITORING AND ASSESSING STATUS OF THE NATIONAL PANDEMIC IMPLEMENTATION PLAN NEEDS TO BE ADDRESSED (GAO-10-73)

Preparedness is a continuous, ongoing, iterative, improvement process based on lessons learned. As indicated above, due to the inherent nature of influenza virus, preparedness is not a fixed endpoint. Guidance needs to be updated based on new scientific discovery and on information obtained from ongoing surveillance of the mutations of the influenza virus (prepandemic or during a pandemic) as it continues to circulate around the globe. Training and exercises should not be considered a one-time activity. There is considerable scientific evidence that refreshing knowledge and skills improves performance when the knowledge and skills are actually needed, particularly if the events do not occur often. The health and public health workforces are not static entities. People move in and out of the workforce and between categories of responsibilities fluidly. Ongoing training is necessary and exercises should be iterative and adapt to lessons learned and from new scientific discovery and information obtained from ongoing surveillance of the influenza virus.

## Appendix V: Comments from the Department of Homeland Security

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



October 23, 2009

Ms. Bernice Steinhardt Director, Strategic Issues U.S. Government Accountability Office 441 G Street, N.W. Washington, DC 20548

Dear Ms. Steinhardt:

RE: Draft Report GAO 10-73 (Reference # 450696) National Pandemic Implementation Plan Action Items

Thank you for the opportunity to review the draft report concerning the National Pandemic Implementation action items. While there were no recommendations for the Department of Homeland Security (DHS) in the draft report, we would like to respectfully offer the following comments:

DHS has reviewed the report and has no substantive comments on the content of the report. The information in the report is generally accurate and DHS recognizes that while improvements can be made in the National Implementation Plan as outlined in the GAO report, it is important to recognize that over the past 3 years, there has been a great deal of significant work accomplished in many different areas of pandemic preparedness and response that are directly related to work completed as outlined in the 2006 National Implementation Plan.

As a direct result of the National Implementation Plan, significant collaboration has occurred at all levels of government and the private sector that has effectively built a strong base for pandemic preparedness and response that enabled a much more efficient and coordinated response for the 2009 H1N1 events that continues today.

While the National Implementation Plan was written to specifically address a severe pandemic, much of the work completed has been vitally important and beneficial in responding to the 2009 H1N1 pandemic, which continues to be a mild to moderate pandemic. The collaboration networks that were established and the significant training and exercises that had already been established as required in the National Implementation Plan, positioned our nation to be in a much better position to respond efficiently to the 2009 H1N1 events and thereby greatly reduced the impact of the current pandemic.

Appendix V: Comments from the Department of Homeland Security

Thank you for the opportunit working with you on future h	nomeland security issu	Draft Report and we loves.  Sincerely,  Jerald E. Levine  Director  Departmental GAO/O	fild	
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# Appendix VI: GAO Contact and Staff Acknowledgments

GAO Contact	Bernice Steinhardt, (202) 512-6543 or steinhardtb@gao.gov
Staff Acknowledgments	In addition to the contact named above, Sarah Veale, Assistant Director; Maya Chakko; Susan Sato; David Fox; Melissa Kornblau; Kara Marshall; Mark Ryan; David Dornisch; Andrew Stavisky; and members of GAO's Pandemic Working Group made key contributions to this report.

### Related GAO Products

Influenza Pandemic: Key Securities Market Participants Are Making Progress, but Agencies Could Do More to Address Internet Congestion and Encourage Readiness. GAO-10-8. Washington, D.C.: October 26, 2009.

Influenza Pandemic: Gaps in Pandemic Planning and Preparedness Need to Be Addressed. GAO-09-909T. Washington, D.C.: July 29, 2009.

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Influenza Pandemic: Increased Agency Accountability Could Help Protect Federal Employees Serving the Public in the Event of a Pandemic. GAO-09-404. Washington, D.C.: June 12, 2009.

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Influenza Pandemic: Opportunities Exist to Address Critical Infrastructure Protection Challenges That Require Federal and Private Sector Coordination. GAO-08-36. Washington, D.C.: October 31, 2007.

### **Related GAO Products**

Influenza Pandemic: Federal Executive Boards' Ability to Contribute to Pandemic Preparedness. GAO-07-1259T. Washington, D.C.: September 28, 2007.

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Related GAO Products

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

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