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ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE

U.S. Department of Health and Human Services Ebola Response Improvement Plan

Based on Lessons Learned from the 2014–2016 Ebola Epidemic

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U.S. Department of Health and Human Services
Office of the Assistant Secretary for Preparedness and Response

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Introduction

In December 2013, the Ebola virus emerged in Guinea and then spread rapidly across West Africa. The resulting epidemic caused an estimated total of 28,000 suspected and confirmed cases, and claimed over 11,000 lives. The global community responded—though slowly at first, and ultimately worked effectively together to end the epidemic. As a partner in this international effort, the U.S. Department of Health and Human Services (HHS) made significant contributions to the response, both in controlling the international epidemic abroad and safeguarding the United States from further spread of the disease.

In an effort to learn from this unprecedented response effort, the Secretary of HHS asked a nonprofit research organization to review the Department's international and domestic responses to the Ebola outbreak. It convened an independent panel of subject matter experts to identify strengths and opportunities to improve the Department's preparedness and response efforts. The resulting document, *Report of the Independent Panel on the HHS Ebola Response*, was published in June 2016.

To guide its work in improving preparedness for subsequent public health crises, HHS developed an Improvement Plan. This plan, developed in response to the Panel's report, describes steps the Department will take or has already taken to address issues identified by the Independent Panel.

Improvement Plan

This Improvement Plan organizes each key priority and improvement action into six main categories. This organization allows for related activities to be considered together. These categories are:

- Global Health Security and Coordination with International Partners
- Incident Management and Operational Coordination
- Public Health and Healthcare Response
- Risk Communication
- Medical Countermeasures
- Response Funding

Each improvement action is followed by a list of the Operating or Staff Divisions responsible for the corrective action in brackets. The agency marked in bold is the designated lead.

1. Global Health Security and Coordination with International Partners

To improve coordination with International Partners and to continue supporting the Global Health Security Agenda, HHS will:

1.1. Support the World Health Organization (WHO) reform efforts that reorganize and improve its capabilities and operations for emergency response. [**Office of Global Affairs (OGA)**, U.S. Centers for Disease Control and Prevention (CDC), Office of the Assistant Secretary for Preparedness and Response (ASPR)]

1.2. Support the Global Health Security Agenda (GHSA), including assisting at least 31 countries to evaluate and strengthen their ability to implement the GHSA targets and other targets related to the International Health Regulations, including their ability to prevent, detect, and respond to urgent public health threats. [**CDC**, OGA, ASPR]

1.3. Confirm the U.S. government focal point within HHS with the responsibility for direct coordination and liaison with senior leadership at WHO to help plan and implement joint emergency response efforts. [**OGA**, CDC, ASPR]

2. Incident Management and Operational Coordination

To improve incident management and operational coordination, HHS will:

2.1 Codify how infectious disease emergencies are managed under the National Response Framework (NRF) through completing the Biological Incident Annex to the NRF and supporting efforts to finalize a Presidential Policy Directive for designating and defining the role of a lead federal agency for complex, non-traditional responses. As part of this effort, clarify the types of infectious disease incidents that would require a coordinated national response, and identify the thresholds for triggering such coordination, particularly for a high-consequence event/threat. Until or unless a separate HHS emergency response fund is created, identify mechanisms to fund such a response, including through suggesting criteria for a Stafford Act declaration. [**ASPR**, CDC]

2.2. Identify and maintain a cadre of senior career officials (SES or equivalent level) who have been involved in previous responses and can provide institutional memory and advice during public health emergency responses. [**ASPR**, CDC, Office of the Assistant Secretary for Health (OASH)]

2.3. Coordinate through the National Security Council (NSC) and with the Department of State, and the U. S. Agency for International Development to develop a U.S. government-wide framework for response to international public health emergencies. The framework should define a government-wide coordination structure for international response and the HHS role within this structure, and should also include provisions for managing a combined international and domestic event. [**ASPR**, OGA, CDC]

2.4. Draft a memorandum of understanding with the U.S. Department of Defense (DoD) that outlines how key aspects of DoD assistance to HHS, such as the transport of HHS staff and specimens in an international emergency, will be operationalized. [**CDC**, Immediate Office of the Secretary (IOS)]

2.5. Review how Department-wide responses to *international* incidents are routinely organized and led. This includes detailing the roles and authorities of ASPR, CDC, OGA and other HHS components during different international response scenarios. [**CDC**, ASPR, OGA, IOS]

