
UNITED STATES GOVERNMENT GLOBAL HEALTH SECURITY STRATEGY

2019



TABLE OF CONTENTS

I. INTRODUCTION	5
VISION	5
PURPOSE	5
THE GLOBAL HEALTH SECURITY CHALLENGE.....	6
II. UNITED STATES GOVERNMENT APPROACH FOR GLOBAL HEALTH SECURITY	6
GOAL 1: STRENGTHENED PARTNER COUNTRY GLOBAL HEALTH SECURITY CAPACITIES	7
GOAL 2: INCREASED INTERNATIONAL SUPPORT FOR GLOBAL HEALTH SECURITY	9
GOAL 3: A HOMELAND PREPARED FOR AND RESILIENT AGAINST GLOBAL HEALTH SECURITY THREATS.....	10
III. CDC AND USAID APPROACHES TO ACCELERATE THE CAPABILITIES OF TARGETED COUNTRIES	11
TECHNICAL PRIORITIES	11
GEOGRAPHIC PRIORITIES	16
MONITORING, EVALUATION, SUSTAINABILITY, AND TRANSITION TO COUNTRY OWNERSHIP.....	17
IV. UNITED STATES GOVERNMENT GLOBAL HEALTH SECURITY ACTIVITIES	19
RESPONSE TO INTERNATIONAL OUTBREAKS	19
INFECTIOUS DISEASE RESPONSE IN HUMANITARIAN EMERGENCIES.....	20
RESEARCH	20
STRENGTHENING INTERNATIONAL BIOSAFETY AND BIOSECURITY	21
V. COORDINATION, ROLES, AND RESPONSIBILITIES	22
A. INTERAGENCY COORDINATION	22
B. AGENCY ROLES AND RESPONSIBILITIES	22
ANNEX I: PROGRESS TO DATE AND LESSONS LEARNED	26
PROGRESS TO DATE	26
LESSONS LEARNED	27
ANNEX II: RELATED UNITED STATES GOVERNMENT GLOBAL HEALTH PROGRAMS THAT SUPPORT GLOBAL HEALTH SECURITY OBJECTIVES	28
ANNEX III: REFERENCES AND RELATED TERMS	31

VISION

The United States, in close cooperation with its international partners, prevents, detects, and responds to infectious disease threats at home and abroad, whether naturally occurring, unintentional, or deliberate.

PURPOSE

The Global Health Security Strategy outlines the United States Government’s approach to strengthen global health security, including accelerating the capabilities of targeted countries to prevent, detect, and respond to infectious disease outbreaks.¹ Together with the National Security Strategy,² National Biodefense Strategy,³ and executive order on “Advancing the Global Health Agenda to Achieve a World Safe and Secure from Infectious Disease Threats,” the Global Health Security Strategy guides the Federal Government in protecting the United States and its partners abroad from infectious disease threats by working with other nations, international organizations, and nongovernmental stakeholders. The Global Health Security Strategy supports the National Security and Biodefense Strategies, and further describes how the United States will prevent, detect, and respond to infectious disease threats globally and domestically. The Global Health Security Strategy also delineates how the United States Government will achieve the National Security Strategy priority actions of “Detecting and Containing Biothreats at their Source” and “Improving Emergency Response” domestically as part of the global health security system.

1 Development of the Global Health Security Strategy was directed in the Fiscal Year 2018 Omnibus and the Joint Explanatory Statement notes: The strategy shall: (i) detail the role and responsibility of each relevant agency of the United States Government in implementing the strategy; (ii) include multi-year cost estimates for operations and programs necessary to implement such strategy, disaggregated by agency; (iii) describe the mechanisms for coordination and oversight of such programs; (iv) review lessons learned from previous efforts to promote global health security; and (v) identify any obstacles to the implementation of such strategy in policy and legislation, and include specific recommendations for addressing such obstacles.

2 <https://www.whitehouse.gov/wp-content/uploads/2017/12/NSS-Final-12-18-2017-0905.pdf>.

3 <https://www.whitehouse.gov/wp-content/uploads/2018/09/National-Biodefense-Strategy.pdf>.

THE GLOBAL HEALTH SECURITY CHALLENGE

Infectious disease threats have the potential to endanger lives and disrupt economies, travel, trade, and the food supply. Outbreaks do not respect national boundaries and can spread rapidly jeopardizing the health, security, and prosperity of the United States. It is in the national security interest of the United States to strengthen global health security and manage the risk of infectious disease outbreaks.

