Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

HHS DID NOT ALWAYS EFFICIENTLY PLAN AND COORDINATE ITS INTERNATIONAL EBOLA RESPONSE EFFORTS

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Office of Inspector General

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Report in Brief
Date: August 2019
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U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES
OFFICE OF INSPECTOR GENERAL

HHS Did Not Always Efficiently Plan and Coordinate Its International Ebola Response Efforts

Why OIG Did This Review

The U.S. Department of Health and Human Services (HHS) is the U.S. Government's principal agency for protecting the health of all Americans and providing essential human services. Included in that role is a charge to respond to international epidemics that could threaten the United States.

When the Ebola crisis in West Africa began in early 2014, it overwhelmed the medical capacity of Liberia, Guinea, Sierra Leone, and the international emergency health response community—ultimately prompting the United States to expend efforts and resources to combat the biological threat. Ultimately, Congress provided more than $5.4 billion in emergency funds for Ebola prevention and response, of which HHS received $2.76 billion.

The objective of this review was to determine whether HHS's Ebola response efforts were effective and efficient.

How OIG Did This Review

We reviewed each of HHS's components' preparation and coordination, both internally and with other components, related to the overall HHS Ebola response activities. We obtained and reviewed applicable documents related to any needs and risk assessments that the components conducted during the planning and creation of its Ebola response plans. Our review covered the period from the identification of the Ebola crisis in 2013 through the issuance of funds from the Consolidated and Further Continuing Appropriations Act.

What OIG Found

As part of a global effort, HHS made significant contributions to controlling the Ebola crisis during 2014 and 2015 and was ultimately effective in accomplishing its mission to help stop the spread of Ebola. However, HHS did not always efficiently plan and coordinate its international Ebola response efforts. Specifically, HHS had no strategic framework in place to coordinate global health security at the international or departmental levels before the Ebola outbreak, HHS was not prepared to deploy the resources needed for such a large-scale international response, and HHS did not have in place internal or external communication channels for responding to an international public health emergency.

HHS's response efforts were further complicated by external factors. Specifically, the World Health Organization did not declare the epidemic an emergency until well after the epidemic had significantly expanded in West Africa, and Congress did not provide funding until HHS's response was well underway.

Without effective internal controls that include a department-wide strategic framework for responding to an international health crisis, HHS may continue to inefficiently plan and coordinate its international response efforts in future health crises.

What OIG Recommends and HHS Comments

We recommend that HHS (1) develop department-wide objectives and a strategic framework for responding to international public health emergencies, (2) develop policies and procedures that clearly define HHS components' roles and responsibilities for responding to international public health emergencies, (3) develop large-scale international response plans, (4) develop various means of obtaining and using quality data for decision making, and (5) work with other U.S. Government agencies to develop a flexible multi-agency international response framework.

In response to our draft report, HHS concurred with our recommendations and discussed actions that it would take or had taken to address the recommendations. For example, HHS stated that it would work across its components to establish a framework for responding to international public health responses.

The full report can be found at https://oig.hhs.gov/oas/reports/region4/41603567.asp.

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INTRODUCTION

WHY WE DID THIS REVIEW

The U.S. Department of Health and Human Services (HHS or the Department) is the U.S. Government's principal agency for protecting the health of all Americans and providing essential human services, especially for those who are least able to help themselves. Included in its role of protecting the health of Americans is a charge to respond to international epidemics that could threaten the United States.

The Ebola epidemic in West Africa overwhelmed the medical capacity of Liberia, Guinea, Sierra Leone, and the international emergency health response community—ultimately prompting the United States to expend efforts and resources to combat the biological threat. HHS officials stated that HHS had never responded to an epidemic of this magnitude before and had to quickly reassign its resources to do so. Ultimately, Congress provided more than $5.4 billion in emergency funds for Ebola prevention and response, of which HHS received $2.76 billion.

The HHS Office of Inspector General (HHS-OIG) worked with the Council of the Inspectors General on Integrity and Efficiency, which included the Offices of Inspector General from the U.S. Agency for International Development (USAID-OIG), Department of Defense (DoD-OIG), and Department of State (DoS-OIG), to produce quarterly reports for Congress addressing U.S. Government activities and OIG oversight of these activities in response to the Ebola crisis. Specifically, HHS-OIG and USAID-OIG coordinated our oversight reviews of Ebola response efforts to determine if parallel findings existed.[1]

OBJECTIVE

Our objective was to determine whether HHS's Ebola response efforts were effective and efficient.

BACKGROUND

The Ebola Crisis

The Ebola virus disease, a hemorrhagic fever, is one of the most fatal infectious diseases. In March 2014, the World Health Organization (WHO) officially reported an outbreak of Ebola in Guinea. By mid-2014, the disease had spread to neighboring Liberia and Sierra Leone, with additional cases in Mali, Nigeria, and Senegal. By May 2015, Ebola had killed 10,880 people and infected an estimated 26,000: including 3,600 in Guinea, 10,300 in Liberia, and 12,400 in Sierra Leone.

[1] USAID-OIG audit report, 9-000-18-001-P, *Lessons From USAID's Ebola Response Highlight the Need for a Public Health Emergency Policy Framework*, issued January 24, 2018. Available online at https://oig.usaid.gov/sites/default/files/2018-06/9-000-18-001-p_0.pdf. Accessed on January 8, 2019.

In November 2014, President Obama submitted a $6.18 billion emergency appropriations request to Congress for domestic and international responses to Ebola. Congress acted on this request as part of its fiscal year (FY) 2015 omnibus appropriation (P.L. No. 113-235) and provided more than $5.4 billion in emergency funds for Ebola prevention and response.[2] Of the $5.4 billion, HHS received $2.76 billion, which it allocated to HHS components. (See the table.)

Table: FY 2015 Allocation of HHS Funding for Ebola Prevention and Response

HHS Component*	Emergency Funding Allocation	Percentage of Total HHS Emergency Funding
Centers for Disease Control and Prevention	$1.77 billion	64%
Public Health and Social Services Emergency Fund†	733 million	26
National Institutes of Health	238 million	9
Food and Drug Administration	25 million	1
Total	**$2.76 billion**	**100%**

* For purposes of this report, we will refer to all HHS internal organizational divisions as "components."