2.6. Review administrative authorities and address obstacles to clearly define whether the Commissioned Corps Ready Reserve can be deployed for short notice responses. [**OASH**, Office of the General Council (OGC)]

2.7. Formalize a structure for obtaining confidential, external advice regarding the execution of a public health response in real time. External groups have often advised CDC, ASPR or other components during emergencies. These groups, which are independent and external, can help highlight perspectives and issues that may not be immediately apparent to those involved in the day to day response. A nimble, standing mechanism, including a working group of the National Preparedness and Response Advisory Board and/or the Advisory Committee to the Director of CDC, to execute this function, should be considered. [**ASPR**, CDC, OGC]

3. Public Health and Healthcare Response

To improve the public health and healthcare response, HHS will:

3.1. Pre-identify facilities that HHS can use for quarantine, isolation and treatment. In doing so, consider how many individuals may need to be simultaneously housed in such a facility, and whether the facilities need to be near hospitals with specific capabilities. [**ASPR**, CDC]

3.2. Review current evidence and codify evidence-based components of a comprehensive, multi-pronged approach for traveler screening for future Ebola or Ebola-like outbreaks, including: (1) actions to be taken on exit from affected countries for travelers to the U.S., (2) actions to be taken for screening travelers entering the U.S. from countries experiencing an outbreak, including, if needed, describing the process of limiting the number of points of entry, (3) how such efforts, if undertaken, would be staffed, (4) how travelers would be monitored for disease appropriate periods of time, once they arrive in the U.S. [**CDC**]

3.3. Develop an evidence-based interagency concept of operations (CONOPS) for the management of waste related to Category A agents; review the appropriateness of the Ebola classification. [**CDC**, ASPR]

3.4. Refine guidance for U.S. government and facility-level Personal Protective Equipment (PPE) stockpiling.

3.4.1. Incorporate outcomes from the ongoing HHS study initiated by the National Institute of Occupational Safety and Health and CDC on PPE use, burn rate, and stockpiling. [**CDC**, ASPR]

3.4.2. Fully coordinate and fund a science preparedness program within the Department to support research response initiatives. [**ASPR**, National Institutes of Health (NIH),CDC]

3.5. Develop mechanisms for involving private sector PPE manufacturers, and for other commodities in potential short supply, in the process of developing departmental recommendations to ensure that Departmental recommendations do not unnecessarily stress the supply chain. [**ASPR**, CDC]

3.6. In collaboration with U.S. federal agencies, develop a mechanism to coordinate the purchase and distribution of PPE and/or medical countermeasures by federal partners. [**ASPR**, CDC]

3.7. Determine whether additional strategies could be employed to ensure healthcare facilities participate in responding to future emerging public health threats. [**ASPR**, CDC]

3.8. Determine whether the Department should establish and maintain a cadre of response staff (both civilians and U.S. Public Health Service (USPHS) Commissioned Corps officers) that is trained and readily available to deploy internationally to provide clinical care. If so, define the size and scope of that cadre, language competencies required and the conditions for their deployment. [**ASPR**,OASH, CDC]

3.9. Document and codify all available surge mechanisms to augment staff (civilian and uniformed USG, Non-USG, and international) for use across HHS Operating and Staff Divisions for large event response support, to include how to efficiently access USPHS staff, establish interagency agreements with FEMA and others, pre-approve international agreements, hire professional organization staff, etc. Widely share the collected information with relevant OPDIV/STAFFDIVs. [**Office of the Assistant Secretary for Administration (ASA)**, ASPR, OASH, CDC, OGA]

3.10. Determine and implement the most feasible approach to using U.S. Public Health Service officers to support prolonged HHS emergency responses. [**OASH**, OGC]

3.11. Evaluate and simplify the processes to enact Direct-Hire Authority as a potential mechanism for surging personnel during responses to urgent public health threats.

[**ASA**, ASPR, OGC]

3.12. Leverage the quarterly meetings sponsored by the National Healthcare Preparedness Programs with their state, local, and territorial public health awardees to outline an effective outreach plan to delineate the role of the government and public health agencies and organizations during an emerging infectious disease response. [**ASPR**, CDC]

4. Risk Communication

To strengthen risk communications, HHS will:

4.1 Develop/codify a Department-wide strategy for communicating risk information to the public during any domestic or international public health emergency, urgent health threat, or health-related incident that may be perceived to pose a significant risk to healthcare providers or the public. The framework should institutionalize the use of crisis and emergency risk communication principles. [**Office of the Assistant Secretary for Public Affairs (ASPA),** CDC]

