# Report of the Independent Panel on the U.S. Department of Health and Human Services (HHS) Ebola Response



June 2016

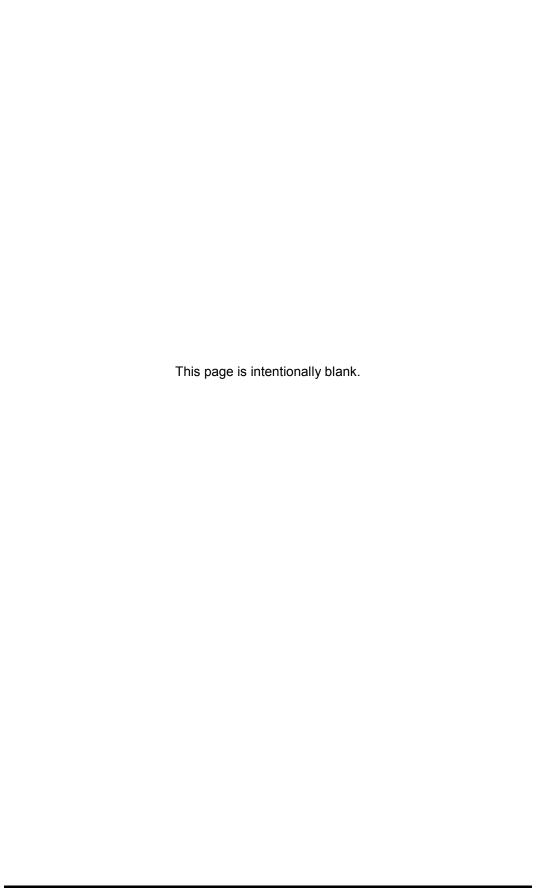
### **Foreword**

The Independent Panel on the U.S. Department of Health and Human Services (HHS) Ebola Response is pleased to provide this report. First, we want to commend HHS for its extraordinary domestic and international response to the largest and most complex Ebola epidemic on record. The performance of thousands of HHS staff members was a testament to the public service ethos of the Department.

Our investigation included research into public and internal documents, interviews with hundreds of individuals inside and outside of government, careful deliberations, and extensive review of our findings and recommendations with government officials and other stakeholders. We found notable opportunities for improvement in leadership and organization, communication, management, and logistics, as well as in development and use of vaccines and treatments. Our report makes recommendations to address each of these areas.

On behalf of the Panel, I want to thank you for your interest in this work. We strongly believe that the actions we recommend will enable HHS to respond even more capably in future outbreaks.

Jonathan Fielding
Chair, Independent Panel on the HHS Ebola Response



### **Executive Summary**

To capture critical lessons from the Ebola epidemic of 2014–2016, the U.S. Department of Health and Human Services (HHS) asked CNA to convene an independent panel of public health, healthcare, emergency response, and communication experts to review the Department's international and domestic responses. This report summarizes the Independent Panel's assessment of HHS's challenges—and, where appropriate, challenges facing the broader U.S. government—and presents recommendations for addressing future urgent public health threats.

The Ebola epidemic that began in West Africa was a seminal event for the global public health response community. The epidemic crystalized the importance of national disease surveillance capacities and timely multilateral coordination. The World Health Organization (WHO) and others acknowledge that investments must be made in the ability of countries to detect, report, and respond to urgent public health threats, and that reforms are needed to strengthen WHO's role as the worldwide protector of health [1-2].

As part of this global community, HHS made significant contributions to controlling the epidemic abroad and safeguarding the United States from the risk of Ebola. Through its efforts, many lessons emerged. The most salient lessons related to internal government coordination, collaboration with international partners, 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.

Lessons from HHS's response to the Ebola epidemic are relevant to current and future outbreaks of infectious diseases, including the current outbreak of the Zika virus. The Independent Panel hopes that the Department will carefully consider the findings and recommendations presented in this report and—if they have not done so already—implement the necessary changes in policy, programs, and plans. By taking action to address issues that emerged during the Ebola response, HHS will help ensure that it and its health response partners around the world are best positioned to address future contagions.

The Independent Panel's findings and key recommendations are summarized below.

#### Findings of the Independent Panel

- 1. The lack of strong leadership and response coordination from WHO hindered HHS and international response efforts.
- 2. The U.S. government was not well prepared to respond to emergent crises that require a rapid, integrated domestic and international response.
- 3. The U.S. government did not use all coordination elements of the *National Response Framework* during the Ebola response.
- 4. HHS did not apply existing pandemic plans and coordination mechanisms during the Ebola response.
- HHS's early communications did not demonstrate an appreciation of the public's perceptions and fear, or discuss the possibility of isolated U.S. Ebola cases.
- In the initial months of the crisis, the U.S. government was not prepared to deploy response personnel at the scale or rate required for the Ebola epidemic.
- Differing perspectives on the most appropriate ways to use and evaluate investigational vaccines and treatments contributed to incomplete evaluation of the efficacy of these products.
- 8. The U.S. government did not anticipate the complications associated with establishing domestic Ebola Treatment Centers and other domestic preparedness measures.
- 9. Screening passengers at selected U.S. airports enabled local authorities to identify and monitor individuals who might have been exposed to Ebola.
- 10. The Public Health Emergency Medical Countermeasures Enterprise collaborated to expedite research, development, manufacturing, and provision of Ebola vaccines and treatments.
- 11. HHS initially had difficulty developing credible guidance for, and ensuring an adequate supply of, personal protective equipment for healthcare workers.
- 12. Federal, state, and local governments applied different—and, at times, conflicting—policies and authorities for specific response measures, such as waste management and quarantine.
- 13. HHS is not configured or funded to respond to a prolonged public health or medical emergency overseas or at home.

#### **Key Recommendations**

HHS should continue to help strengthen the public health and medical care infrastructure and response capabilities of other countries. HHS should pursue the activities of—and commit funding to—the Global Health Security Agenda to help countries implement the 2005 International Health Regulations. HHS can further enhance global health security by partnering with nongovernmental organizations that operate in developing countries, in order to strengthen their ability to identify, report, and respond to urgent public health threats.

HHS should coordinate with the National Security Council and federal partners to develop and finalize a U.S. government framework for multi-agency response to international incidents. The framework should define a government-wide coordination structure for international response, including HHS's role within this structure. It should also identify lead/coordination and support responsibilities for U.S. government agencies in different scenarios, including those dealing with serious infectious diseases. HHS should further coordinate with the National Security Council and federal partners to more clearly define roles for HHS in the management of responses with simultaneous domestic and international components. HHS should consider dividing management of the response into definable parts, with leads for each part reporting to an overall response coordinator.

HHS should coordinate with the National Security Council and federal partners to determine how best to use the *National Response Framework* to respond to urgent public health threats. Plans for responding to urgent public health events that are not declared emergencies under the *Robert T. Stafford Disaster Relief and Emergency Assistance Act (Stafford Act)* should clarify the roles and responsibilities of HHS and other U.S. government agencies and articulate possible funding sources.

HHS should determine whether it will maintain readily deployable medical personnel to treat patients in other countries that request such assistance during urgent public health threats. If the Department pursues this option, it should assess the roles and missions of its mobile forces, including the U.S. Public Health Service Commissioned Corps and the National Disaster Medical System, to determine which personnel should be called to deploy. HHS should work administratively—and with Congress, if needed—to remove remaining barriers to the deployment of HHS responders to other countries. This includes ensuring that pre-identified personnel are trained and equipped to deploy internationally.

HHS should clarify its strategy for communicating risk-related information to the public, to Congress, and to other key stakeholders during responses to urgent public health threats. HHS should develop a public communication framework that conveys the critical concepts of public health response and fully integrates crisis and emergency risk-communication principles. HHS should also encourage and support state

and local public health departments that want to build their capacity to communicate risk-related information in a crisis or an emergency.

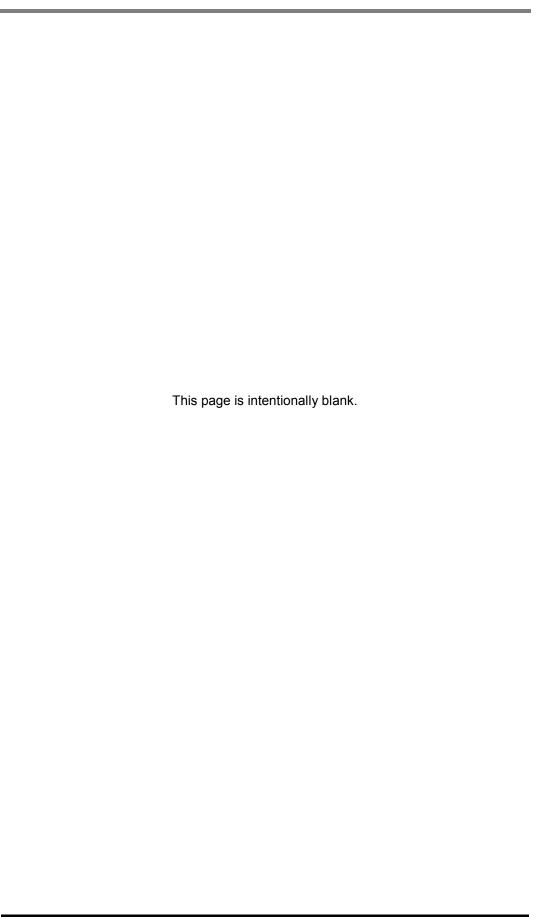
The U.S. government should provide sustained funding to HHS for emergency preparedness and response activities, and contribute to the readiness of its public health partners at the state and local levels. HHS should work with Congress to secure a contingency fund to allow the Department, as well as state and local public health agencies, to initiate and sustain preparedness and response activities.

HHS should designate responsibility for coordinating Department-wide response efforts to urgent public health threats that have both domestic and international components. These assignments should be consistent with the *Pandemic and All-Hazards Preparedness Act*. A career member of the Senior Executive Service who has institutional knowledge of HHS's response capabilities and coordination mechanisms should support the designated lead(s). HHS should institutionalize a response structure that enables the Department to integrate public health and medical services, in accordance with incident command system principles.

HHS should designate a lead entity to arbitrate the differing perspectives on research and development of vaccines and treatments during an outbreak. The National Institutes of Health, the U.S. Food and Drug Administration, the U.S. Centers for Disease Control and Prevention, and the Biomedical Advanced Research and Development Authority (BARDA) all have specific roles—and perhaps differing perspectives—with regard to research, development, and distribution of vaccines and treatments. Using a pre-established and rapid decision-making process, the designated HHS lead should arbitrate these perspectives if the differences risk causing delays or overlaps when responding to an urgent public health threat.

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# Independent Panel on the HHS Ebola Response: Lessons-Learned Review

An independent panel of volunteer subject-matter experts led a review of HHS's response to the 2014–2016 Ebola epidemic to identify lessons learned. The Panel included the following experts:

- Dr. Jonathan Fielding (Panel Chair), Distinguished Professor of Health Policy and Management, and Pediatrics in the University of California, Los Angeles, Fielding School of Public Health and Geffen School of Medicine; former Director of the Los Angeles County Department of Public Health; former Commissioner of the Massachusetts Department of Public Health
- Admiral Thad Allen, U.S. Coast Guard (Ret.); former Commandant of the U.S. Coast Guard; former National Incident Commander for the unified response to the Deepwater Horizon oil spill; former Principal Federal Official for the U.S. government's response and recovery operations following Hurricanes Katrina and Rita throughout the Gulf Coast region
- **Dr. Benjamin Chu**, President of the Southern California Region, Kaiser Foundation Health Plan, Inc. and Hospitals; former President of New York City Health and Hospitals Corporation; former chair of the American Hospital Association Board of Trustees
- Ms. Julia Galdo, Managing Director, Health Communication and Social Marketing, American Institutes for Research; co-author of the Centers for Disease Control and Prevention's (CDC's) Crisis and Emergency Risk Communication
- Dr. Helene Gayle, Chief Executive Officer of the McKinsey Social Initiative; former President and Chief Executive Officer of CARE; former Director of the National Center for HIV, STD, and TB Prevention at CDC and Assistant Surgeon General of the U.S. Public Health Service (USPHS)

### Approach and methodology

The Independent Panel's review included the following activities to gather and assess HHS policies, key decisions, and actions during the 2014–2016 Ebola epidemic:

- Review of documentation prepared by HHS during the Ebola response, including situation reports, leadership briefs, and press releases. (See Appendix A for an overview of HHS activities during the Ebola response.)
- Surveys of HHS staff involved in the Ebola response.

- Interviews with more than 200 individuals involved in the response. (See Appendix B for a list of the organizations interviewed.)
- Reconstruction of a timeline outlining key activities and milestones during the HHS Ebola response. (See Appendix C for the pictorial timeline.)
- Review of after-action reports from the Ebola response that were provided by HHS or by other government agencies or organizations.
- Review of open-source literature regarding the global Ebola response.
- Careful deliberation.