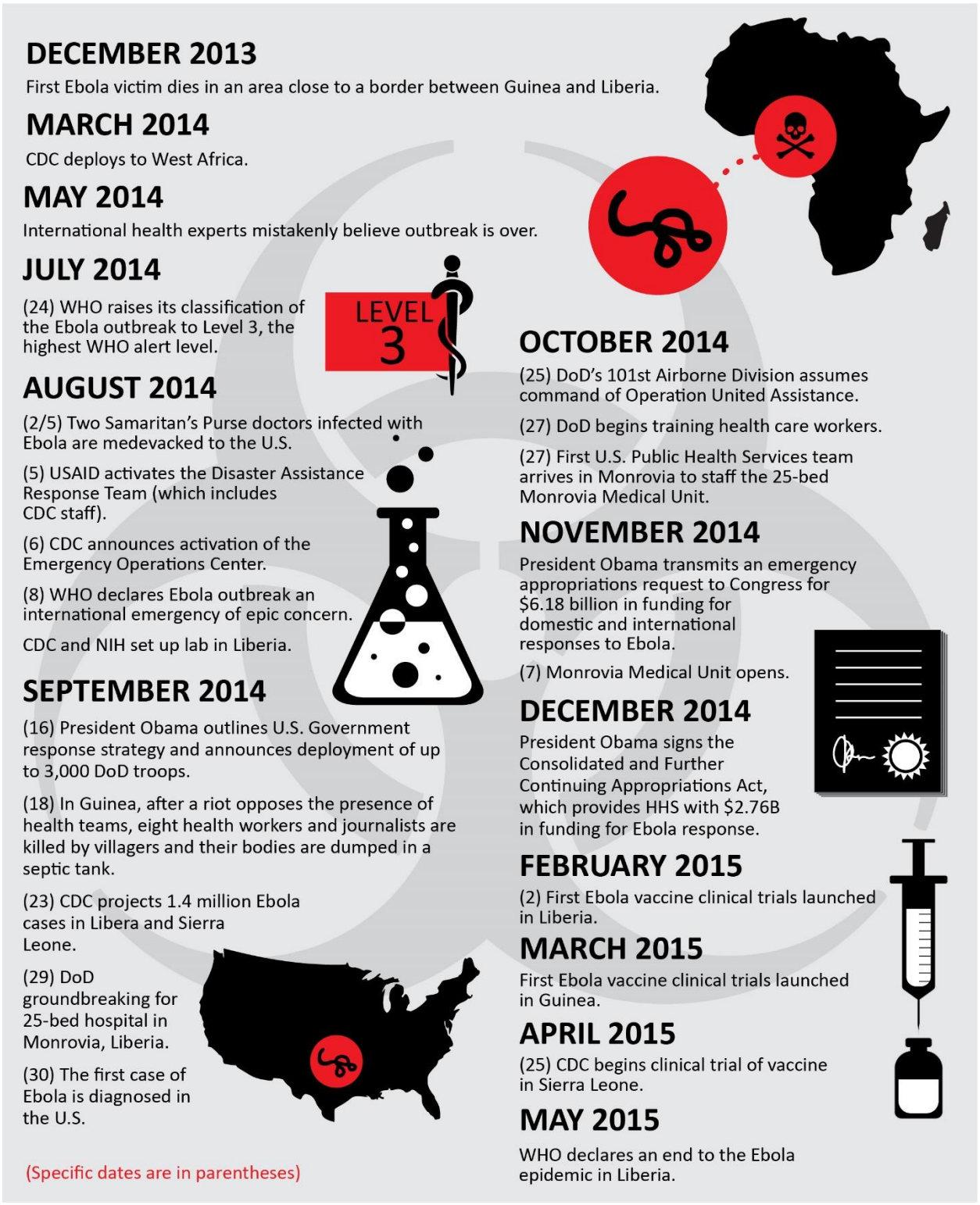
† The Public Health and Social Services (PHSS) Emergency Fund directly supports the Nation's ability to prepare for, respond to, and recover from the health consequences of naturally occurring and manmade threats. Both the Biomedical Advanced Research and Development Authority (BARDA) and the Office of the Assistant Secretary for Preparedness and Response (ASPR) received funding for response and preparedness activities through the PHSS Emergency Fund.

Timeline of Ebola Response Activities

The Ebola outbreak began in December 2013, when the first suspected case was identified. WHO first declared the end of the Ebola epidemic in Liberia in May 2015. During 2014 and 2015, the Ebola epidemic in West Africa, as reported most recently by the Centers for Disease Control and Prevention (CDC) in April 2016, was the largest Ebola epidemic yet recorded. See the timeline of events regarding HHS Ebola-related activities in Figure 1 on the next page.

[2] Although the Ebola crisis continued into 2016, our review covered the period from its identification in 2013 through the issuance of funds from the Consolidated and Further Continuing Appropriations Act.

Figure 1: 2014–2015 Ebola Crisis Timeline



HOW WE CONDUCTED THIS REVIEW

The *Standards for Internal Control in the Federal Government*, published by the Government Accountability Office (GAO), sets the internal control standards for Federal entities.[3] Also known as the Green Book, it defines internal control as a process used by management to help an entity achieve its objectives. Internal control comprises the plans, methods, policies, and procedures used to fulfill the mission, strategic plan, goals, and objectives of the entity (OV1.03).

While there are different ways to present internal control, the Green Book approaches internal control through a hierarchical structure of 5 components and 17 principles (Figure 2).

Figure 2: The 5 Components and 17 Principles of Internal Control

Control Environment

1. The oversight body and management should demonstrate a commitment to integrity and ethical values.
2. The oversight body should oversee the entity's internal control system.
3. Management should establish an organizational structure, assign responsibility, and delegate authority to achieve the entity's objective.
4. Management should demonstrate a commitment to recruit, develop, and retain competent individuals
5. Management should evaluate performance and hold individuals accountable for their internal control responsibilities.

Risk Assessment

6. Management should define objectives clearly to enable the identification of risks and define risk tolerances.
7. Management should identify, analyze, and respond to risks related to achieving the defined objectives.
8. Management should consider the potential for fraud when identifying, analyzing, and responding to risks.
9. Management should identify, analyze, and respond to significant changes that could impact the internal control system.

Control Activities

10. Management should design control activities to achieve objectives and respond to risks.
11. Management should design the entity's information system and related control activities to achieve objectives and respond to risks.
12. Management should implement control activities through policies.

Information and Communication

13. Management should use quality information to achieve the entity's objectives.
14. Management should internally communicate the necessary quality information to achieve the entity's objectives.
15. Management should externally communicate the necessary quality information to achieve the entity's objectives.

Monitoring

16. Management should establish and operate monitoring activities to monitor the internal control system and evaluate the results.
17. Management should remediate identified internal control deficiencies on a timely basis.

To conduct this internal control review, we met with the following HHS components that participated in the Ebola response in West Africa: Office of the Secretary (OS), Office of Global Affairs (OGA), Office of the Assistant Secretary for Health (OASH), U.S. Public Health Service (PHS), Office of the Assistant Secretary for Financial Resources (ASFR), ASPR, BARDA, National Institutes of Health (NIH), Food and Drug Administration (FDA), and CDC. To further our internal control review of HHS preparation and coordination among components and other U.S. Government agencies, we requested and reviewed various documents, white papers, draft

[3] Standards for Internal Control in the Federal Government, GAO-14-704G, published September 2014, page 9.

policies, and departmental emails and memorandums that each component and Governmental agency supplied at our request. When documentation was unavailable, we relied on testimonial evidence that we gathered during the audit. Finally, we reviewed after-action reports (AARs)[4] generated by HHS components, USAID, DoD, and the Department of Homeland Security (DHS) to identify commonalities across various agencies of the U.S. Government in responding to the Ebola crisis. Because HHS's existing strategic plan for domestic responses did not provide information that correlated to international health emergences, we limited our review of HHS's response efforts to assessing only two of the five internal control components:

- the control environment and
- information and communication.

Appendix A contains the details of our audit scope and methodology, and Appendix B lists the criteria we used to conduct this audit.

We conducted this performance audit 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.

FINDINGS

As part of a global effort, HHS was ultimately effective in making significant contributions to controlling the Ebola crisis and accomplishing its mission to help stop the spread of Ebola. However, HHS's response efforts could have been more efficient and effective. Specifically, HHS's response was hindered by HHS's:

- having no strategic framework in place to coordinate global health security at the international or departmental levels before the Ebola outbreak in West Africa,
- not being prepared to deploy the resources needed for such a large-scale international response,
- having ineffective defined internal or external communication protocols for responding to an international public health emergency, and
- not always having access to quality information during the response.

Without an effective internal control system, HHS may continue to inefficiently plan and coordinate its international response efforts in future health crises.

[4] AARs are detailed critical summaries or analyses of past events created to re-assess decisions and consider possible alternatives for future reference.