4.2. Identify and train a cadre of personnel from across HHS that have public health expertise and a thorough understanding of, and fluency in, health crisis and risk communications to serve as spokespersons during domestic or international public health and medical emergencies. This training can draw upon a body of work developed since the 9/11 terrorist attacks. [**ASPA**]

4.3. Develop a mechanism to augment steady state crisis and risk communication staff, as needed. [**ASPA**, CDC]

5. Medical Countermeasures

To improve development of medical countermeasures, HHS will:

5.1 Draft and implement an Emerging Infectious Disease Countermeasure Development Plan. [**ASPR/ Biomedical Advanced Research and Development Authority (BARDA),** NIH, CDC, Food and Drug Administration (FDA)]

5.1.1. Codify a process to rapidly determine the design and conduct of scientific studies while still allowing HHS agencies time and opportunity to offer ample input. **[NIH**, CDC, FDA, ASPR]

5.1.2. FDA should continue to review its implementation of processes for authorizing or licensing new countermeasures when the risk benefit ratio is dramatically shifted (e.g., as it was for Ebola) and continue to work with countermeasure developers, other international regulators, and other relevant USG partners. [**FDA**, NIH/ National Institute of Allergy and Infectious Diseases (NIAID), CDC, ASPR]

5.2. Continue current efforts to solicit input—supported by research and data—from across the Department and the scientific community on clinical trial designs for emerging infectious diseases. This may include development of manuscripts for peer-reviewed journals on the experiences of using randomized, placebo-controlled clinical protocols for vaccine candidates and adaptive common master protocols for therapeutic candidates, and the use of modeling to inform clinical trial design. [**NIH**, FDA, ASPR/BARDA]

6. Response Funding

To improve access to sufficient response funding, HHS will:

6.1 Continue to pursue Secretarial transfer authority to allow HHS to redirect existing funds in order to initiate and sustain response activities. [**Office of the Assistant Secretary for Financial Resources (ASFR),** ASPR]

6.2 Investigate pursuing appropriations for a standing Public Health Emergency Response Fund to enable HHS to begin responding to a potential public health crisis before it becomes a full-blown public health emergency. [**ASFR**, ASPR, CDC, OGA]

6.3 Consider whether additional legal authorities are needed to allow state and local government grantees to use unspent federal grant funds received under an HHS grant program to establish a reserve fund that could pay for the expenses of responding to public health crises and emergencies, with authorization from HHS. [**ASFR**, CDC, ASPR]

Conclusion and Way Forward

The scale and scope of HHS's response to the 2014–2016 Ebola epidemic were unprecedented. Internationally, HHS dedicated immense resources to help affected countries contain the epidemic, prevent disease propagation, conduct epidemiological investigations, and provide clinical treatment and support. Domestically, the Department spearheaded federal efforts to manage isolated Ebola cases and worked to keep the public informed. The vast resources, staff, and expertise that HHS committed are a testament to the Department's preparedness efforts to date.

The *Report of the Independent Panel on the HHS Ebola Response* identified important areas for improvement, which this plan is intended to address. In collaboration with partners and key stakeholders, HHS will continue to address the priorities and implement the actions described in this improvement plan to further enhance the Department's preparedness for and response to future urgent public health threats. Consistent with its statutory responsibilities, ASPR will be responsible for monitoring and coordinating actions to implement this improvement plan. The Department will publish progress reports semi-annually for at least the next year to delineate the progress on each active action item, and help coordinate both departmental and interagency activities where applicable.

HHS Ebola Lessons-Learned Review: Comparison of recommendations in the Independent Panel Report and the HHS Ebola Response Improvement Plan

Independent Panel Recommendations	HHS Improvement Actions and Key Priorities	Applicable Core Capability(ies)
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 Non-governmental organizations (NGOs) that operate in developing countries, in order to strengthen their ability to identify, report, and respond to urgent public health threats. (Finding #1)	**1.1.** Support WHO reform efforts that reorganize and improve its capabilities and operations for emergency response **1.2.** Support the Global Health Security Agenda, including assisting at least 31 countries to evaluate and strengthen their ability to achieve the GHSA targets and other targets relating to implementing the International Health Regulations, including through their ability to detect, prevent, and respond to urgent public health threats. **1.3.** Confirm the U.S. government focal point within HHS with responsibility for direct coordination and liaison with senior leadership at WHO to help plan and implement joint emergency response efforts.	• Long-Term Vulnerability Reduction • Screening, Search, And Detection • Operational Coordination • Public Health, Healthcare, And Emergency Medical Services