A contractor (CNA) and an HHS Program Manager in the Office of the Assistant Secretary for Preparedness Response (ASPR) supported the Independent Panel's work.

The Independent Panel engaged major HHS components and partners—both inside and outside of the federal government—to identify and investigate issues from the HHS Ebola response. HHS senior leadership and the HHS Ebola Lessons Learned Steering Committee reviewed several drafts of this report and provided comments. However, this report from the Independent Panel was not subject to HHS approval.

#### Commendations for HHS

As the lead U.S. government health agency, HHS has a responsibility to prevent and respond to adverse health events that affect or could affect Americans—even when doing so involves supporting the public health response in other countries. During the 2014–2016 Ebola epidemic, HHS responded both globally and domestically, mobilized more than 4,000 personnel [3], played a central role in controlling the epidemic in West Africa, and worked to ensure that the United States remained as safe as possible from Ebola.

The Independent Panel acknowledges the expertise and contributions of the thousands of HHS staff members—including individual responders; those serving on task forces and other response groups; commanders; and operations center personnel—who collectively contributed to the success of HHS's response. Their bravery, sacrifices, and personal commitment to public health service were truly exceptional.

The large deployment also put additional strain on many HHS personnel who were not deployed. While not covered in this report, the Panel acknowledges the importance of minimizing the stress and preventing burn-out of these non-deployed personnel, who deserve credit for maintaining essential core HHS functions during the Ebola response.

<sup>&</sup>lt;sup>1</sup> The Independent Panel interviewed Ebola responders from many HHS components between June and November 2015, and had follow-up conversations through February 2016. They also interviewed individuals from other federal agencies, and from organizations outside of the U.S. government, to discuss their coordination with HHS. Accordingly, this report focuses on HHS's response efforts and its coordination with other agencies and organizations.

### **Findings**

The Independent Panel produced this report to summarize HHS's involvement in combatting both the international Ebola epidemic and domestic cases of the disease, and to present recommendations for addressing future urgent public health threats that may arise from Ebola or other causes. The Independent Panel focused on strategic, policy-level, and major operational issues from the HHS Ebola response, and identified 13 key findings in its review (described below). While the Independent Panel interviewed Ebola responders from across the U.S. government and from other organizations, this report focuses on the Panel's assessment of HHS's challenges.

Finding #1: The lack of strong leadership and response coordination from the World Health Organization (WHO) hindered HHS and international response efforts.

In March 2014, within days of reports of Ebola cases in Guinea, CDC deployed personnel to investigate [3]. Reportedly, the WHO Africa Regional and Country Offices discouraged CDC from establishing a larger presence in the region during the early stage of the epidemic [4].

Later, the disease spread rapidly, fueled by the mobility of the affected populations, the proximity of more densely populated urban areas, and the region's poor public health and medical infrastructure. The affected countries lacked the adequate epidemiological surveillance, laboratory, and investigative capabilities to track and report cases. They also had disincentives to report cases quickly, because news of possible Ebola cases could prompt other countries to impose travel restrictions [1].

Even though the epidemic continued to expand, WHO did not issue a Public Health Emergency of International Concern until August 8, 2014, after the virus had claimed more than 900 lives and spread to Liberia, Sierra Leone, and Nigeria [5]. Leaders from CDC and the U.S. Agency for International Development (USAID) traveled to West Africa in late August 2014, to get firsthand knowledge of the situation. Based on these assessments, they argued for mobilizing a stronger U.S. government response to the Ebola epidemic.

WHO's reluctance to challenge the affected countries' positions on the severity of the situation and to declare the epidemic an emergency, alongside its difficulties with coordinating responding agencies, delayed and hampered both HHS's and the international community's efforts to contain the spread of the disease [6].

### Finding #2: The U.S. government was not well prepared to respond to emergent crises that require a rapid integrated domestic and international response.

The National Security Council initially deferred to USAID and HHS for coordination of the Ebola response. In May 2014, the White House asked the HHS Office of Global Affairs to coordinate the U.S. government response to the Ebola epidemic in West Africa. In August, as the epidemic worsened, the USAID's Office of U.S. Foreign Disaster Assistance (OFDA) served as the lead operational platform for the U.S. government response in West Africa. CDC was designated as the OFDA Disaster Assistance Response Team lead for all technical, public health, and healthcare issues. Reportedly, this arrangement between CDC and OFDA worked well [7].

However, the OFDA Disaster Assistance Response Team did not include the U.S. government research activities being conducted in West Africa under their operational umbrella. This left the National Institutes of Health—the HHS component leading research on investigational Ebola vaccines and treatments—unable to leverage other U.S. government assets that were deployed [8]. Overall, there is no clear policy on how HHS should coordinate with USAID to provide leadership on public health, medical issues, and clinical research during an international response.

As Ebola cases arose in the United States, there was no clear guidance for simultaneously coordinating the overall U.S. government efforts for both the international and the domestic responses. For example, USAID had the lead for communications regarding U.S. response operations in West Africa, while the U.S. Department of State had the lead for communications regarding medical evacuation of U.S. citizens. HHS (including CDC) and the National Security Council handled communications about domestic Ebola cases.

The National Security Council's initial reliance on USAID and HHS for overall coordination of the U.S. government response ultimately created challenges for unity of effort among U.S. federal agencies. In October 2014, in order to integrate and synchronize the U.S. government's international and domestic response efforts, the White House appointed an overall Ebola Response Coordinator. This appointment ensured that HHS's—and other agencies'—efforts were coordinated with those of the rest of the U.S. government, and enabled the White House to maintain policy leadership on important developments.

# Finding #3: The U.S. government did not use all coordination elements of the *National Response Framework* during the Ebola response.

The National Response Framework describes the principles, roles, responsibilities, and coordinating structures for delivering the core capabilities required to respond to a disaster or emergency. The framework is always in effect, and elements can be implemented at any time, whether an event is declared an emergency under the Robert T. Stafford Disaster Relief and Emergency Assistance Act (Stafford Act) or by another authority. Although the National Response Framework applies to urgent public health

threats, the U.S. government has never fully implemented the framework to respond to a public health event resulting from an infectious disease.

Lack of experience using the *National Response Framework* for response to public health events, along with the absence of a formal declaration of emergency for Ebola in the United States, may account for the failure to fully implement the coordination structures described in the *National Response Framework*. For example, the U.S. government did not fully activate Emergency Support Function #8, the *Public Health and Medical Services Annex* to the *National Response Framework*, to coordinate federal government assistance to local, state, territorial, and tribal areas in response to Ebola [9]. This hampered HHS's and the U.S. government's ability to lead federal response efforts.

# Finding #4: HHS did not apply existing pandemic plans and coordination mechanisms during the Ebola response.

When the Ebola cases emerged in West Africa, CDC deployed staff to the affected countries and became the de facto response lead within HHS. As the situation in West Africa worsened, other HHS components (such as Staff Divisions at HHS Headquarters) played larger roles and took on unexpected responsibilities. For example, the HHS Office of Global Affairs was asked by the White House to be the U.S.-based coordinator for the U.S. government's response efforts in West Africa [10], and it had this role from March through August 2014. When the Ebola response escalated to a combined domestic and international event, more HHS components assumed key roles.

HHS is the Lead Federal Agency for coordinating the U.S. government's public health and medical response for emergencies and incidents covered under the *National Response Framework* and *Public Health Service Act* authorities, including infectious disease outbreaks [11]. However, HHS did not make full use of *the U.S. Government Ebola Virus Disease Plan* [11]<sup>2</sup> or applicable parts of the *Interagency Pandemic Operations Plan* [12]<sup>3</sup> during the Ebola response. Furthermore, although HHS ASPR has legislative authority to coordinate domestic incidents on behalf of HHS, HHS did not fully utilize the assets of that office; nor did it clearly designate another HHS office or agency to fulfill that overall coordination role [13].

Instead, the high-profile and large-scale effort of the Ebola response, which involved many parts of HHS and other U.S government agencies, led HHS Headquarters to centralize responsibility within the Immediate Office of the Secretary. The Secretary had daily meetings with senior leaders from across the Department and coordinated directly with leadership from other U.S. government agencies, such as USAID.

Meanwhile, HHS components tried to maintain the relationships established in their response plans, but the new, centralized coordination within HHS Headquarters did not

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<sup>&</sup>lt;sup>2</sup> The *U.S. Government Ebola Virus Disease Plan* was developed during the 2014–2016 Ebola response. It was not finalized when the first Ebola cases in the United States occurred.

<sup>&</sup>lt;sup>3</sup> The Interagency Pandemic Operations Plan was finalized in 2013.

consistently recognize those relationships. Because some HHS components followed their existing response plans and others did not, response partners had to coordinate with multiple HHS offices. This hampered HHS's coordination among different levels of the Department and, in turn, affected coordination for the public health and medical response between HHS and its interagency partners.

# Finding #5: HHS's early communications did not demonstrate an appreciation of the public's perceptions and fear, or discuss the possibility of isolated U.S. Ebola cases.

HHS staff worked diligently to deal with complex communication challenges during the Ebola response, such as the constant need to communicate new information in a rapidly changing environment. HHS needed to reach a wide range of domestic and international audiences—both those who were affected by Ebola and those who were not—and had to do so via traditional and new media channels. HHS did not use a Department-wide risk-communication strategy to coordinate messaging [6].

Early public messages from CDC expressed the need for a stronger U.S. government response in West Africa and, at the same time, confidence that Ebola cases were unlikely to spread widely in the United States. Early public statements from CDC indicated that any "advanced hospital" (i.e., a hospital with an intensive care unit) could safely care for Ebola patients in the United States [14]. After Ebola was transmitted at a hospital in Dallas, TX, many Americans questioned the readiness of the U.S. healthcare system—and HHS's capabilities—to manage the disease. Unlike during the H1N1 influenza outbreak, HHS did not always use crisis and emergency risk-communication principles to emphasize what was unknown or to acknowledge the public's fear.

Because state and local governments hold much of the responsibility for the nation's public health, elected officials at all levels of government spoke publicly about the Ebola response. Some state officials implemented (and made related statements about) their quarantine procedures that did not align with CDC's public health guidelines [15]. Thus, HHS faced the challenge of communicating with an anxious public who was hearing sometimes inconsistent messages from different jurisdictions and levels of government.

In addition, messages were often edited for brevity and clarity during the intergovernmental clearance process. However, this process was time-consuming and made it difficult to effect rapid changes to the messages as new events unfolded [6]. As a result, the messages were, at times, more reassuring than the situation warranted and did not fully address media inquiries and public concerns as the situation continued to develop. This contributed to an environment in which much of the public, as well as many state and local government officials, questioned the readiness of U.S. hospitals and the credibility of HHS information.

Finding #6: In the initial months of the crisis, the U.S. government was not prepared to deploy response personnel at the scale or rate required for the Ebola epidemic.

The Ebola epidemic in West Africa demonstrated that protecting the health and wellbeing of Americans at home may require the U.S. government to provide healthcare, public health, social, and technical services in other countries. Despite the unprecedented scale of deployment by CDC and the USPHS Commissioned Corps, HHS was not prepared to meet the high demand for public health support and clinical care.

HHS does not typically provide direct clinical care on a large scale internationally, because such care is usually available through contracts with nongovernmental organizations (NGOs). However, due to the large scale of the Ebola epidemic, NGOs such as Médecins Sans Frontières (Doctors Without Borders) could not meet the demand for qualified medical staff and called for additional resources [16]. Although HHS capabilities for providing clinical care in a domestic emergency exist in the USPHS Commissioned Corps and the National Disaster Medical System, only a limited number of response teams are trained and equipped for international deployments, and there were other statutory limitations to deploying the National Disaster Medical System. In addition, these teams, as currently structured, have short-duration deployment timelines that are inadequate for prolonged infectious disease responses.

Additional HHS staffing and deployment challenges during the Ebola response included the following:

- Nearly 4,000 retired officers in the USPHS Reserve Corps were unavailable to provide surge capacity during the Ebola response, based on an earlier HHS interpretation of authorities in the Affordable Care Act [17].
- Some agencies within HHS would not release their active-duty USPHS
  Commissioned Corps personnel to volunteer for deployment to West
  Africa because they felt it would be too difficult to continue the agencies'
  work without these staff members [17]. This highlighted the balancing act
  within some HHS agencies, as they had to meet the mandates of the
  agency while also allowing for active-duty USPHS Commissioned Corps
  personnel to be available for deployment.
- The USPHS Commissioned Corps has no fiscal appropriations to train and prepare its officers for deployment. For the Ebola response, officers received just-in-time training that did not include instruction on all of the necessary equipment or procedures for working in the Monrovia Medical Unit [17].
- Host nation officials initially refused to recognize the U.S. health professional licenses of HHS clinicians deployed to staff the Monrovia Medical Unit [10, 17].
- HHS responders needed to complete "Preparing for Work Overseas" training offered by the U.S. Department of State before they could deploy

to West Africa for longer than 30 days [7]. This training course had limited availability, and could not accommodate the numbers of HHS personnel who needed to deploy quickly. As a result, in the initial phase of deployment, CDC personnel had 30-day limits on their deployments to West Africa (this limit was later waived) [7]. This increased the need for training and the rate of staff turnover in the affected countries.