FEDERAL REQUIREMENTS

Section 3512 (c) and (d) of Title 31 of the United States Code (commonly known as the Federal Managers' Financial Integrity Act) requires the Comptroller General to issue standards for internal control in the Federal Government. The Green Book sets the internal control standards for Federal entities. The Green Book defines internal control as a process used by management to help an entity achieve its objectives. Internal control consists of the plans, methods, policies, and procedures used to fulfill the mission, strategic plan, goals, and objectives of the entity. (See Appendix B for detailed criteria.) Office of Management and Budget (OMB) Circular No. A-123 requires management to evaluate the effectiveness of internal controls annually using the Green Book.

The Government Performance and Results Modernization Act of 2010, P.L. No. 111-352, requires Federal agencies to have a strategic plan that includes its mission, goals, and objectives and how the goals and objectives are to be achieved.

HHS HAD NOT ESTABLISHED A FRAMEWORK FOR IMPLEMENTING A DEPARTMENT-WIDE RESPONSE TO AN INTERNATIONAL PUBLIC HEALTH EMERGENCY

HHS's strategic plan did not include a department-wide international response framework to prevent the spread of infectious diseases such as Ebola. Instead, some HHS components relied on existing domestic-focused policies and procedures during their response efforts. In addition, HHS did not establish an oversight body to oversee operations and provide feedback to management during decision making.

Strategic Plan

The Green Book states an entity determines its mission, sets a strategic plan, establishes entity objectives, and formulates plans to achieve its objectives (OV2.03).

The U.S. Government did not have a strategic framework for responding to an international public health crisis.[5, 6] Neither did HHS. During the Ebola epidemic, HHS's strategic plan emphasized the need for maintaining a strong public health and response system abroad to prevent the spread of infectious disease and for working with global health partners to eradicate certain targeted diseases. However, the strategic plan did not include a department-wide framework for responding to an *international* event such as the Ebola crisis. (See Appendices C and D.) For large-scale *domestic* responses, the U.S. Government has a strategic

[5] USAID-OIG audit report, 9-000-18-001-P, *Lessons From USAID's Ebola Response Highlight the Need for a Public Health Emergency Policy Framework*, issued January 24, 2018. Available online at https://oig.usaid.gov/sites/default/files/2018-06/9-000-18-001-p_0.pdf. Accessed on January 8, 2019.

[6] *The Report of the Independent Panel on the U.S. Department of Health and Human Services Ebola Response*. Available online at https://reliefweb.int/sites/reliefweb.int/files/resources/ebola-panel.pdf. Accessed on July 1, 2019.

plan that it follows, the *National Response Framework* (NRF).[7] Similarly, some HHS components have their own *domestic* incident response plans. Neither the NRF, nor the HHS components' domestic plans were designed for use in an international event.

On behalf of HHS, ASPR told us that it had taken some steps toward developing an international framework. However, that framework was not in effect during the Ebola crisis. According to ASPR officials, this international framework document was still in draft in early 2018. (See Appendix E for a summary of each component's mission and strategic plans, if available.)

Policies and Procedures

The Green Book states that management is responsible for designing policies and procedures to fit circumstances and developing them as an integral part of operations (OV2.02).

HHS had not established department-wide policies and procedures to coordinate an *international* response to a public health emergency. While some HHS components had developed internal policies and procedures to aid response efforts, these policies and procedures generally did not address international public health emergencies.

During our review, ASPR officials indicated that they had developed and implemented an Incident Response Plan for domestic situations. This Incident Response Plan references the NRF and follows the coordination responses in the *Biological Incident Annex*,[8] but does not cover an international response effort.

The primary missions of FDA and NIH typically do not include responding to international health emergencies, so neither HHS component had policies and procedures for responding to an event such as the Ebola crisis. However, NIH conducted clinical trials in the affected countries, and FDA established an Ebola Task Force to coordinate with other entities on medical product development and availability. Additionally, NIH provided diagnostic support at facilities in Liberia.

Unlike ASPR, FDA, and NIH, CDC routinely responds to domestic and international public health emergencies and has existing policies and procedures on which it typically relies to guide its response efforts. CDC provides emergency preparedness and response operations planning for all-hazard events (both natural and manmade) affecting public health. To respond to these

[7] The NRF is a written plan for how the Nation should respond to all types of domestic disasters and emergencies. It is built on scalable, flexible, and adaptable concepts to align key roles and responsibilities across the United States. The NRF describes processes for implementing a nation-wide response policy and identifies operational procedures for all types of domestic incidents. It also defines roles and responsibilities by identifying which entity is involved in a particular response area based on the entity's core capabilities. The NRF designates HHS as the lead Federal agency for coordinating the U.S. Government's public health and medical response.

[8] The Biological Incident Annex, which supports policies and procedures outlined in the *National Response Framework,* Emergency Support Function (ESF) #8, outlines the actions, roles, and responsibilities associated with a response to a human disease outbreak of known or unknown origin requiring Federal assistance.

incidents, CDC developed the *Centers for Disease Control and Prevention All-Hazards Plan* (AHP), May 2013, to identify the basic principles, organization, and responsibilities during a public health emergency or response.[9] Essentially, the AHP serves as CDC's policies and procedures for carrying out specific actions at projected times and within specific functional roles of CDC's Incident Management System during a public health emergency. It also defines how CDC coordinates these responsibilities within CDC's Emergency Operations Center. CDC used the AHP when it responded to the Ebola crisis.

Oversight Body

The Green Book defines the role of an oversight body as being responsible for overseeing the strategic direction of the entity and obligations related to the accountability of the entity and defines management as being directly responsible for all of the entity's activities (OV2.14). An oversight body distinguishes itself from management and oversees operations, provides feedback to management, and makes oversight decisions, where appropriate, so that the entity achieves its objectives (Principle 2.03). ASPR, under the authority of *t*he *Pandemic and All-Hazards Preparedness Reauthorization Act of 2013* (PAHPRA) § 102(a)(1), was designated as the lead operational and coordinating body in HHS for public health emergencies. Under PAHPRA, the Office of the Secretary generally serves as the oversight body for HHS during a domestic crisis response effort.

The HHS Secretary assumed responsibility for leading and coordinating HHS's international response to the Ebola epidemic, an operational role generally filled by ASPR, and did not establish a separate oversight body. Instead of providing oversight of the response activities, the Office of the Secretary took on an operational role generally filled by ASPR. Specifically, the Secretary actively conducted daily meetings with the heads of each HHS component involved in the Ebola response. These meetings included a discussion of the "call deliverables," which outlined tasks and assignments that components were responsible for and, in some cases, were to be completed by the end of each day. For example, ASPR used Ebola activity tables to track activities that were being conducted within ASPR. These tables would be emailed to the Office of the Secretary early each day, updated daily, and sent back to the Office of the Secretary by the end of the same day. Similarly, at CDC, tasks would flow from the Director to the division responsible for completing the task. CDC used its response structure to monitor completion of these tasks and report back to the Secretary. This process would begin anew each day.

While the Office of the Secretary's process provided HHS component updates on the status of assigned tasks and creation of new tasks to respond to current events, there was no mechanism in place to consolidate and update this information for overall analysis and decision making as might have happened with an oversight body. The task-oriented information was not sufficient to determine whether goals and objectives were being met or whether internal controls had

[9] The AHP covers the concept of operations; organization and assignment of responsibilities; direction, control, and coordination; information collection, analysis, and dissemination; communications; administration, finance, and logistics; and plan development and maintenance.

been adequately designed and implemented. (See "HHS Did Not Always Have Access to Quality Information for Decision Making" on page 13 of this report.)