Independent Panel Recommendations	HHS Improvement Actions and Key Priorities	Applicable Core Capability(ies)
• 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)	**1.2.** Support the Global Health Security Agenda, including assisting up to 31 countries strengthen their ability to implement the International Health Regulations, including through their ability to identify, report, and respond to urgent public health threats.	• Operational Coordination • Public Health, Healthcare, And Emergency Medical Services
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. • HHS should rapidly resolve disagreements among HHS components regarding evaluation protocols for vaccines and treatments that are under development when an urgent public	**5.1.** Draft and implement an Emerging Infectious Disease Countermeasure Development Plan. **5.1.1.** Codify a process to rapidly determine the design and conduct of scientific studies while still allowing HHS agencies time and opportunity to offer ample input. [NIH, CDC, FDA, ASPR]	• Public Health, Healthcare, And Emergency Medical Services

Independent Panel Recommendations	HHS Improvement Actions and Key Priorities	Applicable Core Capability(ies)
health threat emerges. (Finding #7)	**5.2.** Continue current efforts to solicit input—supported by research and data—from across the Department and the scientific community on clinical trials design for emerging infectious diseases. This may include development of manuscripts for peer-reviewed journals on the experiences of using randomized, placebo-controlled clinical protocols for vaccine candidates and adaptive common master protocols for therapeutic candidates, and the use of modeling to inform clinical trial design.	
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) • 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	**2.3.** Coordinate through the National Security Council (NSC) and with the Department of State, and the U. S. Agency for International Development to develop a U.S. government-wide framework for response to international public health emergencies. The framework should define a government-wide coordination structure for international response and the HHS role within this structure, and should also include provisions for managing a combined international and domestic event. [**ASPR**, OGA, CDC] **2.4.** Draft a memorandum of understanding with the U.S. Department of Defense (DoD) that outlines how key aspects of DoD assistance to HHS, such as the transport of HHS staff and specimens in an international emergency, will be operationalized.	• Operational Coordination • Public Health, Healthcare, And Emergency Medical Services

Independent Panel Recommendations	HHS Improvement Actions and Key Priorities	Applicable Core Capability(ies)
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 pre-scripted 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	**2.1.** Codify how infectious disease emergencies are managed under the National Response Framework (NRF) through completing the Biological Incident Annex to the NRF and supporting efforts to finalize a Presidential Policy Directive for designating and defining the role of a lead federal agency for complex, non-traditional responses. As part of this effort, clarify the types of infectious disease incidents that would require a coordinated national response, and identify the thresholds for triggering such coordination, particularly for a high-consequence event/ threat. Until or unless a separate HHS emergency response fund is created, identify mechanisms to fund such a response, including through suggesting criteria for a Stafford Act declaration.	• Operational Coordination • Public Health, Healthcare, And Emergency Medical Services

Independent Panel Recommendations	HHS Improvement Actions and Key Priorities	Applicable Core Capability(ies)
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	**3.2.** Review current evidence and codify evidence-based components of a comprehensive, multi-pronged approach for traveler screening for future Ebola or Ebola-like outbreaks, including: (1) actions to be taken on exit from affected countries for travelers to the U.S., (2) actions to be taken for screening travelers entering the U.S. from countries experiencing an outbreak, including, if needed, describing the process of limiting the number of points of entry (3) how such efforts, if undertaken, would be staffed, (4) how travelers would be monitored for disease appropriate periods of time, once they arrive in the U.S.	• Screening, Search, And Detection • Public Information and Warning

Independent Panel Recommendations	HHS Improvement Actions and Key Priorities	Applicable Core Capability(ies)
messages for implementing screening procedures. (Finding #9)		
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.	**3.12.** Leverage the quarterly meetings sponsored by the National Healthcare Preparedness Programs with their state, local, and territorial public health awardees to outline an effective outreach plan to delineate the role of the government and public health agencies and organizations during an emerging infectious disease response.	• Operational Coordination

Independent Panel Recommendations	HHS Improvement Actions and Key Priorities	Applicable Core Capability(ies)
(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)	**3.7.** Determine whether additional strategies could be employed to ensure healthcare facilities participate in responding to future emerging public health threats.	• Public Health, Healthcare, And Emergency Medical Services
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)	**2.2.** Identify and maintain a cadre of senior career officials (SES or equivalent level) who have been involved in previous responses and can provide institutional memory and advice during public health emergency responses. **2.5.** Review how Department-wide responses to *international* incidents are routinely organized and led. This includes detailing the roles and	• Operational Coordination • Public Health, Healthcare, And Emergency Medical Services