The increase in the number of naturally occurring outbreaks over the past 15 years (e.g., influenza, Ebola, Zika, and Rift Valley fever) and the risk posed by an accidental or deliberate release of pathogens highlights the critical need for robust prevention, detection, and response mechanisms. Infectious diseases can spread across species, and many human diseases have animal origins. Achieving global health security requires a sustained, coordinated, multisectoral approach that incorporates an understanding of the linkages between human, animal, and environmental health.

II. UNITED STATES GOVERNMENT APPROACH FOR GLOBAL HEALTH SECURITY

Promoting global health security to detect and mitigate outbreaks early remains a core tenet of our National Security Strategy. United States Government investments in global health security can help prevent the spread of human and animal infectious diseases and protect populations at home and abroad, including those serving in our Armed Forces. Furthermore, investments that focus on prevention and preparedness are far more cost-effective than responding to infectious disease epidemics. To maximize global health security and preparedness for infectious disease threats, all countries must address global health security challenges.

United States global health security investments complement and build upon global health assistance programs that the United States has long supported in developing countries. For more than 40 years, the United States Government has supported integrated maternal and child health programs that have contributed to an approximately 50 percent drop in under-5 mortality and a similarly dramatic reduction in maternal mortality. Over the past 20 years, the United States Government has expanded its leadership in global health, saving millions of lives through successful disease-specific global health programs, such as the Global Polio Eradication Initiative, the Presi-

dent's Emergency Plan for AIDS Relief (PEPFAR), and the President's Malaria Initiative (PMI) These programs are an expression of American values, and as noted in the National Security Strategy, the United States will continue to reduce human suffering and "support health programs that save lives." Moreover, many of these global health programs have provided an important foundation for attaining global health security. The direct and indirect outcomes of these global health programs—stronger local laboratory capacity and strengthened epidemiological capacity, along with healthier populations, decreased disease burden, economic prosperity, and greater stabil-

ity—allow nations around the world to sustain stronger health systems that are poised to contribute to global health security (see Annex 2 for more specific information on United States global health programs).

Distinct from its global health programs, the United States Government recognizes the growing need to address epidemic-prone infectious disease threats—whether naturally occurring, unintentional, or deliberate—that pose a risk to all countries. Global health security is the capacity to prevent, detect, and respond to infectious disease threats that can quickly spread across borders. At the core of global health security is a strong health system with the resources and personnel necessary to identify infectious disease threats and respond quickly before regional or global transmission. Global health security does not focus on specific infectious disease threats, rather the technical areas that comprise global health security are designed to identify a threat early, independent of the specific pathogen and

its mode of emergence. While global health security technical areas have been implemented for decades, it was only within the past 5 years—corresponding to an amplified risk of epidemic and pandemic threats—that the international community has codified them in internationally agreed metrics. Building on the foundation laid by many partnerships in global health, the United States has prepared this Global Health Security Strategy to provide guidance and an operational framework for current and future global health security engagement. With this new strategy, the United States recognizes the need to prioritize global health security and, specifically, the capacity to prevent, detect, and respond to infectious disease threats.

The United States Government approach to Global Health Security will pursue three interrelated goals: 1) strengthened partner country global health capacities; 2) increased international support for global health security; and 3) a homeland prepared and resilient against global health threats.

Goal 1: Strengthened Partner Country Global Health Security Capacities

Achieving global health security requires all nation-states to be capable of preventing, detecting, and responding promptly and effectively to health security risks and public health emergencies of international concern. To help those in need while protecting Americans at home and abroad, the United States will help partners achieve international global health security standards.

The need for each state to advance its global health security is widely recognized. The United States Government will continue to collaborate with partners, including countries, multilateral organizations, and nongovernmental stakeholders through the Global Health Security Agenda (GHSA) to strengthen and sustain capacity to prevent, detect, and respond to infectious disease threats. This includes working with partners to make progress toward achieving 2005 International Health Regulations (IHR) core public health capacities while supporting implementation and compliance with the Biological Weapons Convention (BWC),⁴ United Nations Security Council Resolution 1540,⁵ World Organization for Animal Health Performance of Veterinary Services Pathway,⁶ and other international frameworks.

4 Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction (BWC).

5 In April 2004, the United Nations Security Council adopted resolution 1540, which establishes obligations on all States to take and enforce effective measures to establish domestic controls to prevent the proliferation of nuclear, chemical, and biological weapons of mass destruction and their means of delivery.