Because no independent oversight body was designated when the Secretary assumed the responsibility of leading and coordinating HHS's response to the Ebola crisis, the Office of the Secretary did not receive necessary feedback on decision making, such as an oversight body's presenting alternative views, addressing issues that cross organizational boundaries, or overseeing the remediation of identified deficiencies.

HHS WAS NOT PREPARED TO DEPLOY THE RESOURCES NEEDED FOR A LARGE-SCALE INTERNATIONAL RESPONSE

The Green Book states that management should recruit, develop, and retain competent individuals (Principle 4.01 and 4.05).

HHS and its components were not prepared to deploy the personnel needed to respond to the Ebola epidemic in part because HHS did not anticipate the need for it to use its own personnel to provide extensive direct patient care. In addition, some HHS personnel had not received appropriate training to treat Ebola patients. These personnel problems were complicated by a lack of funds that were not available to be easily redirected to the Ebola effort.

Shortage of Available Personnel

HHS was required to provide direct clinical care as part of its response to the Ebola epidemic. Generally, this type of care is available through contracts with nongovernmental organizations (NGOs), but HHS did not anticipate that healthcare professionals world-wide would be reluctant to volunteer to work with Ebola patients. Because of the large scale of the Ebola crisis, NGOs, such as Médecins Sans Frontières (Doctors Without Borders) and others, could not meet the demand for qualified medical staff. In addition, many local health professionals in Africa were the first to contract Ebola because of their proximity to infected patients. The rapid increase in Ebola patients overwhelmed already fragile healthcare systems within these African countries, raising concerns among potential volunteers regarding whether they themselves would receive proper treatment if they became infected.

HHS was limited in its ability to recruit, develop, or retain the number of competent personnel needed to respond to a large-scale international public health emergency. For example, the U.S. Public Health Service Commissioned Corps (Commissioned Corps) maintained a roster of its personnel that identified each person's specialty and current medical certifications and whether he or she is practicing medicine.[10] These Commissioned Corps personnel are capable of providing clinical care during a *domestic* emergency. However, the Commissioned Corps was not staffed or prepared for an international response of this magnitude. In addition, the number of response personnel dwindled even more when qualified Commissioned Corps

[10] Most Commissioned Corps personnel do not currently practice medicine, but they are required to maintain their professional certifications.

personnel working at other U.S. Government agencies became unavailable to HHS. Some of those agencies indicated that they would not fund Commissioned Corps salaries during the employees' deployment to Africa. The agencies also felt that a temporary loss of Commissioned Corps personnel would have hindered their ability to accomplish their agencies' missions.[11]

Similar to the Commissioned Corps, CDC maintained a roster of internationally deployable personnel. CDC had a goal to initially deploy 50 epidemiologists within 30 days of activating its Emergency Operations Center on July 9, 2014. These 50 individuals were on CDC's roster as "cleared for international deployment;" i.e., they had met all CDC and DoS requirements for working overseas. However, CDC needed more than just these initial 50 epidemiologists to respond to the Ebola crisis, and other staff were not ready for deployment. While waiting for other CDC staff to complete the required DoS training for those traveling overseas for longer than 30 days, CDC rotated staff in and out of the West African region every 30 days. The DoS ultimately provided a waiver for some CDC staff so that they could stay beyond the 30-day time limit while other staff obtained the proper DoS clearances before deployment. CDC also had to reassign staff and reprioritize resources to conduct its Ebola response efforts.

NIH and FDA also had to reprioritize their respective staffs and workloads for their Ebola response efforts. NIH used subject matter experts[12] and paid them with its own funding. A significant portion of FDA's workload is mandated by statutes,[13] which limited the availability of staff to respond to an international public health emergency. Since 2010, FDA has received appropriations from Congress to increase its staff. However, at the time of our review, the level of funding needed had not kept pace with the frequency, complexity, severity, and speed of public health emergencies. As a result, FDA had not been able to sustain the number of staff and other resources needed to staff an international emergency.

Further complicating personnel shortages during the Ebola crisis, the U.S. Office of Personnel Management did not waive authority for direct hire, despite multiple requests from HHS and support for the waiver from the White House.

Insufficient Training

HHS's response efforts were delayed because its staff had not received the training they needed to treat Ebola patients, such as specialized medical training and safety training. One

[11] Commission Corps officers work in a variety of positions in non-HHS Federal agencies and programs that offer professional opportunities in the areas of disease control and prevention; biomedical research; regulation of food, drugs, and medical devices; mental health and drug abuse; and healthcare delivery.

[12] NIH established a group of subject matter experts, which consisted of NIH employees and previously used contractors who had experience responding to HIV in Africa and Asia.

[13] Examples of statutes that mandate FDA work include: The Family Smoking Prevention and Tobacco Control Act of 2009, the Patient Protection and Affordable Care Act of 2010, the FDA Food Safety Modernization Act of 2011, the FDA Safety and Innovation Act of 2012, and the Drug Quality and Security Act of 2013.

example of steps taken to address this gap occurred in July 2014, when CDC helped organize a training course[14] for Commissioned Corps clinicians who were scheduled to deploy to work in the Monrovia clinic. Creating and conducting training delayed the deployment of the first of 4 deployments of 70 Commissioned Corps personnel to Liberia. The first team of Commissioned Corps personnel completed training and arrived in Liberia on October 27, 2014, to staff the clinic. As a result of this delay, the Monrovia Medical Unit opening was delayed, and the first team deployed had its tour of duty extended until the next team of Commissioned Corps personnel received training. Like CDC staff, the Commissioned Corps also needed to complete the required DoS training before going overseas for longer than 30 days. A backlog in DoS training further delayed HHS's response.

Shortage of Funding

The response to the crisis was also affected by a lack of readily available, flexible, and unobligated funds. These funds that were not available during the early stages of the crisis and components had difficulties in using money that had been assigned to other purposes. For example, the Commissioned Corps had no fiscal appropriations to train and prepare its officers for an international public health crisis. CDC, which was involved with the Ebola response early on, had to analyze more than 100 programs, projects, and activities associated with its many lines of budgetary appropriations to (1) identify any available funds and (2) determine whether it had the authority to use any available funds for Ebola activities. Additionally, HHS had difficulty covering the extra costs of its response efforts until Congress provided funding 9 months into the Ebola crisis. (See "Other Matters" later in this report.)

HHS COMMUNICATION PROTOCOLS COULD BE MORE EFFECTIVE IN RESPONDING TO AN INTERNATIONAL PUBLIC HEALTH EMERGENCY

HHS did not have effective communication protocols during its Ebola crisis response. In spite of this, some HHS components involved in the Ebola response used effective collaboration, which facilitated clinical trials and vaccine deliveries.

Internal Communication

The Green Book states that management should internally communicate necessary quality information (Principle 14.01). Internal communication involves management communicating and receiving quality information down, up, across, and around reporting lines to all levels of the entity, which enables personnel to perform their roles in achieving objectives (Principles 14.02 and 14.03). Additionally, management should select appropriate methods for internal communications (Principle 14.07).

HHS did not have effective internal communication protocols that applied to an international situation: the Ebola crisis response. With no framework to define these protocols, some HHS

[14] The course was designed to provide medical training related to Ebola, as well as the safe and effective use of personal protective equipment by emergency responders operating in an infectious disease environment.

components defaulted to their domestic communication protocols. For example, during a domestic response, ASPR conducts meetings with HHS components and staff who can quickly disseminate information and assign tasks to appropriate staff to implement the meeting's decisions. Because the Office of the Secretary centralized communications during the Ebola response, domestic communication protocols such as ASPR's were not effective and HHS components experienced delays in their response efforts due to the time involved in disseminating information.