Independent Panel Recommendations	HHS Improvement Actions and Key Priorities	Applicable Core Capability(ies)
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, 33]. 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)	authorities of ASPR, CDC, OGA and other HHS components during different international response scenarios. **2.7.** Formalize a structure for obtaining confidential, external advice regarding the execution of a public health response, in real time. External groups have often advised CDC, ASPR or other components during emergencies. These groups, which are independent and external, can help highlight perspectives and issues that may not be immediately apparent to those involved in the day to day response. A nimble, standing mechanism, including a working group of the National Preparedness and Response Advisory Board and/or the Advisory Committee to the Director of CDC, to execute this function, should be considered. **3.4.2** Fully coordinate and fund a science preparedness program within the Department to support research response initiatives. **3.9.** Document all available surge mechanisms to augment staff (civilian and uniformed USG, Non-USG and international) for use across HHS Operating and Staff Divisions for large event response support, to include how to efficiently access USPHS staff, establish interagency agreements with FEMA and others,	

Independent Panel Recommendations	HHS Improvement Actions and Key Priorities	Applicable Core Capability(ies)
• 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)	pre-approved international agreements, hire professional organization staff, etc. Widely share the collected information with relevant OPDIV/STAFFDIVs. **3.11.** Evaluate and simplify the processes to enact Direct-Hire Authority as a potential mechanism for surging personnel during responses to urgent public health threats.	
HHS should designate a lead entity to arbitrate the differing perspectives on research and development of vaccines and treatments	**5.1.1.** Codify a process to rapidly determine the design and conduct of scientific studies, while still	• Public Health, Healthcare, And Emergency Medical Services

Independent Panel Recommendations	HHS Improvement Actions and Key Priorities	Applicable Core Capability(ies)
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)	allowing HHS agencies time and opportunity to offer ample input. [NIH, CDC, FDA, ASPR] **5.2.** Continue current efforts to solicit input —supported by research and data—from across the Department and the scientific community on clinical trial design for emerging infectious diseases. This may include development of manuscripts for peer-reviewed journals on the experiences of using randomized, placebo-controlled clinical protocols for vaccine candidates and adaptive common master protocols for therapeutic candidates, and the use of modeling to inform clinical trial design.	
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	**5.1.** Draft and implement an Emerging Infectious Disease Countermeasure Development Plan: **5.1.1.** Codify a process to rapidly determine the design and conduct of scientific studies while still allowing HHS agencies time and opportunity to offer ample input. [NIH, CDC, FDA, ASPR] **5.1.2.** FDA should continue to review its implementation of processes for	• Public Health, Healthcare, And Emergency Medical Services

Independent Panel Recommendations	HHS Improvement Actions and Key Priorities	Applicable Core Capability(ies)
and treatments during an epidemic. (Finding #7)	authorizing or licensing new countermeasures when the risk benefit ratio is dramatically shifted (e.g., as it was for Ebola) and continue to work with countermeasure developers, other international regulators, and other relevant USG partners.	
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	**3.3.** Develop an evidence-based interagency concept of operations (CONOPS) for the management of waste related to Category A agents; review the appropriateness of the Ebola classification. **3.4.** Refine guidance for U.S. government and facility-level PPE stockpiling. **3.4.1** Incorporate outcomes from the ongoing HHS study initiated by the National Institute of Occupational Safety and Health and CDC on PPE use, burn rate, and stockpiling. **3.4.2** Fully coordinate and fund a science preparedness program within the Department to support research response initiatives. **3.5.** Develop mechanisms for involving private sector PPE manufacturers, and for other commodities in potential short supply, in the process of developing departmental recommendations to ensure that Departmental recommendations do not unnecessarily stress the supply chain.	• Logistics And Supply Chain Management

Independent Panel Recommendations	HHS Improvement Actions and Key Priorities	Applicable Core Capability(ies)
a potentially diverse range of urgent public health threats. (Finding #11)	**3.6.** In collaboration with U.S. federal agencies, develop a mechanism to coordinate the purchase and distribution of PPE and/or medical countermeasures by federal partners.	
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	**4.1.** Develop/codify a Department-wide strategy for communicating risk information to the public during any domestic or international public health emergency, urgent health threat, or health-related incident that may be perceived to pose a significant risk to healthcare providers or the public. The framework should institutionalize the use of crisis and emergency risk communication principles. **4.2.** Identify and train a cadre of personnel from across HHS that have public health expertise and a thorough understanding of, and fluency in, health crisis and risk communications to serve as spokespersons during domestic or international public health and medical emergencies. This training can draw upon a body of work developed since the 9/11 terrorist attacks. **4.3.** Develop a mechanism to augment steady state crisis and risk communication staff, if needed.	• Public Information and Warning