6 The World Organization for Animal Health (OIE) Performance of Veterinary Services Pathway is a global program for the sustainable improvement of a country's veterinary services.

The United States Government will partner with countries, other donors, the nongovernmental sector, and regional and international organizations, to strengthen selected country capacities to prevent, detect, and respond to infectious disease threats, as well as advance scientific understanding of how these capacities can best be achieved. Activities will be multisectoral, leveraging the strengths of numerous United States departments and agencies, and will be consistent with current nationally and internationally accepted standards and frameworks for capacity development. Support for capacity building in selected countries is intended to be temporary, and include a transparent and systematic transition to sustain health security capacities by the partner country. The United States Government's support will be targeted based on global health security risks, policy priorities, and national security, and activities will be milestone-driven and time-limited.

For example, using the World Health Organization (WHO) Joint External Evaluation (JEE)⁷ process and associated indicators as a common set of metrics, the United States will help selected countries to improve their JEE scores. This assistance will contribute to the GHSA 2024 Target of more than 100 countries strengthening capacity in at least five technical areas to a level of "demonstrated capacity." The United States will encourage countries to achieve a level 4 or greater (i.e., core capacities are in place and sustainable); in countries with very low base capacity, the United States will encourage these countries to achieve a level 3 (i.e., capacities in place but sustainability has not yet been assured). Targeted approaches used by the Centers for Disease Control and Prevention (CDC) and the United States Agency for International Development (USAID) are outlined in Section III of this strategy.

The United States is also committed to serving as a leader when outbreaks exceed the capacity of an individual nation's ability to respond. As part of this role, the United States will work closely with affected countries, international organizations, and private and public partners, and will encourage other donors to provide resources. The United States Government will also continue to use and refine existing mechanisms for coordination to ensure an efficient, effective, and multisectoral response, and will leverage the vast technical expertise of the Federal Government and its partners to build health security capacity in the wake of infectious disease outbreaks.

Prevent: To prevent epidemics, countries require health systems that can provide routine services and strong veterinary and public health infrastructure that can address both endemic and emerging health threats. Important areas of work within this category include: National Legislation, Policy, and Financing; IHR Coordination, Communication, and Advocacy; Antimicrobial Resistance; Zoonotic Disease; Food Safety; Biosafety and Biosecurity; and Immunization. An additional capacity for the prevention of infectious disease threats is in-country research to develop new prevention measures, especially vaccines and diagnostics for identified threats.

Detect: Timely and accurate detection and reporting of infectious disease outbreaks and events are critical to controlling the course of the outbreak and avoiding large-scale epidemics. Important areas of work in this category include: National Laboratory Systems; Surveillance; Reporting; and Human Resources/Workforce Development. These activities build national capacities to detect, identify, report, and investigate health threats in both human and animal populations.

Respond: It is critical that countries have multisectoral emergency measures in place to respond to infectious disease events effectively. These measures include coordination mechanisms; emergency operations centers; communications infrastructure; agreements between multisectoral partners on animal and human health, security, and law enforcement (LE) authorities and other sectors; and frameworks for the deployment and management of medical and non-medical countermeasures. Important areas in this category include: Emergency Preparedness; Emergency Response Operations; Linking Public Health and Security/LE Authorities; Medical Countermeasures and Personnel Deployment; and Risk Communication. In addition, managing infectious disease threats at points of entry is critical to a country's capacity to control infectious disease threats, which do not respect international borders.

⁷ World Health Organization, Joint External Evaluation tool (JEE tool) - second edition, 2018.

Goal 2: Increased International Support for Global Health Security

Achieving global health security requires all countries to contribute to preventing, detecting, and responding to infectious disease. In addition to the contributions outlined in Goal 1, the United States will coordinate with partner governments, multilateral organizations, and the nongovernmental sector to promote sustainable donor and domestic financing to build health security capacity beyond the lifespan of United States Government's investments.

The United States will use bilateral, regional, and multilateral engagements to encourage countries to make health security a national priority, and to invest in their own domestic capacities. Such outreach is also critical for ensuring burden-sharing among donor countries, so that countries support capacity building outside their own borders. Additionally, the United States Government will encourage multilateral organizations and international financial institutions to commit to and invest in advancing global health security. The United States will demonstrate and advocate for inclusion of all relevant sectors to strengthen health security, including human, animal, and environmental health, as well as diplomatic, defense, security, finance, and research disciplines.