In addition, some HHS components did not provide deployed staff with communication devices or email access so that they could conduct basic internal communication. As a result, some HHS personnel used their personal mobile phones to communicate with each other in the field and to report results and progress to HHS staff back in the United States. The use of personal devices put at risk sensitive Ebola response information and hindered the staff's ability to communicate during the crisis.

Finally, we noted that when a new Secretary took office in June 2014, the incoming HHS leadership may not have been informed of the HHS disaster response structure. HHS creates a formal HHS presidential transition book for each incoming administration, and the new HHS leadership presumably received a copy of the transition book even though it joined HHS in the middle of a presidential administration. The leadership would also have gotten an update on various departmental issues. However, the transition book, which summarized HHS's role during a domestic public health emergency, placed more emphasis on HHS's continuity of operations and testing the continuity of operations plan within a specified time rather than the command response structure of HHS.

External Communication

The Green Book states that management should communicate externally using quality information to achieve the entity's objectives (Principle 15.01). External communication involves management communicating quality information using two-way external reporting lines that allows for communicating with and obtaining quality information from external parties (Principle 15.02). Because government entities report not only to the head of government but also the general public, they should consider appropriate methods of communication with a broad audience (Principle 15.09).

HHS did not have effective external communication protocols during its Ebola crisis response. According to one component, unlike during a domestic response, HHS did not have a designated point of contact for sharing or receiving information with the public and other HHS partners. In addition, some documents for public release also required extensive inter-governmental clearance, which was time-consuming and made it difficult to revise public messages as new events unfolded. The rapidly changing nature of the Ebola crisis, coupled with a time-consuming inter-governmental process to clear public messages, often delayed communication with the public regarding the status of the crisis.

Because of this delay in communicating to the public, people often used CDC's website to access information regarding the status of the Ebola response activities, which was often more current than the messages that had been cleared for public release. In addition, other U.S. Government agencies and HHS partners operating in West Africa commented that they were obtaining information and receiving communications from various sources in HHS, some of which was conflicting. Centralizing external communication could have reduced the confusion relating to HHS response activities.

Effective Collaboration Facilitated Clinical Trials and Vaccine Development

Some HHS components effectively collaborated and communicated with their external partners to facilitate a quick assembly of scientists and manufacturers that fast-tracked development of Ebola vaccines and clinical trials. HHS supported the use of investigational treatments through expanded access mechanisms and clinical trial protocols under the FDA Investigational New Drug requirements. Given the emergent nature of Ebola, NIH, FDA, and BARDA conducted an unprecedented meeting of experts to determine which clinical trials of vaccines and therapeutics were promising. Several components told us that, before the Ebola crisis, they had not conducted this type of collective information sharing, decision making, and fast-tracking.

The meeting allowed officials to collaborate with pharmaceutical manufacturers and quickly decide which therapeutic trials could potentially save lives at the Ebola treatment centers. Under normal circumstances, pharmaceutical manufacturers would not have shared product information with each other. However, BARDA's established relationship with the manufacturing companies permitted an agreement that no one would disclose product information shared during this meeting. The combination of having the right mix of individuals at the table and their ability to make immediate decisions based on current product information led to selecting vaccine and clinical trial candidates for immediate production testing.

HHS DID NOT ALWAYS HAVE ACCESS TO QUALITY INFORMATION FOR DECISION MAKING

Quality information is needed to achieve an entity's goals and objectives. The Green Book states that management obtains relevant and timely data from reliable sources to process into quality information and use for decision making. Quality information is appropriate, current, complete, accurate, accessible, and timely (Principle 13.04 and 13.05).

During the Ebola crises, CDC created interim progress reports, whereas HHS convened an independent panel to review its international and domestic responses that resulted in a report to HHS well after the crisis had ended. While the Office of the Secretary held daily meetings with deliverables, the information that was available to the Secretary was (1) not consolidated to facilitate analysis and decision making and (2) insufficient to determine whether the goals and objectives for stopping the Ebola crisis were being met.

Interim Progress Reviews and After-Action Reports

CDC issued three separate interim progress reviews (IPRs) during the 17 months of the Ebola crisis. These IPRs allowed CDC to assess its response efforts, monitor its progress, and make adjustments as needed. The IPRs included information such as CDC's deployment coordination efforts, data collection, situational awareness, communication and coordination within and between task forces and teams in CDC's headquarters and internationally, and interagency and partner coordination dynamics. CDC used information from these IPRs to adjust its response efforts during the crisis.

Unlike CDC, the Office of the Secretary and ASPR did not issue IPRs but relied on daily meetings and emails for information. The daily meetings and emails could only be used to assess progress in those daily tasks. While this information was current and timely, there was no system in place to consolidate the information. As a result, the Office of the Secretary could not effectively analyze the information it was collecting, which affected decision making and its ability to determine whether goals and objectives were being met during the Ebola crisis.

At the conclusion of the Ebola crisis response, ASPR contracted with an outside agency, on behalf of HHS, to capture the critical lessons from the Ebola crisis in an AAR. An independent panel of subject-matter experts (in public health, healthcare, emergency response, and communication) led the review of HHS's response to the Ebola crisis. The independent panel focused on strategic, policy-level, and major operational issues. This AAR, entitled the *Report of the Independent Panel on the U.S. Department of Health and Human Services Ebola Response*[15] (Ebola Report*),* was issued in June 2016 and contained 13 findings and related recommendations. The Ebola Report provided feedback to HHS more than a year after the crisis response was completed and therefore did not provide real-time, quality information that could have been used to adjust response efforts during the crisis.

The Ebola Report and HHS Response Partners

The Ebola Report commends HHS, as part of the global community, for its response to the Ebola epidemic, but many lessons emerged.[16] The most "salient lessons [learned] related to internal government coordination, collaboration with international parties, communication with the public and key stakeholders, and the need to meet the high demand for public health and medical support at home and abroad." The Ebola Report confirmed that:

- the centralized process hampered HHS's coordination among its different levels and, in turn, affected coordination for the public health and medical response between HHS and its interagency partners;

[15] *The Report of the Independent Panel on the U.S. Department of Health and Human Services Ebola Response*.

[16] Unlike this audit report, the Ebola Report is an internal assessment of HHS's response efforts. Recommendations made in that report by the independent panel were strictly for the benefit of the Department, and the independent contractors making those recommendations had no enforcement authority.

- for planning an international response, a career member of the Senior Executive Service who had knowledge of HHS's international response capabilities and coordination mechanisms should have been assigned to support the designated leader;

- the Office of the Secretary did not recognize established relationships and communication channels across HHS when responding to the Ebola crisis; and

- HHS did not use a department-wide communication strategy to coordinate messaging.

HHS was not the only Federal agency that experienced internal issues related to organizational structure, responsibility, and delegation of authority during the Ebola crisis. For example, both DoD's and USAID's AARs cited a lack of defined roles and responsibilities, along with a hesitancy to delegate authority from Washington to those in Africa as reasons for confusion and unnecessary complication of operations during the Ebola crisis response. Furthermore, USAID's AAR points to the lack of understanding by each U.S. agency regarding its respective role within the "whole of government" response as a problem in the beginning of the U.S. response efforts. This AAR notes that there were no U.S. Government parameters for dividing the labor between agencies when more than one agency responded to an international public health crisis. This lack of defined organization, structure, and responsibilities led some in HHS, as well as in USAID, to characterize the initial response efforts as "building the plane as it was flying."

Additionally, the rapid spread of Ebola overwhelmed the available capacity of staffing from USAID and DoD, which hindered their ability to sustain an adequate level of technical expertise and medical services in such a large-scale, international crisis.