Independent Panel Recommendations	HHS Improvement Actions and Key Priorities	Applicable Core Capability(ies)
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	**2.7.** Formalize a structure for obraining	• Public Information and Warning

Independent Panel Recommendations	HHS Improvement Actions and Key Priorities	Applicable Core Capability(ies)
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)	confidential, external advice regarding the execution of a public health response, in real time. External groups have often advised CDC, ASPR or other components during emergencies. These groups, which are independent and external, can help highlight perspectives and issues that may not be immediately apparent to those involved in the day to day response. A nimble, standing mechanism, including a working group of the National Preparedness and Response Advisory Board and/or the Advisory Committee to the Director of CDC, to execute this function, should be considered. **4.1.** Develop/codify a Department-wide strategy for communicating risk information to the public during any domestic or international public health emergency, urgent health threat, or health-related incident that may be perceived to pose a significant risk to healthcare providers or the public. The framework should institutionalize the use of crisis and emergency risk communication principles. **4.3.** Develop a mechanism to augment steady state crisis and risk communication staff, if needed.	
HHS should determine whether it will maintain readily deployable medical personnel to treat	**3.8.** Determine whether the Department should establish and maintain a cadre	• Public Health, Healthcare, And Emergency Medical Services

Independent Panel Recommendations	HHS Improvement Actions and Key Priorities	Applicable Core Capability(ies)
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	of response staff (both civilians and USPHS Commissioned Corps officers) that is trained and readily available to deploy internationally to provide clinical care. If so, define the size and scope of that cadre, language competencies required, and the conditions for their deployment. **2.6.** Review administrative authorities to clearly define whether the Commissioned Corps Ready Reserve can be deployed for short notice responses. **3.10.** Determine and implement the most feasible approach to using U.S. Public Health Service officers to support prolonged HHS emergency responses.	

Independent Panel Recommendations	HHS Improvement Actions and Key Priorities	Applicable Core Capability(ies)
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)	**3.1.** Pre-identify facilities that HHS can use for quarantine, isolation and treatment. In doing so, consider how many individuals may need to be simultaneously housed in such a facility, and whether the facilities need to be nearby hospitals with specific capabilities.	• Public Health, Healthcare, And Emergency Medical Services
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	**6.1.** Continue to pursue Secretarial transfer authority to allow HHS to redirect existing funds in order to initiate and sustain response activities. **6.2.** Investigate pursuing appropriations for a standing Public Health Emergency Response Fund to	• Public Health, Healthcare, And Emergency Medical Services

Independent Panel Recommendations	HHS Improvement Actions and Key Priorities	Applicable Core Capability(ies)
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	enable HHS to begin responding to a potential public health crisis before it becomes a full-blown public health emergency. **6.3.** Consider whether additional legal authorities are needed to allow state and local government grantees to use unspent federal grant funds received under an HHS grant program statute to establish a reserve fund that could pay for the expenses of responding to public health crises and emergencies, with authorization from HHS, to the extent authorized under relevant HHS statutes, grant regulations, and policies.	

List of Acronyms

ASA	Office of the Assistant Secretary for Administration
ASFR	Office of the Assistant Secretary for Financial Resources
ASPA	Office of the Assistant Secretary for Public Affairs
ASPR	Office of the Assistant Secretary for Preparedness and Response
BARDA	Biomedical Advanced Research and Development Authority (HHS/ASPR)
CDC	U.S. Centers for Disease Control and Prevention
CONOPS	Concept of Operations
DoD	Department of Defense
FDA	U.S. Food and Drug Administration
FEMA	Federal Emergency Management Agency (DHS)
HHS	U.S. Department of Health and Human Services
IOS	Immediate Office of the Secretary (HHS)
NIAID	National Institute of Allergy and Infectious Diseases (NIH)
NIH	National Institutes of Health
OASH	Office of the Assistant Secretary for Health
OGA	Office of Global Affairs
OGC	Office of the General Counsel
OPDIV	Operating Division (HHS)
PHEMCE	Public Health Emergency Medical Countermeasures Enterprise
PPE	Personal Protective Equipment
STAFFDIV	Staff Division (HHS)
USG	United States Government
USPHS	United States Public Health Service
WHO	World Health Organization