 Confusion regarding the U.S. government's capacity and funding to provide nonfederal employees with medical evacuation assurances limited HHS's ability to recruit personnel from the private sector (such as universities) for deployment to West Africa.

Furthermore, HHS and other U.S. government agencies do not have sufficient staff or training to rapidly deploy a large number of individual responders with expertise in other disciplines, such as health communications experts, treatment unit managers, and social scientists. These subject-matter experts often have important roles in disease outbreak control.<sup>4</sup>

Finding #7: Differing perspectives on the most appropriate ways to use and evaluate investigational vaccines and treatments contributed to incomplete evaluation of the efficacy of these products.

The global community expressed varying perspectives on the most appropriate ways to test and distribute investigational vaccines and treatments for Ebola. Generally, the U.S. government supports evaluating investigational vaccines and medications in rigorously designed clinical trials to determine their safety and efficacy. In contrast, given the emergent nature of the Ebola epidemic, some international entities believed that the investigational vaccines and treatments should be used primarily for mass vaccination campaigns or to treat Ebola patients, despite the limited scientific evidence regarding potential risks and benefits.<sup>5</sup>

Despite HHS's successful collaboration with other federal agencies and private-sector partners to expedite research, development, and manufacturing, the Department was unable to forge consensus among its own components regarding the optimal clinical trial designs for investigational vaccines or treatments. The inability to do so was the result of

<sup>&</sup>lt;sup>4</sup> For example, social scientists are vital to helping responders understand cultural characteristics of the impacted community and to facilitating effective implementation of response activities.

<sup>&</sup>lt;sup>5</sup> Before clinical trials were established, HHS supported compassionate use of investigational treatments for Ebola patients through approval of Emergency Investigational New Drug (EIND) applications via the U.S. Food and Drug Administration; in fact, these EIND applications were processed and approved in record time. Although there was some perception of unfair distribution of the investigational treatments, the U.S. Food and Drug Administration followed appropriate protocols for their distribution. Once clinical trials for the investigational treatments are established, HHS protocol requires that patients receive those treatments through enrollment in clinical trials rather than through EINDs, as little to no information about the investigational treatments can be learned through EINDs.

differing perspectives, largely reflective of each organization's primary responsibility (e.g., controlling the epidemic, or establishing the safety and efficacy of the products).

The differing perspectives among international partners and HHS components led to three vaccine trials with different designs and to many treatment trials. In addition, due to a decrease in the number of Ebola cases, these investigational vaccines and treatments could not be fully evaluated. Some of the clinical trials did not yield sufficient interpretable results, and data from the investigational Ebola vaccine trials have not been submitted to the U.S. Food and Drug Administration at the time of this writing.

# Finding #8: The U.S. government did not anticipate the complications associated with establishing domestic Ebola Treatment Centers and other domestic preparedness measures.

Concerns about contagion and costs associated with treatment of suspected or confirmed Ebola cases discouraged hospitals from volunteering to be Ebola Treatment Centers early in the domestic response. Although hospitals do have the duty to evaluate and treat all patients presenting to their Emergency Departments for treatment, some were concerned about the potential loss of revenue if prospective patients had concerns about receiving care in the same facility as Ebola patients. The hospitals would lose revenue if non-Ebola patients sought care in other healthcare facilities.

During the Ebola response, the HHS Hospital Preparedness Program—along with other HHS components—requested supplemental funding from Congress to address such potential shortfalls. However, by the time the supplemental funding was available to state and local public health agencies, the peak in the number of global Ebola cases and U.S. response activities had already passed.

Many state and local public health departments also felt that they were not adequately prepared to advise hospitals or conduct active surveillance if Ebola cases presented in their jurisdictions. Furthermore, nurses and other staff caring for patients expressed concerns about whether their healthcare facility was providing them with sufficient training and personal protective equipment (PPE) for treating Ebola patients [6].

# Finding #9: Screening passengers at selected U.S. airports enabled local authorities to identify and monitor individuals who might have been exposed to Ebola.

Enhanced entry screening at U.S. airports alleviated intense public and political pressure for stricter containment measures, such as travel bans and border closures. Enhanced entry screening provided a means to identify potential Ebola cases quickly, and allowed state and local governments to rapidly learn the Ebola risk profile of people in their

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<sup>&</sup>lt;sup>6</sup> HHS leads two of the three clinical trials for Ebola vaccines in West Africa: the Sierra Leone Trial to Introduce a Vaccine against Ebola ("STRIVE"), and the Partnership for Research on Ebola Vaccines in Liberia ("PREVAIL"). The third vaccine trial is led by WHO in Guinea.

jurisdictions. However, it was also a large resource burden (requiring both time and money) for the U.S. government and state and local health departments.

CDC and the CDC Foundation developed novel solutions for monitoring some travelers after their arrival in the United States. By providing free and dedicated cell phones to the travelers, public health officials could contact them quickly and consistently. In addition, some public health officials used video capabilities (such as Apple® FaceTime) to check in with individual travelers when visual contact was needed. These solutions were more cost-effective and efficient than repeatedly conducting in-person visits.

Active screening of these travelers at selected U.S. airports—and plans for their subsequent monitoring by state and local health departments, if appropriate—was an important strategic public health action, but also acknowledged and addressed public concerns about the spread of Ebola in the United States [6].

Finding #10: The Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) collaborated to expedite research, development, manufacturing, and provision of Ebola vaccines and treatments.

Early during the Ebola outbreak, the PHEMCE<sup>7</sup> leveraged assets across the U.S. government to accelerate development and appropriate use of investigational Ebola vaccines and treatments. It accomplished this by using both existing and new partnerships with government, academia, and industry stakeholders.

The PHEMCE partners also used novel contracting methods and moved funding quickly to support development and evaluation of candidate vaccines and treatments. HHS conducted vaccine trials in Liberia and Sierra Leone, and developed and implemented a novel clinical trial design in West Africa to test ZMapp (an experimental drug for Ebola treatment [18]) and other medications that may have applicability in future outbreaks.

While some trials are still ongoing, the current (and fortunate) lack of cases has created scientific challenges in assessing product efficacy.

Finding #11: HHS had difficulty developing credible guidance for, and ensuring an adequate supply of, personal protective equipment for healthcare workers.

Early in the response, individual healthcare centers independently stockpiled PPE regardless of their specific risk [19]. Although such stockpiling was not always appropriate, the impulse for centers to do so was understandable, especially since supply

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<sup>&</sup>lt;sup>7</sup> The ASPR-led PHEMCE coordinates U.S. government efforts to enhance medical countermeasure preparedness for chemical, biological, radiological, and nuclear (CBRN) threats and emerging infectious diseases (such as Ebola). The PHEMCE includes HHS internal agency partners and several interagency partners.

of PPE was not coordinated, and neither CDC nor any other authority provided guidance on how much PPE a facility should stockpile, based on the facility's level of risk.

The first incidence of Ebola transmission in the United States led CDC to recommend more stringent PPE guidelines. HHS adjusted its PPE guidance to reflect the more invasive and comprehensive treatment of Ebola patients in U.S. hospitals. This tacit acknowledgment that the original guidelines did not afford sufficient protection undermined CDC's credibility with its stakeholders [6]. This development, along with the absence of guidance for PPE stockpiling based on a facility's level of risk, contributed to nationwide shortages of some recommended PPE items, such as powered air purifying respirators [20-21].

PPE manufacturers maximized their production capacities using their existing resources and infrastructure. To increase production, they would have had to invest in new infrastructure. Reportedly, the manufacturers were reluctant to do so without a guarantee that there would be a future market for their products.

In addition, both the USPHS Commissioned Corps and NGOs cited difficulties finding standard PPE in West Africa, which hindered their training and treatment efforts and their compliance with CDC's guidance [6, 19].

Finding #12: Federal, state, and local governments applied different—and, at times, conflicting—policies and authorities for response measures, such as waste management and quarantine.

The application of federal, state, and local legal authorities differed throughout the domestic response. For example, nationally inconsistent transportation procedures and the public's fear hampered the movement of Ebola medical waste across state borders, as well as acceptance at final disposal sites [22].

U.S. Department of Transportation regulations classify Ebola waste as a Category A infectious agent, meaning that transporting Ebola waste requires more complicated packaging than regular medical waste [23]. Clarifying the packaging and transport requirements took time and created backlogs of Ebola waste. Furthermore, many wastemanagement contractors felt that they could not legally transport Ebola waste, which temporarily left hospitals without means of disposal [23].

The U.S. Department of Transportation eventually issued special permits for waste transportation, but several states remained reluctant to accept the waste. In some instances, state governments required that Ebola waste transported through their states be accompanied by armed escorts [23]. Nearly all states were also reluctant to accept Ebola waste for incineration. Throughout the response, there were only two sites (one in Florida, and one in Texas) that would accept Ebola waste [22]. As a result, Ebola waste from treatment of U.S. patients was transported across many states for incineration.

In addition, quarantine policies were inconsistent across levels of government and did not adequately address the complex and extensive requirements associated with implementation [24]. Several states (New York, New Jersey, and Maine) implemented quarantine policies that were more restrictive than the CDC's recommendations [6].

Differences in quarantine procedures also created confusion among the public and concerns that mandatory quarantine for returning healthcare workers would keep them from volunteering to help fight the outbreak overseas [25].

Another challenge was the logistics of providing assistance, such as food and social services, to isolated and quarantined individuals [26]. The Ebola response revealed quarantine and isolation issues that are often overlooked within the emergency management community, and thus often not included in training exercises.

The rapid evolution of national-level guidelines for Ebola response, as well as differences in guidelines and perspectives within state and local authorities, resulted in a lack of coordinated implementation and enforcement across levels of government, and confused responders' understanding of existing policies and authorities. Recommendations to address this need for policy coordination should acknowledge that states have primary responsibility for public health preparedness.

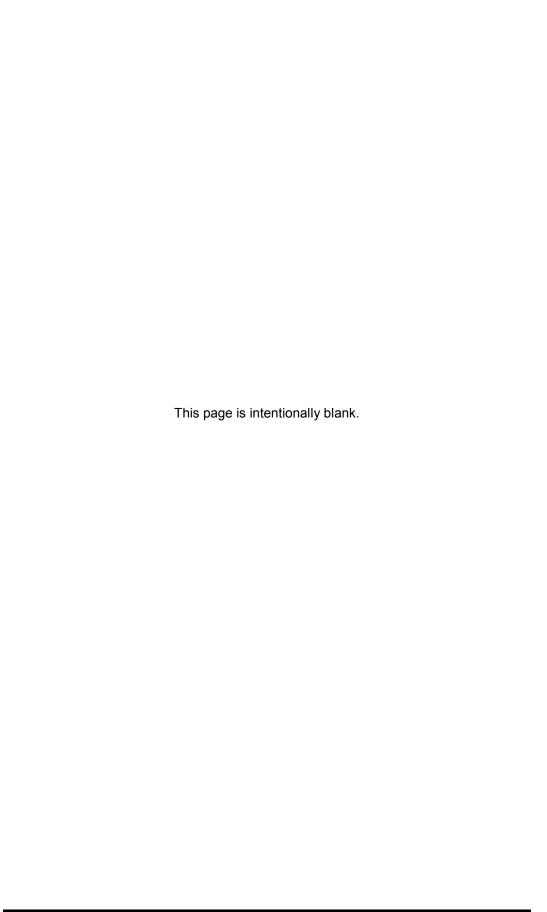
# Finding #13: HHS is not configured or funded to rapidly respond to a prolonged public health or medical emergency overseas or at home.

As the Ebola outbreak rapidly expanded, HHS slowly mounted a robust response. Because the outbreak was not declared an emergency under the *Stafford Act* and HHS does not have ready access to a response contingency fund, the Department had difficulty funding its initial efforts to contain the outbreak in West Africa. Congress did not grant supplemental appropriations to fund the international effort until the response was well underway. The U.S. Office of Personnel Management did not waive authority for direct hire, despite multiple requests from HHS and support from the White House [27-28]. Many aspects of the response were delayed by the lack of readily available, flexible, unobligated funds. Consequently, HHS relied on private organizations, such as the CDC Foundation, to fund critical response activities and supplies [29]. In turn, other private organizations and other nations provided donations to the CDC Foundation [30-31].