Other U.S. Government agencies and HHS partners operating in West Africa were obtaining information from various sources in HHS, some of which was conflicting. DoD identified in its AAR that U.S. Government agencies operating in West Africa communicated similar response activities using different departmental terminology. Both oral and electronic communication between agencies in the field was difficult.

CONCLUSION

As part of a global community, HHS made significant contributions to controlling the Ebola crisis, both abroad and at home. However, HHS was not prepared to respond to such a large-scale international health crisis. Before the Ebola crisis, most U.S. Government agencies' response activities related to domestic natural or manmade physical disasters that were humanitarian. Like HHS, other U.S. Government agencies responding to the international Ebola crisis acknowledged that there was no single NRF-like policy or framework to guide U.S. Government coordination during an international public health emergency.

Without effective internal controls that include a department-wide strategic framework for responding to an international health crisis, HHS may continue to inefficiently plan and coordinate its international response efforts in future health crises. An effective internal control system should include a strategic plan, policies and procedures, qualified and trained

personnel, effective internal and external communication channels, and quality information, among other attributes. We make the recommendations below to assist HHS in implementing the basic internal controls needed to improve the efficiency of future response efforts.

RECOMMENDATIONS

We recommend that HHS:

- develop department-wide objectives and a strategic framework for responding to international public health emergencies;

- develop policies and procedures, along the lines of the NRF, that:

    - define the roles and responsibilities of each component when responding to an international public health emergency, which will allow the components to respond using their core competencies;

    - more clearly define the oversight body that monitors international response activities; and

    - include in the transition plan for incoming administrations and department heads the operational authorities of HHS during international response efforts;

- develop large-scale international response plans that include;

    - working with OPM to develop guidelines that would allow HHS to request and receive direct hiring authority during an international health response;

    - working with DoS to develop a process to streamline overseas deployment of HHS staff during an international health crisis;

    - updating the training and preparation needed for certain HHS staff to be readily deployable for international emergencies—both DoS-required clearances and training on infectious diseases;

    - updating the training course developed during this crisis to train Commissioned Corps staff in the handling of infectious diseases to prepare staff for future response efforts;

    - working with OMB to determine the viability of a contingency fund for international response efforts when congressionally requested funds are not immediately available; and

    - establishing communication protocols for responding to an international crisis that (1) identify key communication resources needed by responders in the field,

(2) develop a plan to provide these resources to staff, and (3) establish a single communication channel from which the public can obtain information;

- develop various means, including IPR, of obtaining and using quality data needed for effective decision making during a public health crisis; and

- work with other U.S. Government agencies to develop a flexible framework focusing on each agency's mission and define each agency's roles and responsibilities for responding to a multi-agency international public health emergency.

ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE AND CENTERS FOR DISEASE CONTROL AND PREVENTION COMMENTS

In response to our draft report, the Department concurred with all of our recommendations and discussed actions that it would take or had taken to address the recommendations.

Regarding our first recommendation, the Department stated that the development of department-wide objectives and a strategic framework would be built around component capabilities and roles in an international response.

With respect to our second recommendation regarding policies and procedures for responding to international responses, the Department stated that it would work across its components to establish a framework, similar to the NRF, for international responses.

In response to our third recommendation regarding developing large scale international response plans, the Department stated that it would develop a high-level framework focusing on the most likely public health threats. In addition, the framework would encompass an international response plan, which would address difficult, yet common, issues, such as surge staffing capacity for extended deployments and language needs for those deployers.

Regarding our fourth recommendation, the Department stated that it currently has a variety of data systems and information tools available and would continue to improve the integration of data from other countries during an emergency for effective public health decision making.

With respect to our fifth recommendation regarding the development of a government-wide flexible framework that defines each agency's roles and responsibilities for responding to an international public health emergency, the Department stated that it would develop the public health component of a framework and work across the U.S. Government to not only integrate that framework into existing response plans but also determine a chain of command.

The Department provided technical comments, which we addressed, as appropriate, in the report. The Department's written comments, excluding the technical comments, are included as Appendix F.

OTHER MATTERS

During our audit, we identified external factors that further complicated HHS's response efforts:

- The World Health Organization did not declare the epidemic to be an emergency until well after hundreds of cases of Ebola were reported and the epidemic had significantly expanded in West Africa.

- Congress did not provide dedicated funding until 9 months after HHS began its response.

World Health Organization Did Not Declare the Epidemic an Emergency Until the Epidemic Had Significantly Expanded in West Africa

On March 23, 2014, the Ministry of Health of Guinea notified WHO of a rapidly evolving outbreak of Ebola. Forty-nine cases, including 29 deaths, had been reported. CDC was already aware of the Ebola cases because it was conducting continuous, world-wide monitoring of disease outbreaks. In March 2014, CDC deployed a limited number of staff to investigate. However, because the United States does not have jurisdiction in Africa, WHO discouraged CDC from establishing a larger presence.

The disease spread rapidly, and the affected countries lacked the adequate surveillance, laboratory, or investigative capabilities to track and report cases. By June 2014, both ASPR's and CDC's disease monitoring noted 599 cases of Ebola in West Africa. WHO declared a "Public Health Emergency of International Concern" in August 2014 when the virus had killed more than 900 people and spread into neighboring countries.

HHS Response Underway Before Congress Approved Supplemental Funding

In November 2014, President Obama requested from Congress $6.18 billion in emergency appropriations funding for domestic and international responses to Ebola. This request was designed to enable the U.S. Government to implement its strategy to contain and then end the Ebola epidemic in West Africa, strengthen domestic preparedness, accelerate testing and procurement of related medicines, and advocate for global capacity to prevent the spread of infectious disease outbreaks in the future. Congress acted on this request as part of its FY 2015 omnibus appropriations (P.L. No. 113-235). The President signed the omnibus appropriations bill into law on December 16, 2014, nearly 4 months after WHO officially declared the Ebola epidemic a public health emergency of international concern and 9 months after HHS had already started responding to the crisis. In total, Congress provided more than $5.4 billion in emergency funds for Ebola prevention and response. Of the $5.4 billion, HHS received $2.76 billion. However, HHS had to respond to the Ebola crisis before it received this congressional funding.

APPENDIX A: SCOPE AND METHODOLOGY

SCOPE

To conduct this internal control review, we met with the following HHS components that participated in the Ebola response in West Africa: OS, OGA, OASH, U.S. PHS, ASFR, ASPR, BARDA, NIH, FDA, and CDC. To further our internal control review of HHS preparation and coordination among components and other U.S. Government agencies, we requested and reviewed various documents, white papers, draft policies, and departmental emails and memorandums that each component and governmental agency supplied at our request. When documentation was unavailable, we relied on testimonial evidence that we gathered during the audit. Finally, we reviewed AARs generated by HHS components, USAID, DoD, and DHS to identify commonalities across various agencies of the U.S. Government in responding to the Ebola crisis.

The Green Book sets the internal control standards for Federal entities and defines internal control as a process used by management to help an entity achieve its objectives. Internal control comprises the plans, methods, policies, and procedures used to fulfill the mission, strategic plan, goals, and objectives of the entity. While there are different ways to present internal control, the Green Book approaches internal control through a hierarchical structure of 5 components and 17 principles. Because HHS's existing strategic plan for domestic responses did not provide a strong link to international health emergences, we limited our review of HHS's response efforts to assessing only two of the five internal control components:

- the control environment and
- information and communication.

The control environment is the foundation for an internal control system. It provides discipline and structure, which affects the overall quality of the internal control system. Effective information and communication are vital for an entity to achieve its objectives.