Bilateral and Regional Engagement: The United States will encourage new partner commitments to global health security through targeted bilateral and regional diplomacy. The United States will:

- in addition to supporting specific partners, as described in Goal 1, encourage all countries to prioritize their domestic health security capabilities and invest in building and sustaining these capacities;
- work with donor countries and regional organizations to coordinate plans and ensure efficient capacity building in third countries;
- advocate for an objective and transparent accountability framework that encourages donors and partners to fulfill existing commitments, including in multilateral forums; and
- work with host-country partners to strengthen financial and programmatic sustainability in health security capacity building.

Multilateral Engagement: The United States will help lead international efforts through the GHSA to advance health security priorities multilaterally, bilaterally, and domestically. The GHSA, launched in 2014 and re-affirmed in 2018, is a catalyst for progress toward a world safe from global health threats posed by infectious diseases, whether naturally occurring, deliberately released, or the result of an accident. It is a collaborative multisectoral initiative of countries, regions, international organizations, and the nongovernmental sector (including the private sector) to accelerate and optimize global health security.

In November 2018, the GHSA multilateral initiative was re-imagined and re-launched for a second 5-year term (2019–2024). The revised GHSA framework (hereafter GHSA 2024) sets a global target for implementation of global health security, seeking to drive robust commitments, action, and accountability. GHSA 2024 includes a renewed vision, mission, core principles, and mandate.⁸ It also establishes new and updated structures to enhance coordination, including a secretariat function, task forces, and revised Action Package working groups. The United States will maintain and expand its role in GHSA 2024 in a multisectoral way, and will:

- maintain leadership roles to drive actions of the steering group, Action Package groups, task forces, and other GHSA mechanisms;
- encourage existing GHSA member countries to make concrete political and financial commitments to advance GHSA 2024; and
- encourage non-GHSA member countries to join GHSA 2024 and make tangible political and financial commitments to strengthen global health security.

⁸ <https://www.ghsagenda.org/docs/default-source/default-document-library/ghsa-2024-files/ghsa-2024-framework.pdf?sfvrsn=4>.

The United States will also work through other multilateral channels, such as the G7 and G20, to ensure that health security remains a global, leader-level priority. The United States will leverage, as appropriate, the frameworks, tools, and capacity-building programs established by international organizations such as the World Health Organization, the Food and Agricultural Organization (FAO), the World Organisation for Animal Health (OIE), the World Bank Group, the Organisation for Economic Co-operation and Development, and regional development banks.

Nongovernmental Engagement: The United States will continue to partner with nongovernmental stakeholders to achieve JEE capacity-building goals and advance critical networks for global health security research and development. Nongovernmental stakeholders, including the GHSA Consortium (GHSAC), the GHSA Private-Sector Roundtable (PSRT), the Next Generation for Global Health Security Network (NextGen), and other organizations, are critical partners in building, maintaining, and sustaining international capacity. Nongovernmental stakeholders generate and implement solutions to global health security challenges and contribute expertise to fill health security gaps in crisis and non-crisis settings. The United States will:

- expand existing relationships and partnerships with the GHSAC, PSRT, and NextGen to achieve goals laid out in this strategy;
- expand existing and develop new partnerships with the nongovernmental sector that address identified gaps in strengthening global health security capacities; and
- encourage and facilitate concrete relationships and partnerships between other countries and the nongovernmental sector to close identified health security gaps.

Goal 3: A Homeland Prepared for and Resilient against Global Health Security Threats

The United States Government will continue to build more effective preparedness and response mechanisms to combat infectious diseases at home. This includes accelerated research on medical countermeasures, increased opportunities as appropriate and planning for clinical trials during emergency response, and better communications with affected populations on public health measures, including vector control and research goals. This also includes enhancing and sustaining critical health security capacities for epidemiology, surveillance, medical entomology, and laboratory diagnostics, among other technical areas. The United States Government will incorporate the lessons of previous outbreaks into planning and preparedness for preventing, detecting, and responding to infectious disease outbreaks.

The United States promotes and contributes to global health security through ongoing domestic activities that strengthen national preparedness. In May 2016, the United States underwent a JEE with 15 international evaluators and observers. The evaluation resulted in specific recommendations for strengthening core capacities. Even in technical areas that received the highest scores, the United States and international experts identified actions to strengthen and sustain these capacities.