Within the United States, the HHS Hospital Preparedness Program and the Public Health Emergency Program provide grants to support state and local preparedness activities. This funding is obligated for preparedness projects and is not intended for response operations. State and local public health agencies must wait for additional emergency funding to cover their immediate response to an urgent public health threat. Also, significant declines in funding in recent years have made it difficult to sustain investments in preparedness—such as maintenance of PPE stockpiles and staff training—that state and local public health agencies made years ago. As a consequence, some state and local partners lacked the capabilities and capacities necessary to respond appropriately to Ebola.

Unfortunately, HHS does not have a reserve, emergency response fund as some other departments do. Delays in supplemental appropriations hampered HHS's ability to support state and local response efforts. In addition, congressional appropriations often included rules and conditions that limited what expenses could be reimbursed to private-sector medical services.

Overall, HHS lacks both a source and a flexible mechanism to distribute financial assistance rapidly to state, local, and private-sector entities responding to urgent public health threats. Finally, U.S. healthcare organizations had to make significant financial and other resource investments—without guarantee of reimbursement—to prepare for a confirmed or suspected Ebola patient.



### Recommendations

Based on the findings presented above, the Independent Panel developed recommendations to further enhance U.S. government coordination and HHS's public health preparedness and response capabilities. The recommendations aim to:

- Help strengthen public health and medical care capabilities through implementation of the Global Health Security Agenda.
- Improve coordination with U.S. government response partners.
- Improve collaboration with state, local, and private-sector partners.
- Improve internal coordination for preparedness and response.
- Ensure that the Department communicates effectively with the public.
- Ensure that the Department has sufficient and readily accessible resources.

The Panel further recommends that HHS develop an improvement plan for response to urgent public health threats.

Specific recommendations are provided below. The Panel recognizes that HHS has taken steps to address many issues that arose during the 2014–2016 Ebola response. As a result, some of the actions recommended below may have already been taken or be underway.

Addressing these findings and recommendations should be a near-term priority for HHS and its partners in order to improve their preparedness for, and response to, urgent public health threats. HHS should particularly work to address those findings and recommendations that emerged from other recent public health and medical responses—such as the H1N1 influenza outbreak or the earthquake in Haiti—but were not implemented prior to the Ebola epidemic.

Strengthen public health and medical care capabilities through implementation of the Global Health Security Agenda.

HHS should continue to help strengthen the public health and medical care infrastructure and response capabilities of other countries.

 HHS should pursue the activities of—and commit funding for—the Global Health Security Agenda to help countries implement the 2005 International Health Regulations. This initiative includes enhancing global disease surveillance by strengthening the ability of national governments to detect, report, and respond to urgent public health threats. (Finding #1)

- To better integrate research response into international public health response, HHS should consider creating a corollary to the GHSA for clinical research. (Finding #1)
- HHS can further enhance global health security by partnering with NGOs that operate in developing countries, in order to strengthen their ability to identify, report, and respond to urgent public health threats. (Finding #1)
- HHS should expand its financial, technical, and logistical support to WHO, in order to enhance its multilateral response capabilities, such as the Global Outbreak Alert and Response Network. (Finding #1)

HHS should build upon existing international response networks to strengthen multilateral alliances for public health response.

- Member countries of the multilateral alliances should coordinate to rapidly
  provide assistance to other countries for responding to urgent public health
  threats. The alliances may also provide a means to broadly source
  responders who have in-demand, specialized expertise. (Finding #6)
- HHS should lead this effort by hosting an international conference to develop the basis for requesting, providing, and accepting assistance. (Finding #6)

HHS should share the U.S. government's perspectives with—and seek consensus among—U.S. and international partners regarding the evaluation of investigational vaccines and treatments during an outbreak.<sup>8</sup>

 HHS should rapidly resolve disagreements among HHS components regarding evaluation protocols for vaccines and treatments that are under development when an urgent public health threat emerges. (Finding #7)

Improve HHS's coordination with U.S. government response partners.

HHS should coordinate with the National Security Council and federal partners to develop and finalize a U.S. government framework for multi-agency response to international incidents.

 The framework should define a government-wide coordination structure for international response and the HHS role within this structure. It should also identify lead/coordination and support responsibilities for U.S. government agencies in different scenarios, including those dealing with serious infectious diseases. (Finding #2)

<sup>&</sup>lt;sup>8</sup> See the "Improve HHS's internal coordination for preparedness and response" section for discussion of HHS arbitration of differing perspectives on research and development of vaccines and treatments during an outbreak.

- HHS should further coordinate with the National Security Council and federal partners to more clearly define roles for HHS in the management of responses with simultaneous domestic and international components. HHS should consider dividing management of the response into definable parts, with leads for each part reporting to an overall response coordinator. (Finding #2)
- HHS should work with the National Security Council, the Federal Emergency Management Agency, and USAID to explore whether prescripted mission assignments could be used for international deployment of public health and medical personnel to support U.S. government response efforts. (Finding #2)

### The U.S. government should determine how best to use the *National Response Framework* to respond to urgent public health threats.

- Plans for responding to urgent public health events that are not declared emergencies under the Stafford Act should clarify the roles and responsibilities of HHS and other U.S. government agencies and articulate possible funding sources. The plans should be tested in interagency exercises that include representatives from state and local agencies. (Finding #3)
- HHS should clarify the decision points for activating each Emergency Support Function in the *National Response Framework*, and, correspondingly, the roles and responsibilities of HHS and other U.S. government agencies for responding to non-*Stafford Act* events. (Findings #2 and #3)

HHS should work with interagency partners to codify the policies associated with enhanced entry screening, clarify the rationale for implementing these procedures, and further build the relationships and infrastructure needed to support such screenings.

- Policies for enhanced entry screening should include planning criteria that identify situations when airport screening is appropriate and feasible—and when it is not. HHS should work with the U.S. Department of Homeland Security's Customs and Border Protection to determine whether there are policies and authorities that can facilitate more effective and efficient entry screening and monitoring. (Finding #9)
- HHS and the U.S. Department of Homeland Security should further develop plans for innovative solutions that were used during the Ebola response (such as providing dedicated cell phones to individuals who were being monitored for Ebola symptoms) so that these solutions can be used if enhanced entry screening is implemented again in the United States. (Finding #9)
- HHS should develop clear public messages for implementing screening procedures. (Finding #9)

## Improve HHS's collaboration with state, local, and private-sector partners.

HHS should develop and implement an outreach plan that leverages HHS's regional offices, Operating Division field staff, and relationships with public health agencies and organizations to coordinate and communicate among federal, state, and local governments.

- HHS should work with the National Association of County and City Health Officials, the Association of State and Territorial Health Officials, and the National Public Health Information Coalition to develop the outreach plan. The plan should delineate the role for each level of government, as well as the roles of public health agencies and organizations, in establishing and implementing policies and regulatory authorities for public health and medical emergencies. HHS can use national-level exercises with both elected leaders and public health leaders to discuss and resolve the most difficult policy issues. (Findings #5 and #11)
- HHS should engage its regional offices to develop the outreach plan, including using its Regional Emergency Coordinators, in order to better connect public health agencies with emergency response agencies within each region. (Findings #5 and #11)

In coordination with the hospital community and state and local public health departments, HHS should maintain a national network of identified treatment centers.

- Leveraging efforts from the domestic Ebola response, HHS can extend the network of tiered hospitals for Ebola case management to enhance the identification and treatment of other urgent public health threats. (Finding #8)
- HHS should develop clear standards for each treatment center. These standards should include requirements for size, staff training, equipment, and protocols to triage patients to different levels of care. In addition, HHS should develop long-term funding streams to support these treatment centers and to support the care of individual patients. (Finding #8)

#### Improve HHS's internal coordination for preparedness and response.

HHS should designate responsibility for coordinating Department-wide response efforts to urgent public health threats that have both domestic and international components.

 A career member of the Senior Executive Service who has institutional knowledge of HHS's response capabilities and coordination mechanisms should support the designated lead(s) throughout the response. (Finding #4)

- HHS should define and institutionalize a response structure that integrates public health and medical services throughout the Department, in accordance with incident command system principles. The HHS response structure should build on the authorities of the *Pandemic and All-Hazards Preparedness Act* and the *Pandemic and All-Hazards Preparedness Reauthorization Act* [13, 32]. It should be clear on and broadly acknowledge the issue of whether and how the structure should change if the Secretary of HHS declares a Public Health Emergency. (Finding #4)
- If HHS Headquarters decides to use new plans and procedures for response to an urgent public health threat, the Department should clearly communicate the new coordination structure to its internal and external response partners. (Finding #4)
- HHS should ensure full distribution across the Department of applicable U.S. government response plans, such as the *Interagency Pandemic* Operations Plan and the U.S. Government Ebola Virus Disease Plan. (Finding #4)
- The HHS Office of the ASPR should conduct briefings and exercises with incoming HHS leadership and all relevant HHS components to ensure ongoing, shared understanding of existing coordination mechanisms and available resources for response to urgent public health threats. Results of these exercises should be reviewed and incorporated (as appropriate) into HHS response plans, policies, and executive orders. (Finding #4)
- HHS should pursue acquiring Direct-Hire Authority when the Department
  has a severe shortage of personnel to respond to urgent public health
  threats. The Office of Personnel Management's waiver process may need
  to be evaluated and revised in order to do so. (Finding #6)
- HHS should better integrate research response into its domestic and international public health response. This should include clinical research as well as studies to support actions in the areas of communications and health services. (Finding #1)

HHS should designate a lead entity to arbitrate the differing perspectives on research and development of vaccines and treatments during an outbreak.

• The National Institutes of Health, the U.S. Food and Drug Administration, CDC, and Biomedical Advanced Research and Development Authority (BARDA) all have specific roles—and perhaps differing perspectives—with regard to research, development, and distribution of vaccines and treatments. Using a pre-established and rapid decision-making process, the designated HHS lead should arbitrate these perspectives if the differences risk causing delays or overlaps when responding to an urgent public health threat. Arbitration is critical to rapidly resolving disagreements over evaluation protocols for vaccines and treatments that are under development when an urgent public health threat emerges. (Finding #7)

HHS should document the new processes that were used for expediting development and testing of Ebola vaccines and treatments.

- These new processes should be institutionalized and applied during future urgent public health threats. (Finding #10)
- The PHEMCE should develop a U.S. government position statement regarding preferred study designs for testing investigational vaccines and treatments during an epidemic. (Finding #7)

HHS should continue supporting the interagency and stakeholder working groups that were established to develop national-level policies for addressing PPE and medical waste management.

- Lessons from the 2014–2016 Ebola epidemic regarding PPE and medical waste management should be incorporated into training and exercises. (Finding #11)
- HHS should work with domestic and international partners to identify financial incentives, or legal and regulatory means, for quickly marshaling the full resources and capacities of the PPE manufacturing sector and distribution supply chain to support future response to urgent public health threats. (Finding #11)
- HHS should continue to leverage existing collaborative relationships, such as ASPR's ongoing partnership with the Association for Healthcare Resources and Materials Management, to examine the applicability of various public-private partnership frameworks for a potentially diverse range of urgent public health threats. (Finding #11)

#### Ensure that HHS communicates effectively with the public.

HHS should clarify its strategy for communicating risk-related information to the public, to Congress, and to other stakeholders during responses to urgent public health threats.

- HHS should develop a public communication framework that conveys the critical concepts of public health response and that fully integrates crisis and emergency risk-communication principles. (Finding #5)
- HHS should develop basic messaging for specific issues and actions that are likely to occur in serious public health crises (e.g., disease transmission, treatment decisions, triage, waste management, radiation exposure). These messages can be leveraged to develop communications during emergencies. The messages should be cleared in advance; HHS should consider coordinating the development of messages with the U.S. Department of Homeland Security, the American Red Cross, and other relevant agencies to encourage consistency in messaging to the public. HHS should also prepare to repeatedly communicate these concepts to

the public using traditional media and social networking/digital messaging platforms. (Finding #5)

- HHS should identify and train a cadre of personnel from across HHS to be
  potential spokespersons during public health and medical emergencies.
  These personnel should have public health expertise and a thorough
  understanding of health crisis/risk communication. They should receive
  training in these concepts annually, at a minimum. (Finding #5)
- HHS should establish a clear, systematic, and rapid way for messages to be reviewed and cleared that enables timely and relevant communication with the public. The Department must also exchange and verify information with internal and external response partners, and be prepared to supplement or correct information if the facts are misconstrued or conveyed improperly. (Finding #5)
- HHS should set clear expectations for what good risk communication can and cannot accomplish (e.g., it cannot compensate for poor operational response). (Finding #5)

HHS should encourage and support state and local public health departments that want to build their capacity to communicate risk-related information in a crisis or emergency.