METHODOLOGY

To accomplish our objective, we:

- reviewed applicable Federal laws, regulations, policies, and guidance;
- conducted interviews with HHS staff at different components and different levels of authority;
- reviewed the components' internal strategy planning documents, needs assessments, and internal reports, if available;
- reviewed AARs from DHS, DoD, and USAID that responded to the Ebola crisis; and

- discussed our findings with each component.

We conducted this performance audit 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.

APPENDIX B: CRITERIA

STANDARDS FOR INTERNAL CONTROL IN THE FEDERAL GOVERNMENT (GAO-14-704G)

Fundamental Concepts of Internal Control

O*V1.03* – Internal control comprises the plans, methods, policies, and procedures used to fulfill the mission, strategic plan, goals, and objectives of the entity. Internal control serves as the first line of defense in safeguarding assets. In short, internal control helps managers achieve desired results through effective stewardship of public resources.

Establishing an Effective Internal Control System

OV2.02 – In implementing the Green Book, management is responsible for designing the policies and procedures to fit an entity's circumstances and building them as an integral part of the entity's operations.

OV2.03 – An entity determines its mission, sets a strategic plan, establishes entity objectives, and formulates plans to achieve its objectives.

OV2.14 – The oversight body is responsible for overseeing the strategic direction of the entity and obligations related to the accountability of the entity, whereas management is directly responsible for all of the entity's activities.

Principle 2 – Exercise Oversight Responsibility

Principle 2.03 – An oversight body oversees the entity's operations; provides constructive criticism to management; and, where appropriate, makes oversight decisions so that the entity achieves its objectives in alignment with the entity's integrity and ethical values.

Principle 3 – Establish Structure, Responsibility, and Authority

Principle 3.02 – Management establishes the organizational structure necessary to enable the entity to plan, execute, control, and assess the organization in achieving its objectives.

Principle 3.03 – Management develops the organizational structure with an understanding of the overall responsibilities and assigns these responsibilities to discrete units to enable the organization to operate in an efficient and effective manner, comply with applicable laws and regulations, and reliably report quality information.

Principle 3.04 – As part of establishing an organizational structure, management considers how units interact to fulfill their overall responsibilities.

Principle 4 – Demonstrate Commitment to Competence

Principle 4.01 – Management should recruit, develop, and retain competent individuals.

Principle 4.05 – Management recruits, develops, and retains competent personnel to achieve the entity's objectives.

Principle 13 – Use Quality Information

Principle 13.04 – Management obtains relevant data from reliable internal and external sources in a timely manner based on the identified information requirements. Management obtains data on a timely basis so that they can be used for effective monitoring.

Principle 13.05 – Management processes the obtained data into quality information that supports the internal control system. Quality information is appropriate, current, complete, accurate, accessible, and provided in a timely manner for management to use in decision making.

Principle 14 – Communicate Internally

Principle 14.01 – Management should internally communicate the necessary quality information to achieve the entity's objectives.

Principle 14.02 – Management communicates quality information throughout the entity using established reporting lines.

Principle 14.03 – Management communicates quality information down and across reporting lines to enable personnel to perform key roles in achieving objectives, addressing risks, and supporting the internal control system.

Principle 14.07 – Management selects appropriate methods to communicate internally.

Principle 15 – Communicate Externally

Principle 15.01 – Management should externally communicate the necessary quality information to achieve the entity's objective.

Principle 15.02 – Management communicates with, and obtains quality information from, external parties using established reporting lines. Open two-way external reporting lines allow for this communication.

Principle 15.09 – Government entities not only report to the head of the government, legislators, and regulators but also to the general public as well.

APPENDIX C: SUMMARY OF HHS STRATEGIC PLAN FOR FISCAL YEARS 2010 THROUGH 2015

Strategic Goal 1 **Strengthen Healthcare**
Objective A: Make coverage more secure for those who have insurance, and extend affordable coverage to the uninsured.
Objective B: Improve healthcare quality and patient safety.
Objective C: Emphasize primary and preventive care linked with community prevention services.
Objective D: Reduce the growth of healthcare cost while promoting high-value, effective care.
Objective E: Ensure access to quality, culturally competent care for vulnerable populations.
Objective F: Promote the adoption and meaningful use of health information technology.
Strategic Goal 2 **Advance Scientific Knowledge and Innovation**
Objective A: Accelerate the process of scientific discovery to improve patient care.
Objective B: Foster innovation at HHS to create shared solutions.
Objective C: Invest in the regulatory sciences to improve food and medical product safety.
Objective D: Increase our understanding of what works in public health and human service practice.
Strategic Goal 3 **Advance the Health, Safety, and Well-Being of the American People**
Objective A: Promote the safety, well-being, resilience, and healthy development of children and youth.
Objective B: Promote economic and social well-being for individuals, families, and communities.
Objective C: Improve the accessibility and quality of supportive services for people with disabilities and older adults.
Objective D: Promote prevention and wellness.
Objective E: Reduce the occurrence of infectious diseases.
Objective F: Protect Americans' health and safety during emergencies, and foster resilience in response to emergencies.
Strategic Goal 4 **Increase Efficiency, Transparency, and Accountability of HHS Programs**
Objective A: Ensure program integrity and responsible stewardship of resources.
Objective B: Fight fraud and work to eliminate improper payments.
Objective C: Use HHS data to improve the health and well-being of the American people.
Objective D: Improve HHS environmental, energy, and economic performance to promote sustainability.
Strategic Goal 5 **Strengthen the Nation's Health and Human Service Infrastructure**
Objective A: Invest in the HHS workforce to meet America's health and human service needs today and tomorrow.
Objective B: Ensure that the Nation's healthcare workforce can meet increased demands.
Objective C: Enhance the ability of the public health workforce to improve public health at home and abroad.
Objective D: Strengthen the Nation's human service workforce.
Objective E: Improve national, state, local, and tribal surveillance and epidemiology capacity.

APPENDIX D: SUMMARY OF HHS STRATEGIC PLAN FOR FISCAL YEARS 2014 THROUGH 2018

Strategic Goal 1 **Strengthen Healthcare**
Objective A: Make coverage more secure for those who have insurance, and extend affordable coverage to the uninsured.
Objective B: Improve healthcare quality and patient safety.
Objective C: Emphasize primary and preventive care, linked with community prevention services.
Objective D: Reduce the growth of healthcare cost while promoting high-value, effective care.
Objective E: Ensure access to quality, culturally competent care, including long-term services, for vulnerable populations.
Objective F: Improve healthcare and population health through meaningful use of health information technology.
Strategic Goal 2 **Advance Scientific Knowledge and Innovation**
Objective A: Accelerate the process of scientific discovery to improve patient care.
Objective B: Foster and apply innovative solutions to health, public health, and human services challenges.
Objective C: Advance the regulatory sciences to enhance food safety, improve medical product development, and support tobacco regulation.
Objective D: Increase our understanding of what works in public health and human service practice.
Objective E: Improve laboratory, surveillance, and epidemiology capacity.
Strategic Goal 3 **Advance the Health, Safety, and Well-Being of the American People**
Objective A: Promote the safety, well-being, resilience, and healthy development of children and youth.
Objective B: Promote economic and social well-being for individuals, families, and communities.
Objective C: Improve the accessibility and quality of supportive services for people with disabilities and older adults.
Objective D: Promote prevention and wellness across the life span.
Objective E: Reduce the occurrence of infectious diseases.
Objective F: Protect Americans' health and safety during emergencies, and foster resilience in response to emergencies.
Strategic Goal 4 **Ensure Efficiency, Transparency, Accountability, and Effectiveness of HHS Programs**
Objective A: Strengthen program integrity and responsible stewardship by reducing improper payments; fighting fraud; and integrating financial, performance, and risk management.
Objective B: Enhance access to and use of data to improve HHS programs and to support improvements in the health and well-being of the American people.
Objective C: Invest in the HHS workforce to help meet America's health and human services needs.
Objective D: Improve HHS environmental, energy, and economic performance to promote sustainability.