- The HHS public communication framework should extend beyond individuals and administrations to form the basis for a common information system for public health at all levels. At a minimum, HHS should provide annual training on the framework to decision-makers and potential spokespersons for domestic and international responses to ensure that it is understood and adopted. (Finding #5)
- HHS should support state-level communications networks to extend this capacity. (Finding #5)
- HHS should consider developing the capacity to convene outside advisory expertise in risk communication, as needed, to provide additional support and perspectives, both for preparedness and for response. (Finding #5)

#### Ensure that HHS has sufficient and readily accessible resources.

HHS should determine whether it will maintain readily deployable medical personnel to treat patients in other countries that request such assistance for responding to urgent public health threats.

- If the Department pursues this option, it should assess the roles and missions of its mobile forces, including the USPHS Commissioned Corps and the National Disaster Medical System, to determine which personnel should be called upon to deploy. (Finding #6)
- HHS should work administratively—and with Congress, if needed—to remove remaining barriers to the deployment of HHS responders to other

- countries. This includes ensuring that pre-identified personnel are trained and equipped to deploy internationally. (Finding #6)
- HHS should explore ways to expand and support use of the USPHS Ready Reserve Corps to provide surge capabilities for urgent public health threats. (Finding #6)
- HHS should ensure that the USPHS Commissioned Corps is ready to deploy—as required by statutory authorities—by providing funding and resources to train and prepare its officers. (Finding #6)
- HHS should consider establishing multidisciplinary assessment teams, with personnel from appropriate HHS components, that could be deployed early and internationally to respond to an urgent public health threat. These assessment teams could rapidly assess what public health and medical resources are needed, and make recommendations about the scope and extent of an appropriate HHS response. (Finding #4)

HHS should ensure that it has the necessary and appropriate policies and plans to support quarantine and isolation.

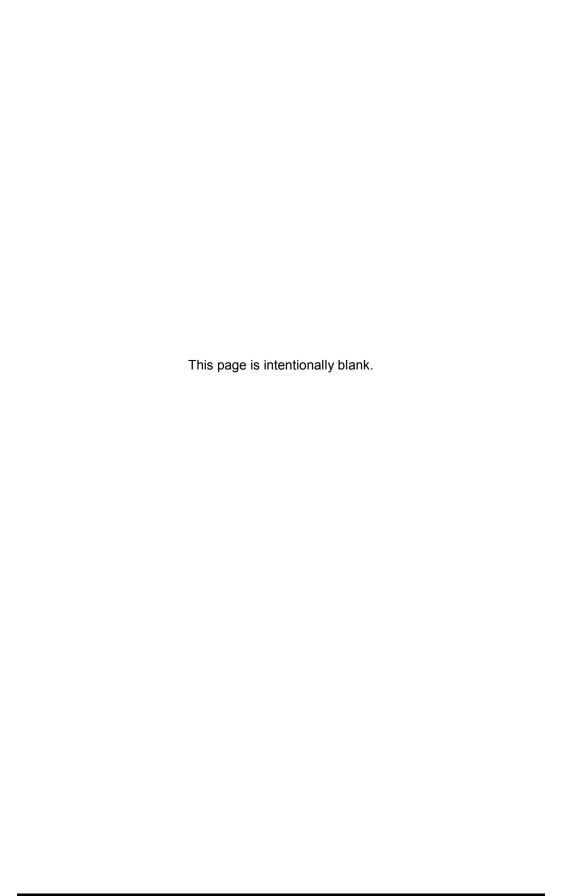
 Specific guidance and planning considerations should ensure that policies and actions are appropriate, safe, and effective. It is important to balance concerns of individual autonomy with the needs and safety of the surrounding population. The plans should also include guidance on messaging for affected populations and the general public, and be incorporated into exercises to prepare for future urgent public health threats. (Findings #11 and #12)

The U.S. government should provide sustained funding to HHS for emergency preparedness and response activities, and contribute to the readiness of its public health partners at the state and local levels.

- HHS should work with Congress to secure a contingency fund to allow the Department, as well as state and local public health agencies, to initiate and sustain preparedness and response activities. (Finding #13)
- HHS should explore how to flexibly use its existing budget authority to support rapid response to urgent public health threats. (Findings #8 and #13

### Develop an improvement plan for an HHS response to urgent public health threats.

HHS and the U.S. government can build upon existing plans and coordination mechanisms to better prepare for and respond to a range of infectious disease outbreaks and other urgent public health threats. As a result, the Independent Panel's findings and recommendations can apply to other adverse public health events beyond the Ebola epidemic. HHS has identified a number of authorities and operational opportunities that would enable a stronger and more flexible response in the future. The Independent Panel anticipates that HHS leadership will carefully consider the findings and recommendations presented in this report when developing an improvement plan to strengthen HHS's public health preparedness and response capabilities.



### Glossary

ASPR Office of the Assistant Secretary for Preparedness and Response

BARDA Biomedical Advanced Research and Development Authority cAd3-EBOZ chimpanzee adenovirus type 3-Zaire Ebola virus vaccine

CBP Customs and Border Protection

CBRN chemical, biological, radiological, and nuclear CDC Centers for Disease Control and Prevention

DHS U.S. Department of Homeland Security

DOD U.S. Department of Defense

EIND Emergency Investigational New Drug

EOC Emergency Operations Center

FDA U.S. Food and Drug Administration

FEMA Federal Emergency Management Agency

HHS U.S. Department of Health and Human Services

HPP Hospital Preparedness Program

IO International organization

LRN Laboratory Response Network

MSF Médecins Sans Frontières (Doctors Without Borders)

MMU Monrovia Medical Unit

NGO nongovernmental organization

NIH National Institutes of Health

OFDA Office of U.S. Foreign Disaster Assistance

OGA Office of Global Affairs
OS Office of the Secretary

PHEMCE Public Health Emergency Medical Countermeasures Enterprise

PPE personal protective equipment

PREP Act Public Readiness and Emergency Preparedness Act
PREVAIL Partnership for Research on Ebola Vaccines in Liberia

rVSV-ZEBOV recombinant vesicular stomatitis virus-Zaire Ebola virus vaccine

STRIVE Sierra Leone Trial to Introduce a Vaccine against Ebola

UN United Nations

UNMEER United Nations Mission for Ebola Emergency Response

USAID U.S. Agency for International Development

USG U.S. government

USPHS U.S. Public Health Service WHO World Health Organization

# Appendix A: Overview of the HHS Ebola Response

The most widespread Ebola epidemic to date began in December 2013 in a small town in Guinea [33]. The virus spread quickly and easily, passing through rural communities and porous borders to reach crowded cities [16].

Inadequate public health infrastructure in Guinea, Liberia, and Sierra Leone—the three countries most severely affected by Ebola—greatly contributed to the spread of disease [16]. Moreover, Ebola's nature of transmission posed a threat to healthcare workers and other front-line workers (e.g., burial workers), creating a dangerous environment for those tasked with treating patients, as well as those investigating and containing the outbreak [34].

From December 2013 to November 2015, the virus claimed more than 11,000 lives and infected more than 28,000 people [35]. In late 2015, sporadic cases continued to emerge in Guinea and Liberia [36].

#### International response

The U.S. government began its international response to the Ebola epidemic in early 2014 (see Table 1). In March 2014, the Centers for Disease Control and Prevention (CDC) deployed personnel to investigate Ebola cases in Guinea [37]. In May, the White House asked the HHS Office of Global Affairs to coordinate the U.S. government's response efforts in West Africa. As the epidemic worsened, in early August, the Office of U.S. Foreign Disaster Assistance (OFDA) within the U.S. Agency for International Development served as the lead operational platform for the growing U.S. government response effort in West Africa, and OFDA deployed a Disaster Assistance Response Team to West Africa to help coordinate the U.S. government response [37].

The Disaster Assistance Response Team responders worked closely with the cadre of nongovernmental organizations (NGOs) in West Africa and helped coordinate a combined public-private response. In particular, the Disaster Assistance Response Team helped coordinate the U.S. government's response with Médecins Sans Frontières (Doctors Without Borders), the NGO providing most of the clinical care to Ebola patients in West Africa [38].

<sup>&</sup>lt;sup>9</sup> Nigeria, Senegal, and Mali also had Ebola cases, the first of which were confirmed in July, August, and October 2014, respectively. These countries were able to respond more quickly to the Ebola epidemic, due to increased vigilance and stronger public health response capabilities [16].

In late August 2014, the Director of CDC and the Director of USAID/OFDA traveled to Liberia [39]. After they returned to the United States, CDC warned that the epidemic was spiraling out of control and that prompt action by the international community was necessary to contain the epidemic [40].

Table 1. Major U.S. government international response activities during the 2014–2016 Ebola epidemic

Date	Event
March 14, 2014	Médecins Sans Frontières receives a report from the Ministry of Health in Guinea about a "mysterious disease" [16].
March 31, 2014	CDC deploys its first team to Guinea to investigate the disease outbreak [41].
May 2014	The White House asks the HHS Office of Global Affairs to serve as the U.Sbased coordinator for the government's response efforts in West Africa. [10].
July 2014	By the end of the month, CDC has 100 personnel in West Africa to support Ebola response efforts [4].
August 4, 2014	OFDA deploys a Disaster Assistance Response Team to West Africa [37].
August 24, 2014	CDC and USAID leaders travel to West Africa to personally observe the outbreak [39].
September 16, 2014	President Obama declares that the U.S. will send 3,000 troops to Liberia to support the Ebola response [42].
October 2, 2014	U.S. Public Health Service (USPHS) Commissioned Corps sends an Advance Team to establish partnerships in Liberia [17].
October 19, 2014	USPHS Commissioned Corps officers deploy to staff the Monrovia Medical Unit in Liberia [43].
February 2015	PREVAIL, a Liberia-U.S. clinical research partnership led by the HHS's National Institutes of Health, launches a randomized, placebo-controlled Phase II/III clinical trial of two candidate Ebola vaccines in Liberia [44].
April 14, 2015	CDC helps the Sierra Leone Ministry of Health and Sanitation launch an Ebola vaccine clinical trial in that country [45].
July 31, 2015	The World Health Organization (WHO) reports that the rVSV-ZEBOV <sup>10</sup> vaccine is highly effective against Ebola, according to Phase III trials in Guinea [47].

<sup>&</sup>lt;sup>10</sup> The rVSV-ZEBOV vaccine uses genetically engineered recombinant vesicular stomatitis virus (rVSV) to carry a Zaire Ebola virus (ZEBOV) gene. VSV is an animal virus that primarily affects cattle. It has been successfully tested as an experimental vaccine platform against several other viruses [46].

The U.S. government responded quickly and, on September 16, 2014, President Obama traveled to CDC headquarters in Atlanta, GA, to announce the deployment of 3,000 U.S. troops to Liberia [48]. U.S. Department of Defense forces in Liberia constructed hundreds of new beds and treatment centers for Ebola patients, including the Monrovia Medical Unit (MMU), an Ebola treatment unit created to treat healthcare workers in Liberia [49]. The USPHS Commissioned Corps sent an Advanced Echelon Team to Liberia in early October to establish partnerships for operating the MMU. The USPHS treated patients at the MMU from November 2014 through April 2015 [50].

# **Domestic response**

While the U.S. government supported efforts to contain the disease overseas, several cases of Ebola in the United States tested HHS's ability to respond domestically (see Table 2). In July 2014, two American aid workers were diagnosed with Ebola while working in Liberia. In early August, they were medically evacuated to the United States and admitted to Emory University Hospital for treatment [51].

In September 2014, the first U.S. case of Ebola was diagnosed in Dallas, TX [52]. A Liberian traveler visiting the United States was admitted to Texas Health Presbyterian Hospital and diagnosed with Ebola [53]. Despite receiving treatment, the patient died. Two nurses who cared for him contracted Ebola, marking the first known incidents of domestic transmission of Ebola [53].

The Ebola cases in Texas raised a number of issues regarding domestic public health preparedness and response, including roles and responsibilities among local, state, and federal health authorities; hospital preparedness; waste management; public communications; civil liberties; travel restrictions; and quarantine considerations. They also perpetuated media interest and led to an increase in the public's fear about Ebola risks [53].

HHS also worked with the U.S. Department of Homeland Security to screen people traveling from Guinea, Liberia, and Sierra Leone and arriving at any of five major U.S. airports [54]. This process was called "enhanced entry screening" and involved taking each traveler's temperature; asking questions about possible exposure to Ebola; and collecting contact information for subsequent follow-up with the traveler, if needed [55]. From October 2014 through August 2015, more than 30,000 airline passengers were screened [56]. CDC conducted additional medical screening on some (less than 10 percent) of the travelers. None of the travelers tested positive for Ebola.