APPENDIX E: SUMMARY OF HHS COMPONENT STRATEGIC PLANS

The mission of HHS is to enhance the health and well-being of Americans by providing for effective health services and by fostering sound, sustained advances in the sciences underlying medicine, public health, and social services.

THE OFFICE OF THE ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE

ASPR is legally defined within the *Pandemic and All-Hazards Preparedness Reauthorization Act of 2013* (PAHPRA) as the lead coordinating body in HHS for public health emergencies.

ASPR's strategic plan focused on its responsibility for providing integrated policy coordination and strategic direction for all matters related to public health, medical preparedness, and deployment of the Federal response for public health emergencies and incidents. Although the strategic plan was primarily focused on domestic matters, the fourth goal of the plan was geared toward leading, coordinating, and developing forward thinking policies that support national and international public health and medical preparedness, response, and recovery capabilities. Specifically, ASPR's policy and planning responsibilities included promoting preparedness, response, and recovery policy development and analysis across ASPR and HHS, nationally and internationally.

BARDA is a core component of ASPR and contributes to the broader ASPR mission. Specifically, BARDA supports the transition of medical countermeasures such as vaccines, drugs, and diagnostics from research through advanced development toward consideration for approval by the FDA and inclusion into the Strategic National Stockpile.

THE CENTERS FOR DISEASE CONTROL AND PREVENTION

CDC's mission is to protect the Nation from health, safety, and security threats, both foreign and in the U.S. CDC is responsible for controlling the introduction and spread of infectious diseases and provides consultation and assistance to other nations and international agencies in disease prevention and control, improving environmental health, and health promotion activities.

CDC did not have a strategic plan in place before or during the Ebola crisis. The current plan (covering 2016–2020), however, addresses the need to improve health security at home and around the world. During the Ebola crisis, CDC prepared IPRs that included the mission statement to coordinate with the U.S. Government; Health Ministries of the affected countries; WHO; Médecins Sans Frontières; and other domestic, regional, and international partners to provide epidemiologic health communications and laboratory, infection control, and Emergency Management support to interrupt and mitigate Ebola virus transmission.

THE FOOD AND DRUG ADMINISTRATION

FDA is charged with protecting the public health by ensuring the safety, effectiveness, and security of human and veterinary drugs, biological products, and medical devices. FDA aims to provide effective and innovative leadership—domestically and internationally—to protect health, prevent illness, prolong life, and promote wellness. FDA's strategic plan pledges that it will continue to promote the adoption of safety and quality policies, practices, and standards, both domestically and internationally, and to reduce risks in the manufacturing, production, and distribution of FDA-regulated products.

NATIONAL INSTITUTES OF HEALTH

The NIH mission is to seek fundamental knowledge about the nature and behavior of living systems and to apply that knowledge to enhance health, lengthen life, and reduce illness and disability. Although NIH did not provide a copy of its strategic plan that was in place during the Ebola crisis, its current plan focuses on enhancing biomedical research to improve the health of people throughout the Nation and the world.

PUBLIC HEALTH SERVICE COMMISSIONED CORPS

The mission of the Commissioned Corps is to protect, promote, and advance the health and safety of our Nation. Composed of uniformed service men and women, the Commissioned Corps is a team of more than 6,000 public health professionals who serve within various U.S. Government agencies as both public health officials and clinical specialists. Headed by the Surgeon General and Assistant Secretary of Health, the Commissioned Corps roster of administrators, clinicians, and support staff provides rapid response to public health needs. The Commissioned Corp falls under HHS's strategic plan. Commissioned Corps officers are currently involved in healthcare delivery to underserved and vulnerable populations, disease control and prevention, biomedical research, food and drug regulation, mental health and drug abuse services, and response efforts for natural and man-made disasters as an essential component of the largest public health program in the world.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of t he Secretary

DATE: June 21, 2019

TO: Office of Inspector General, Department of Health and Human Services

FROM: Assistant Secretary for Preparedness and Response (ASPR)
Director, Centers for Disease Control and Prevention (CDC)

SUBJECT: OIG Draft Report: *HHS Did Not Always Efficiently Plan and Coordinate Its International Ebola Response Efforts (A-04-16-03567)* – **INFORMATION**

The Department of Health and Human Services' (HHS) Office of the Assistant Secretary for Preparedness and Response (ASPR), Centers for Disease Control and Prevention (CDC), National Institutes of Health (NIH), and the U.S. Food and Drug Administration (FDA) appreciate the opportunity to review and comment on this draft report. ASPR, CDC, NIH, and FDA all worked together to respond at the President's request to the International Ebola Epidemic. All four agencies worked together to support a successful, novel international response in which an Ebola outbreak in the U.S. was avoided. The Office of Inspector General's (OIG) recommendations and the Departments responses are discussed below.

OIG Recommendation 1:
HHS should develop department-wide objectives and a strategic framework for responding to international public health emergencies.

HHS Response 1:
Concur. The objectives and framework will be built around each OPDIV and STAFFDIV capabilities and roles in an international response. This helps ensure a unified preparedness posture across HHS, both organizationally and individually.

OIG Recommendation 2:
HHS should develop policies and procedures, along the lines of the NRF [National Response Framework], for responding to international responses.

HHS Response 2:
Concur. As Emergency Support Function #8 (ESF-8) lead, HHS is very familiar with the domestic response aspects covered under the NRF, and will work across the agency to establish a similar framework for international responses. It will be critical to work with Department of State in their role as the lead for international activities.

OIG Recommendation 3:
Develop large-scale international response plans.

HHS Response 3:
Concur. The outcome of this planning will be a high-level framework rather than a detailed plan because of wide variation in possible circumstances. HHS will focus efforts on the most likely public health threats. In addition to threat specific planning, an international response plan will address difficult issues common across threats such as surge staffing capacity for extended deployments and language needs for those deployers. HHS must work in concert with Department of State and Department of Defense to coordinate planning of this magnitude.

OIG Recommendation 4:
Develop various means, including IPR, of obtaining and using quality data needed for effective decision making during a public health crisis

HHS Response 4:
Concur. HHS has a variety of data systems and information management tools available, and will continue to improve the integration of data from other jurisdictions (countries) during an emergency for effective public health decision-making. While IPRs are an important tool to assess and evaluate the agency's response efforts during a response, they are not a tool for obtaining and using data for decision-making. Some responses are too short to allow an interim progress review to yield meaningful impact. For longer responses, an IPR (or other means) may be helpful as long as data analysis is done on a regular basis for real-time decision-making. Many of the key data elements are scientific in nature and need to be assessed in scientific meetings/settings.

OIG Recommendation 5:
Work with other U.S. Government agencies to develop a flexible framework focusing on each agency's mission and define each agency's roles and responsibilities for responding to a multi-agency international public health emergency.

HHS Response 5:
Concur. HHS will develop the public health component of this ERF-like structure and work across the USG – particularly Department of State – to integrate it into existing response plans and determine the appropriate leadership and chain of command structures.

Robert Kadlec, MD, MTM&H, MS
Assistant Secretary, HHS

Robert R. Redfield, MD
Director, CDC

Attachments:

Tab A – HHS Technical Comments to *"HHS Did Not Always Efficiently Plan and Coordinate Its International Ebola Response Efforts" (A-04-16-03567)*