In October 2014, a returning traveler—an NGO physician who had been caring for Ebola patients in Guinea—was diagnosed with Ebola in New York City. Because the city is a major international travel hub, the New York City Department of Health and Mental Hygiene had begun planning for the possibility of Ebola cases months before the single confirmed case arrived in the city. Their planning focused on developing processes for active monitoring; developing public messages and outreach campaigns; conducting exercises and no-notice drills; and implementing travel history and fever screening at all New York City hospitals [26]. The NGO physician was monitored and later showed signs

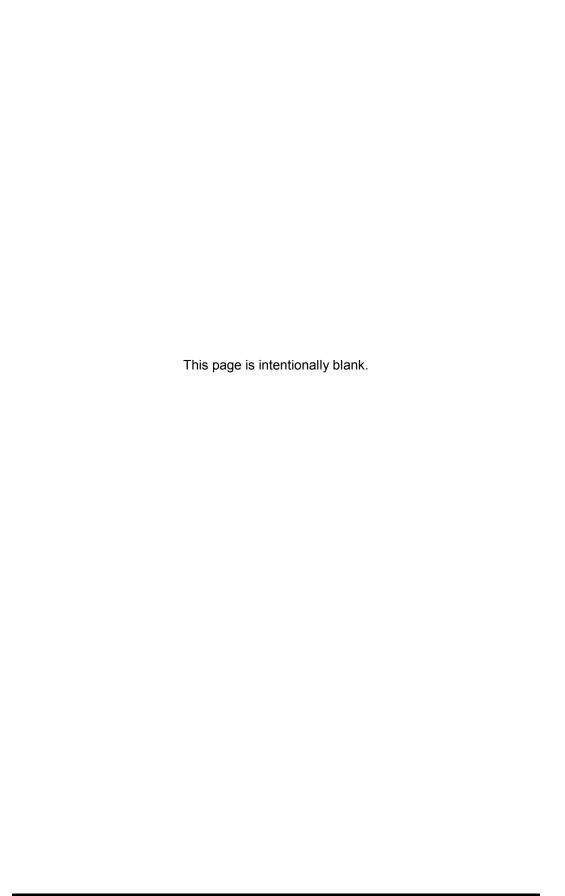
of Ebola [26, 57]. He was admitted and treated at Bellevue Hospital in New York City, and did not transmit the disease [26].

Table 2. Major U.S. Ebola response activities during the 2014–2016 Ebola epidemic

Date	Event
July 9, 2014	CDC activates its Emergency Operations Center to coordinate technical assistance and activities with Ebola response partners [58].
August 2–5, 2014	Two American healthcare workers are airlifted to the United States after contracting Ebola while conducting missionary work in Liberia; they are the first Ebola patients treated in the United States [59-60].
August 5, 2014	CDC elevates its Emergency Operations Center to Level 1 [61].
September 2, 2014	Biomedical Advanced Research and Development Authority (BARDA) funds development and manufacturing of ZMapp, a medication to treat Ebola.
September 22, 2014	CDC launches a training course at the FEMA Center for Domestic Preparedness to prepare healthcare workers who intend to work in Ebola Treatment Units in West Africa [62].
September 26, 2014	CDC modeling estimates there could be 1.4 million Ebola cases in West Africa by January 2015, if no further intervention occurs [63].
September 30, 2014	CDC confirms that a Liberian who traveled to Dallas, TX, has Ebola, marking the first case of Ebola diagnosed in the United States [52].
October 11, 2014	The U.S. Department of Homeland Security's Customs and Border Protection and CDC begin enhanced entry screening at U.S. airports for travelers arriving in the United States from Guinea, Liberia, and Sierra Leone [56].
October 12, 2014	Two nurses who treated the Liberian traveler in Dallas, TX, are diagnosed with Ebola, marking the first known transmission of the virus in the United States [59].
October 20, 2014	CDC releases new guidance for U.S. healthcare workers on personal protective equipment for Ebola [64].
October 23, 2014	The New York Department of Health and Mental Hygiene reports that a physician returning to New York City from volunteering in West Africa has tested positive for Ebola [52].
December 2, 2014	HHS designates 35 U.S. hospitals as Ebola Treatment Centers [65].
February 6, 2015	ASPR and CDC identify 697 Assessment Hospitals and 55 Ebola Treatment Centers in the United States [66]
July 1, 2015	HHS launches the National Ebola Training and Education Center [67].

To prepare for the possibility of emergent Ebola cases, HHS worked with local health authorities and hospital administrators to identify hospitals in different parts of the United States that were equipped to care for Ebola patients. These hospitals were designated as Ebola Treatment Centers [68]. HHS provided training and equipment to those hospitals [65]. For example, CDC assembled personal protective equipment kits that could be deployed to them [69]. The Office of the HHS Assistant Secretary for Preparedness and Response awarded approximately \$20 million through its Hospital Preparedness Program to enhance the Ebola Treatment Centers' capabilities [70].

Through its Laboratory Response Network, HHS approved more than 50 laboratories across the United States to test for Ebola virus [71]. As early as April 2014, the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) was activated to review potential Ebola vaccine and treatment candidates, and to put steps in place to accelerate the development of the most promising candidates. In addition, the PHEMCE and BARDA supported the late-stage development and manufacturing of candidate vaccine and treatments for Ebola. The U.S. Food and Drug Administration rapidly reviewed and approved Emergency Investigational New Drug applications for using these medications to treat Ebola patients. The PHEMCE partners worked together to support the vaccine and treatment trials led by the National Institutes of Health and CDC.



# Appendix B: Organizations Interviewed for this Report

# HHS / Immediate Office of the Secretary

#### HHS / Office of the Assistant Secretary for Preparedness and Response

Biomedical Advanced Research and Development Authority Office of Emergency Management Office of Policy and Planning

#### **HHS / Office of Global Affairs**

# HHS / Office of the Assistant Secretary for Public Affairs

#### HHS / Office of the Assistant Secretary for Health

Division of Commissioned Corps Personnel and Readiness Monrovia Medical Unit Readiness and Deployment Operations Group

#### HHS / Centers for Disease Control and Prevention

Center for Global Health

Division of Global Migration and Quarantine

Domestic Task Force

**Ebola Policy Unit** 

**Emergency Operations Center** 

Global Migration Task Force

International Task Force

Joint Information Center

National Center for Emerging Zoonotic and Infectious Diseases

National Center for Immunization and Respiratory Diseases

Office for State, Tribal, Local, and Territorial Support

Office of Public Health Preparedness and Response

Office of Public Health Scientific Services

Office of the Associate Director for Communication

STRIVE Vaccine Task Force

#### HHS / U.S. Food and Drug Administration

Office of the Chief Scientist

#### **HHS / National Institutes of Health**

National Institute of Allergy and Infectious Diseases

#### U.S. Department of State

Office of Medical Services

#### U.S. Department of Homeland Security

Federal Emergency Management Agency

# **U.S. Agency for International Development**

Office of U.S. Foreign Disaster Assistance

# U.S. Department of Agriculture

One Health Coordination Center

# **U.S. Department of Defense**

Defense Threat Reduction Agency
Office of the Under Secretary of Defense for Policy

# **National Security Council**

#### **American Hospital Association**

# **Texas Department of State Health Services**

# City of Dallas

Fire-Rescue Department
Office of Emergency Management
Police Department
Public Information Office

# **New York City**

Department of Mental Health and Hygiene Fire Department Office of Emergency Management Office of the Chief Medical Examiner

# **Greater New York Hospital Association**

# **Bellevue Hospital Center**

# **Emory University**

Emory University Hospital School of Medicine

# **University of Nebraska Medical Center**

# **Constituency for Africa**

# **Mercy Corps**

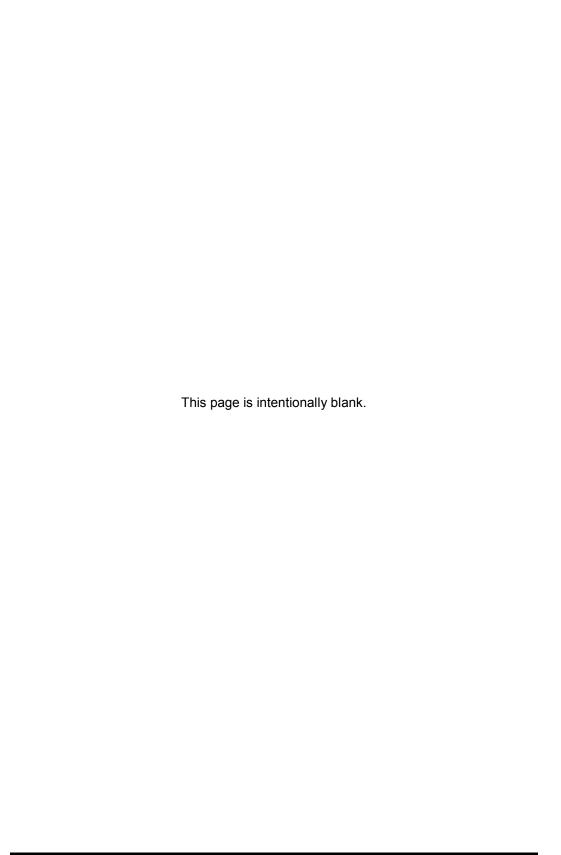
# Partners in Health

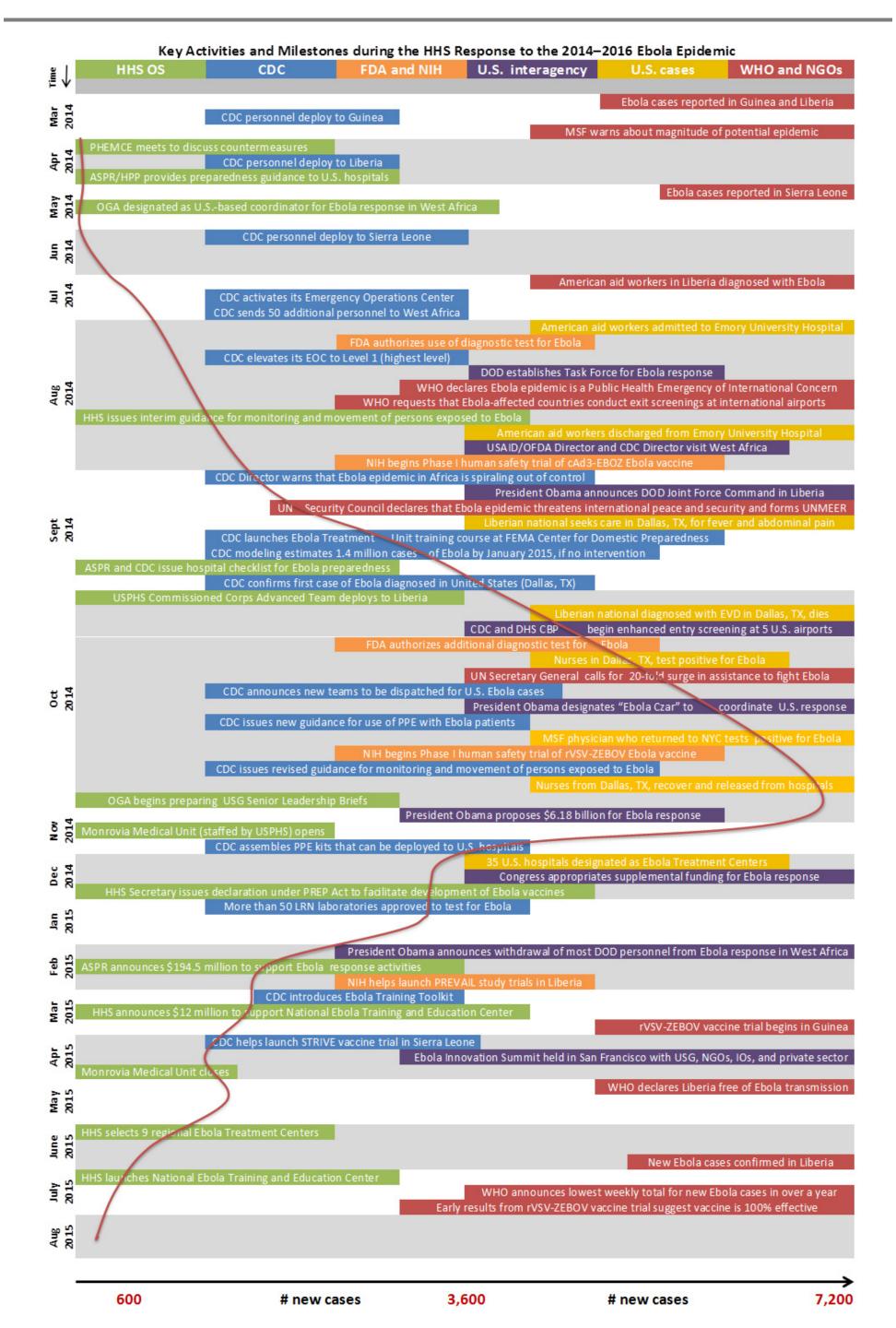
# **Global Communities**

# Appendix C: Timeline of Key Activities and Milestones during the HHS Response to the 2014–2016 Ebola Epidemic

The following pages summarize key activities and milestones for the HHS Ebola response, from March 2014 through August 2015. (Note that HHS Ebola response activities (e.g., vaccine trials) have continued into 2016.) A pictorial timeline of activities and milestones is on page 37. An epidemic curve showing the number of new Ebola cases per month in Guinea, Liberia, and Sierra Leone is overlaid on the timeline. Data for the case counts are from CDC [72]. Table 3, on pages 39-42, displays the same information as the timeline.

Acronyms used in the timeline and in the table are defined in the glossary on pages 25-26 of this report.





This is a pictorial timeline of key activities and milestones during the HHS response to the 2014–2016 Ebola epidemic. There are six columns to represent the actor or category for each activity or milestone: HHS OS, CDC, FDA and NIH, U.S. interagency, U.S. cases, and WHO and NGOs. An epidemic curve showing the number of new Ebola cases per month in Guinea, Liberia, and Sierra Leone is overlaid on the timeline. Table 3, on pages 39-42, displays the same information as the timeline.



Table 3. Key activities and milestones during the HHS response to the 2014–2016 Ebola epidemic<sup>11</sup>

Month	Key activity or milestone (actor or category)
March 2014	<ul> <li>There are 120 new Ebola cases in Guinea, Liberia, and Sierra Leone</li> <li>Ebola cases reported in Guinea and Liberia (WHO and NGOs)</li> <li>CDC personnel deploy to Guinea (CDC)</li> <li>MSF warns about magnitude of potential epidemic (WHO and NGOs)</li> </ul>
April 2014	<ul> <li>There are 114 new Ebola cases in Guinea, Liberia, and Sierra Leone</li> <li>PHEMCE meets to discuss countermeasures (HHS OS)</li> <li>CDC personnel deploy to Liberia (CDC)</li> <li>ASPR/HPP provides preparedness guidance to U.S. hospitals (HHS OS)</li> </ul>
May 2014	<ul> <li>There are 75 new Ebola cases in Guinea, Liberia, and Sierra Leone</li> <li>Ebola cases reported in Sierra Leone (WHO and NGOs)</li> <li>OGA designated as U.Sbased coordinator for Ebola response in West Africa (HHS OS)</li> </ul>
June 2014	<ul> <li>There are 290 new Ebola cases in Guinea, Liberia, and Sierra Leone</li> <li>CDC personnel deploy to Sierra Leone (CDC)</li> </ul>
July 2014	<ul> <li>There are 723 new Ebola cases in Guinea, Liberia, and Sierra Leone</li> <li>American aid workers in Liberia diagnosed with Ebola (WHO and NGOs)</li> <li>CDC activates its Emergency Operations Center (CDC)</li> <li>CDC sends 50 additional personnel to West Africa (CDC)</li> </ul>

<sup>&</sup>lt;sup>11</sup> Ebola case counts are from CDC [72].

#### Month

# **Key activity or milestone (actor or category)**

#### August 2014

- There are 1,730 new Ebola cases in Guinea, Liberia, and Sierra Leone
- American aid workers admitted to Emory University Hospital (U.S. cases)
- FDA authorizes use of diagnostic test for Ebola (FDA and NIH)
- CDC elevates its EOC to Level 1 (highest level) (CDC)
- DOD establishes Task Force for Ebola response (U.S. interagency)
- WHO declares Ebola epidemic is a Public Health Emergency of International Concern (WHO and NGOs)
- WHO requests that Ebola-affected countries conduct exit screenings at international airports (WHO and NGOs)
- HHS issues interim guidance for monitoring and movement of persons exposed to Ebola (HHS OS)
- American aid workers discharged from Emory University Hospital (U.S. cases)
- USAID/OFDA Director and CDC Director visit West Africa (U.S. interagency)
- NIH begins Phase I human safety trial of cAd3-EBOZ Ebola vaccine (FDA and NIH)

# September 2014

- There are 3,501 new Ebola cases in Guinea, Liberia, and Sierra Leone
- CDC Director warns that Ebola epidemic in Africa is spiraling out of control (CDC)
- President Obama announces DOD Joint Force Command in Liberia (U.S. interagency)
- UN Security Council declares that Ebola epidemic threatens international peace and security and forms UNMEER (WHO and NGOs)
- Liberian national seeks care in Dallas, TX, for fever and abdominal pain (U.S. cases)
- CDC launches Ebola Treatment Unit training course at FEMA Center for Domestic Preparedness (CDC)
- CDC modeling estimates 1.4 million cases of Ebola by January 2015, if no intervention (CDC)
- ASPSR and CDC issue hospital checklist for Ebola preparedness (HHS OS)
- CDC confirms first case of Ebola diagnosed in United States (Dallas, TX) (CDC)

#### Month

# **Key activity or milestone (actor or category)**

#### October 2014

- There are 6,987 new Ebola cases in Guinea, Liberia, and Sierra Leone
- USPHS Commissioned Corps Advanced Team deploys to Liberia (HHS OS)
- Liberian national diagnosed with EVD in Dallas, TX, dies (U.S. cases)
- CDC and DHS CBP begin enhanced entry screening at 5 U.S. airports (U.S. interagency)
- FDA authorizes additional diagnostic test for Ebola (FDA and NIH)
- Nurses in Dallas, TX, test positive for Ebola (U.S. cases)
- UN Secretary General calls for 20-fold surge in assistance to fight Ebola (WHO and NGOs)
- CDC announces new teams to be dispatched for U.S. Ebola cases (CDC)
- President Obama designates "Ebola Czar" to coordinate U.S. response (U.S. interagency)
- CDC issues new guidance for use of PPE with Ebola patients (CDC)
- MSF physician who returned to NYC tests positive for Ebola (U.S. cases)
- NIH begins Phase I human safety trial of rVSV-ZEBOV Ebola vaccine (FDA and NIH)
- CDC issues revised guidance for monitoring and movement of persons exposed to Ebola (CDC)
- Nurses from Dallas, TX, recover and released from hospitals (U.S. cases)
- OGA begins preparing USG Senior Leadership Briefs (HHS OS)

#### November 2014

- There are 3,359 new Ebola cases in Guinea, Liberia, and Sierra Leone
- President Obama proposes \$6.18 billion for Ebola response (U.S. interagency)
- Monrovia Medical Unit (staffed by USPHS) opens (HHS OS)
- CDC assembles PPE kits that can be deployed to U.S. hospitals (CDC)

# December 2014

- There are 3,272 new Ebola cases in Guinea, Liberia, and Sierra Leone
- 35 U.S. hospitals designated as Ebola Treatment Centers (U.S. cases)
- Congress appropriates supplemental funding for Ebola response (U.S. interagency)
- HHS Secretary issues declaration under PREP Act to facilitate development of Ebola vaccines (HHS OS)

Month	Key activity or milestone (actor or category)
January 2015	<ul> <li>There are 1,886 new Ebola cases in Guinea, Liberia, and Sierra Leone</li> <li>More than 50 LRN laboratories approved to test for Ebola (CDC)</li> </ul>
February 2015	<ul> <li>There are 1,637 new Ebola cases in Guinea, Liberia, and Sierra Leone</li> <li>President Obama announces withdrawal of most DOD personnel from Ebola response in West Africa (U.S. interagency)</li> <li>ASPR announces \$194.5 million to support Ebola response activities (HHS OS)</li> <li>NIH helps launch PREVAIL study trials in Liberia (FDA and NIH)</li> </ul>
March 2015	<ul> <li>There are 1,178 new Ebola cases in Guinea, Liberia, and Sierra Leone</li> <li>CDC introduces Ebola Training Toolkit (CDC)</li> <li>HHS announces \$12 million to support National Ebola Training and Education Center (HHS OS)</li> <li>rVSV-ZEBOV Ebola vaccine trial begins in Guinea (WHO and NGOs)</li> </ul>
April 2015	<ul> <li>There are 1,405 new Ebola cases in Guinea, Liberia, and Sierra Leone</li> <li>CDC helps launch STRIVE vaccine trial in Sierra Leone (CDC)</li> <li>Ebola Innovation Summit held in San Francisco with USG, NGOs, IOs, and private sector (U.S. interagency)</li> <li>Monrovia Medical Unit closes (HHS OS)</li> </ul>
May 2015	<ul> <li>There are 736 new Ebola cases in Guinea, Liberia, and Sierra Leone</li> <li>WHO declares Liberia free of Ebola transmission (WHO and NGOs)</li> </ul>
June 2015	<ul> <li>There are 430 new Ebola cases in Guinea, Liberia, and Sierra Leone</li> <li>HHS selects nine regional Ebola Treatment Centers (HHS OS)</li> <li>New Ebola cases confirmed in Liberia (WHO and NGOs)</li> </ul>
July 2015	<ul> <li>There are 305 new Ebola cases in Guinea, Liberia, and Sierra Leone</li> <li>HHS launches National Ebola Training and Education Center (HHS OS)</li> <li>WHO announces lowest weekly total for new Ebola cases in over a year (WHO and NGOs)</li> <li>Early results from rVSV-ZEBOV vaccine trial suggest vaccine is 100% effective (WHO and NGOs)</li> </ul>
August 2015	There are 257 new Ebola cases in Guinea, Liberia, and Sierra Leone

# References

- [1] World Health Organization. 2015. <u>Report of the Ebola Interim Assessment Panel</u>. http://www.who.int/csr/resources/publications/ebola/report-by-panel.pdf.
- [2] Director-General of the World Health Organization. May 8, 2015. *WHO Reform:* Overview of Reform Implementation. Sixty-Eigth World Health Assembly.
- [3] Frieden, Thomas R., and Inger K. Damon. Nov. 2015. "Ebola in West Africa CDC's Role in Epidemic Detection, Control, and Prevention." <u>Emerging Infectious Diseases</u> 21 (11). http://wwwnc.cdc.gov/eid/article/21/11/15-0949\_article.
- [4] Frieden, Thomas R. "<u>Lessons Learned After the Ebola Crisis</u>." Council on Foreign Relations, Nov. 24, 2015. http://www.cfr.org/diseases-infectious/lessons-learned-after-ebola-crisis/p37278.
- [5] World Health Organization. "<u>Statement on the 1st Meeting of the IHR Emergency Committee on the 2014 Ebola Outbreak in West Africa.</u>" Media Centre. August 8, 2014. http://www.who.int/mediacentre/news/statements/2014/ebola-20140808/en/.
- [6] Personal communication with staff from CDC, Interview for HHS Ebola Lessons Learned Review, August 2015.
- [7] Personal communication with staff from the CDC International Task Force, Interview for HHS Ebola Lessons Learned Review, August 2015.
- [8] Personal communication with staff from the National Institutes of Health, Review comments for the HHS Ebola Lessons Learned Review, March 2016.
- [9] U.S. Department of Homeland Security, Federal Emergency Management Agency. May 2013. <u>Emergency Support Function #8 - Public Health and Medical Services Annex</u>. Subject: Unclassified. http://www.fema.gov/media-library-data/20130726-1914-25045-5673/final\_esf\_8\_public\_health\_medical\_20130501.pdf.
- [10] Personal communication with staff from HHS Office of Global Affairs, Interviews for the HHS Ebola Lessons Learned Review, September 2015.
- [11] U.S. Department of Health and Human Services. May 2015. *U.S. Government Ebola Virus Disease Plan.* Pre-Decisional Draft.
- [12] U.S. Department of Health and Human Services. 2013. *Interagency Pandemic Operations Plan.*
- [13] Pandemic and All-Hazards Preparedness Reauthorization Act. March 13, 2013. Public Law 113-5.
- [14] Centers for Disease Control and Prevention. "CDC Telebriefing on the Update on Ebola outbreak in West Africa." Atlanta, GA, July 31, 2014. http://www.cdc.gov/media/releases/2014/t0731-ebola.html.

- [15] State of New Jersey. "Gov. Christie with Gov. Cuomo: Mandatory Quarantine Is to Protect People of NY & NJ." October 24, 2014. http://www.state.nj.us/governor/news/news/552014/approved/20141024c.html.
- [16] Medecins Sans Frontieres. 2015. <u>Pushed to the Limit and Beyond: A Year into the Largest-Ever Ebola Outbreak</u>. https://www.doctorswithoutborders.org/sites/usa/files/msf143061.pdf.
- [17] Personal communication with USPHS Commissioned Corps officers, Interview for HHS Ebola Lessons Learned Review, October 2015.
- [18] Mapp Biopharmaceutical. "ZMapp." http://mappbio.com/z-mapp/.
- [19] Personal communication with staff from Partners in Health, Interview for HHS Ebola Lessons Learned Review. October 2015.
- [20] Personal communication with staff from Bellevue Hospital, Interview for HHS Ebola Lessons Learned Review, July 2015.
- [21] Personal communication with staff from the American Hospital Association, Interview for HHS Ebola Lessons Learned Review, September 2015.
- [22] Morin, Monte. "Another Ebola Challenge: Disposing of Medical Waste." Los Angeles Times. October 19, 2014. http://www.latimes.com/science/la-sci-ebola-waste-disposal-20141020-story.html.
- [23] Steenhuysen, Julie. "<u>U.S. Hospitals Unprepared to Handle Ebola Waste</u>." *Reuters*. September 24, 2014. http://www.reuters.com/article/us-health-ebola-usa-hospitals-insight-idUSKCN0HJ0AD20140924.
- [24] Santora, Marc. "First Patient Quarantined Under Strict New Policy Tests

  Negative for Ebola." New York Times. October 24, 2014.

  http://www.nytimes.com/2014/10/25/nyregion/new-york-ebola-case-craig-spencer.html.
- [25] Susman, Tina, and Melissa Healy. "<u>Disorder Among States' Ebola Strategies Raises Worries</u>." Los Angeles Times. October 27, 2014. http://www.latimes.com/nation/la-na-ebola-quarantine-20141028-story.html.
- [26] Esposito, Joseph, and Mary Bassett. 2014. NYC Citywide Ebola After-Action Report. NYC Office of the Mayor.
- [27] Centers for Disease Control and Prevention. 2014. "2014 Ebola Response Supplemental Funding: PHEP Supplemental Funding for Ebola Preparedness and Response Activities." Office of Public Health Preparedness and Response. http://www.cdc.gov/phpr/phep.htm.
- [28] Personal communication with staff from the HHS Office of the Secretary, Interview for HHS Ebola Lessons Learned Review, September 2015.
- [29] CDC Foundation. 2014. "Support CDC's Response to the Ebola Epidemic in West Africa." http://www.cdcfoundation.org/ebola-outbreak.
- [30] CDC Foundation. "CDC Foundation Receives \$25 Million Donation from Mark Zuckerberg and Dr. Priscilla Chan for Ebola Response." October 14, 2014. http://www.cdcfoundation.org/pr/cdc-foundation-receives-25-million-donation-mark-zuckerberg-and-priscilla-chan-ebola-response.

- [31] CDC Foundation. "Taiwan Provides \$1 Million Donation to CDC Foundation for Ebola Response Effort." December 4, 2014. http://www.cdcfoundation.org/pr/2014/taiwan-provides-1-million-donation-cdc-foundation-ebola-response-effort.
- [32] Pandemic and All-Hazards Preparedness Act. December 19, 2006. Public Law No. 109-417.
- [33] World Health Organization. January 2015. <u>Origins of the 2014 Ebola Epidemic</u>. http://www.who.int/csr/disease/ebola/one-year-report/virus-origin/en.
- [34] Szabo, Liz. "Why Ebola May Pose a Greater Threat in the ICU." USA Today. October 14, 2014. Accessed November 19, 2015. http://www.usatoday.com/story/news/nation/2014/10/14/ebola-spreads-easily-hospitals/17247157/.
- [35] World Health Organization. 2015. <u>Ebola Situation Report 25 November 2015</u>. http://apps.who.int/ebola/current-situation/ebola-situation-report-25-november-2015.
- [36] World Health Organization. 2015. <u>Ebola Situation Report 2 December 2015</u>. http://apps.who.int/ebola/ebola-situation-reports.
- [37] U.S. Agency for International Development. "<u>USAID and CDC Announce Additional Assistance for West Africa Ebola Response</u>." August 5, 2014. www.usaid.gov/news-information/press-releases/aug-5-2014-usaid-and-cdc-announce-additional-assistance-west-africa-ebola.
- [38] Torbay, Rabih. 2014. Statement of Mr. Rabih Torbay, Senior Vice President for International Operations on behalf of International Medical Corps. <u>The Ebola Crisis: Coordination of a Multi-Agency Response</u>. House Committee on Oversight and Government Reform. October 24, 2014. Accessed at https://oversight.house.gov/wp-content/uploads/2014/10/Torbay-IMC-Statement-10-24-Ebola.pdf.
- [39] U.S. Agency for International Development. 2014. "West Africa Ebola Outbreak Fact Sheet No. 3."
  www.usaid.gov/sites/default/files/documents/9276/USG%20West%20Africa%20 Ebola%20Outbreak%20Fact%20Sheet%20%233.pdf.
- [40] CBS News. "Ebola is 'Spiraling Out of Control,' CDC Director Says." September 2, 2014. http://www.cbsnews.com/news/ebola-is-spiraling-out-of-control-cdcdirector-says/.
- [41] Centers for Disease Control and Prevention. 2014. "Previous Updates: 2014 West Africa Outbreak-October 31, 2014." October 31, 2014. www.cdc.gov/vhf/ebola/outbreaks/2014-west-africa/previous-updates.html.
- [42] U.S. Agency for International Development. 2014. "West Africa Ebola Outbreak Fact Sheet No. 6."
  www.usaid.gov/sites/default/files/documents/1864/09.17.14%20-%20USG%20West%20Africa%20Ebola%20Outbreak%20Fact%20Sheet%20%2 36.pdf.
- [43] Chaves, Karen. <u>MMU Deployment Spotlight</u>. Asian Pacific American Officers Committee Newsletter, Spring 2015. https://dcp.psc.gov/osg/apaoc/Documents/2015\_Spring\_Edition.pdf.

- [44] National Institutes of Health, National Institute of Allergy and Infectious Diseases. "Ebola Vaccine Trial Opens in Liberia." NIH News. February 2, 2015. https://www.niaid.nih.gov/news/newsreleases/2015/Pages/PREVAIL.aspx.
- [45] Centers for Disease Control and Prevention. "Ebola Vaccine Trial Begins in Sierra Leone." CDC Newsroom. April 14, 2015. http://www.cdc.gov/media/releases/2015/p0414-ebola-vaccine.html.
- [46] National Institutes of Health, National Institute of Allergy and Infectious Diseases. "Singe Dose Ebola Vaccine Is Safe and Effective in Monkeys against Outbreak Strain." NIH News. August 6, 2015. https://www.niaid.nih.gov/news/newsreleases/2015/Pages/VSV-EBOV.aspx.
- [47] World Health Organization. "World on the verge of an effective Ebola vaccine." WHO Media Centre. July 31, 2015. http://www.who.int/mediacentre/news/releases/2015/effective-ebola-vaccine/en/.
- [48] The White House. 2014. "Fact Sheet: U.S. Response to the Ebola Epidemic in West Africa." http://www.whitehouse.gov/the-press-office/2014/09/16/fact-sheet-us-response-ebola-epidemic-west-africa.
- [49] Malac, Deborah. "<u>Liberia: Monrovia Medical Unit Aids Health Care Workers in Ebola fight</u>." AllAfrica. November 25, 2014. www.allafrica.com/stories/201411261146.html.
- [50] Crusher, Megan. 2013. "Maritime Civil Affairs departs CJTF-HOA, for good." Combined Joint Task Force - Horn of Africa. 19 Sep 2013.
- [51] U.S. Department of State, Office of Medical Services. 2015. *Medical Support and Response to the 2014-2015 Ebola Crisis in West Africa: Lessons Learned and Emerging Best Practices.* For Official Use Only.
- [52] Centers for Disease Control and Prevention. 2015. <u>Cases of Ebola Diagnosed in the United States</u>. http://www.cdc.gov/vhf/ebola/outbreaks/2014-west-africa/united-states-imported-case.html.
- [53] Burrough, Bryan. "Trial by Ebola." Vanity Fair. January 31, 2015.
- [54] Centers for Disease Control and Prevention. "Enhanced Ebola Screening to Start at Five U.S. Airports and New Tracking Program for All People Entering U.S. from Ebola-affected Countries." October 10, 2014. www.cdc.gov/media/releases/2014/p1008-ebola-screening.html.
- [55] Centers for Disease Control and Prevention. <u>Fact Sheet: Screening and Monitoring Travelers to Prevent the Spread of Ebola.</u> http://www.cdc.gov/vhf/ebola/travelers/ebola-screening-factsheet.html.
- [56] U.S. Department of Homeland Security. 2015. <u>DHS's Coordinated Response to Ebola</u>. www.dhs.gov/ebola-response.
- [57] New York City Department of Health and Mental Hygiene. "Health Department Conducts the Largest No-Notice Emergency Response Exercise in New York City History." NYC Health. August 1, 2014. www.nyc.gov/html/doh/html/pr2014/pr025-14.shtml.

- [58] U.S. Department of Homeland Security, Office of Health Affairs, National Biosurveillance Integration Center, Ebola Situation Report 9 February 2015.
- [59] Christensen, Jen. "Out of control: how the world reacted as Ebola spread." CNN.com. November 2014. http://www.cnn.com/interactive/2014/11/health/ebola-outbreak-timeline.
- [60] McClam, Erin. "Nancy Writebol, second American Ebola patient, arrives at Atlanta hospital." NBCNEWS.com. August 5, 2014. http://www.nbcnews.com/storyline/ebola-virus-outbreak/nancy-writebol-second-american-ebola-patient-arrives-atlanta-hospital-n173146.
- [61] Personal communication staff from the CDC Emergency Operations Center, Interview for HHS Ebola Lessons Learned Review, August 2015.
- [62] Centers for Disease Control and Prevention. "Preparing Healthcare Workers to Work in Ebola Treatment Units (ETUs) in Africa." Aug. 2015. http://www.cdc.gov/vhf/ebola/hcp/safety-training-course/.
- [63] Martin I. Meltzer, Charisma Y. Atkins, Scott Santibanez, Barbara Knust, Brett W. Petersen, Elizabeth D. Ervin, Stuart T. Nichol, Inger K. Damon, and Michael L. Washington,. Sept. 26, 2014. "Estimating the Future Number of Cases in the Ebola Epidemic Liberia and Sierra Leone, 2014-2015." Morbidity and Mortality Weekly Report, 63 (03): 1-14. http://www.cdc.gov/mmwr/preview/mmwrhtml/su6303a1.htm.
- [64] Centers for Disease Control and Prevention. "CDC Tightened Guidance for U.S. Healthcare Workers on Personal Protective Equipment for Ebola." CDC Newsroom. October 20, 2014. http://www.cdc.gov/media/releases/2014/fs1020-ebola-personal-protective-equipment.html.
- [65] Centers for Disease Control and Prevention. "35 U.S. Hospitals Designated as Ebola Treatment Centers." December 16, 2014. http://blogs.cdc.gov/safehealthcare/2014/12/02/35-u-s-hospitals-designated-asebola-treatment-centers.
- [66] Centers for Disease Control and Prevention. "Hospital Preparedness: A Tiered Approach." Feb. 2015. http://www.cdc.gov/vhf/ebola/healthcare-us/preparing/current-treatment-centers.html.
- [67] U.S. Department of Health and Human Services. "HHS Launches National Ebola Training and Education Center." July 1, 2015. http://www.hhs.gov/about/news/2015/07/01/hhs-launches-national-ebola-training-and-education-center.html.
- [68] U.S. Department of Health and Human Services. "35 U.S. Hospitals Designated as Ebola Treatment Centers." HHS News. December 2, 2014. http://www.hhs.gov/about/news/2014/12/02/35-us-hospitals-designated-as-ebola-treatment-centers.html.
- [69] Centers for Disease Control and Prevention. "CDC Increasing Supply of Ebolaspecific Personal Protective Equipment for U.S. Hospitals." CDC Newsroom. November 7, 2014. http://www.cdc.gov/media/releases/2014/p1107-ebolappe.html.

- [70] U.S. Department of Health and Human Services. "HHS Selects Nine Regional Ebola and Other Special Pathogen Treatment Centers." HHS.gov. June 12, 2015. http://www.hhs.gov/about/news/2015/06/12/hhs-selects-nine-regional-ebola-and-other-special-pathogen-treatment-centers.html.
- [71] CDC / National Center for Emerging and Zoonotic Infectious Diseases. "Ebola Response Update to the Vaccines and Related Biological Products Advisory Committee [by Rita Helfand, MD, Acting Deputy Director, NCEZID]." May 12, 2015.

  http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials /BloodVaccinesandOtherBiologics/VaccinesandRelatedBiologicalProductsAdvisoryCommittee/UCM448000.pdf.
- [72] Centers for Disease Control and Prevention. "2014 Ebola Outbreak in West Africa - Reported Case Graphs." Ebola (Ebola Virus Disease). http://www.cdc.gov/vhf/ebola/outbreaks/2014-west-africa/cumulative-cases-graphs.html.