Following the publication of the JEE recommendations, a multisectoral team of federal program leaders collaborated on actions to fill the most pressing gaps and challenges in national public health preparedness and response. The United States Health Security National Action Plan,⁹ published on October 18, 2018, summarizes and combines input from more than 13 federal departments and agencies that have programs relevant to the IHR and JEE frameworks.

⁹ United State Health Security National Action Plan: <https://www.phe.gov/Preparedness/international/Documents/jee-nap-508.pdf>.

The action items in the United States Health Security National Action Plan adapt and build upon existing programmatic activities in individual departments and agencies. The action items also leverage ongoing interagency collaborations such as the National Action Plan for Combating Antibiotic Resistant Bacteria and long-standing agreements between federal and state entities to increase laboratory capacities and enhance the collection and analysis of human, animal, food, and environmental health data. The United States will:

- document progress under the United States Health Security National Action Plan in annual reports as well as the annual self-assessment as required under the IHR using the WHO State-Party Self-Assessment Reporting Tool; and
- request assistance from the WHO and the Pan American Health Organization in 2020 to conduct a full-scale, follow-up external evaluation using the JEE tool.

III. CDC AND USAID APPROACHES TO ACCELERATE THE CAPABILITIES OF TARGETED COUNTRIES

Many departments and agencies contribute to GHSA. CDC and USAID have been the principal implementers of international GHSA capacity-building activities for the United States Government. The funding reflected in the Multi-year Cost Estimates table below, which is a multi-year cost estimate for operations and programs, will be used by CDC and USAID to continue to support GHSA partner countries. Through close coordination and drawing upon each agency's unique strengths, CDC and USAID will help countries to comply with the IHR by developing their capacity aligned with the metrics described in the WHO's JEE tool. Prioritization of activities will vary depending on the specific requirements of each country and will aim to maximize impact and ensure sustainability. Whenever possible, activities will be implemented with other countries and international organizations to maximize overall support for global health security capacity-building.

a. Technical Priorities

To date, the United States Government's technical priorities include working with other countries and international organizations to build partner country capacities across 16 JEE technical areas as outlined below. CDC and USAID support will focus on the specific technical areas identified in a review of selected countries' existing capacities and identified gaps, needs, and risks and consistent with their National Action Plans for Health Security.

National Legislation, Policy, and Financing: Having an adequate legal framework and sufficient funding to support and enable implementation of the IHR are essential elements of health security. The United States Government will help selected countries assess, adjust, and align legislation, policies, and administrative requirements for implementation in compliance with IHR. Activities could include helping countries:

- assess current laws, regulations, and policies to identify gaps and revisions needed for more efficient and effective implementation of IHR;
- recommend changes to laws, regulations, and policies to improve compliance with IHR; and
- prioritize domestic resource mobilization through national budgets and/or other mechanisms to implement IHR.

Antimicrobial Resistance: Antimicrobial resistance (AMR) is one of the biggest threats to global health and can reverse health gains across society. Many common infections that were once easily treated are becoming more resistant to the current antimicrobial medicines, resulting in prolonged illnesses and preventable deaths. Many of the same class of antimicrobial medicines are often used within human and animal populations, and inappropriate, non-judicious use contributes to resistance. Mitigating the threat of AMR will require coordinated action across multiple sectors and disciplines, with a broad range of stakeholders including the private sector.

Consistent with the United States Strategy on Combating Antibiotic-Resistant Bacteria, the United States Government will help selected countries use a multisectoral approach to develop and implement a national response to combat AMR. Activities could include helping countries:

- improve the capacity of laboratories to identify priority WHO AMR pathogens and perform susceptibility testing on them;
- prevent AMR transmission in health care facilities and in the community through infection prevention and control measures;
- train human and animal health care workers on basic infection prevention and control policy guidelines and practices;
- implement evidenced-based internationally endorsed guidelines on appropriate antimicrobial use within humans and animals; and
- implement drug quality surveillance.

Zoonotic Disease: Nearly 75 percent of newly emerging infectious diseases originate from animals, with more than 60 percent of infectious diseases currently circulating in people originally being of zoonotic origin.¹⁰ With more frequent and changing interactions between people, animals, and our shared environment, the risk of emerging and re-emerging infectious diseases, especially those of zoonotic origin, are a growing concern within the global health community. This technical area recognizes these risks and works to bring together the animal, human, and environmental health sectors to improve surveillance and reporting systems, communication, and to strengthen multisectoral mechanisms for preventing, investigating, and responding to these emerging health threats. Preventing epidemics can be partly achieved by stopping these pathogens at their source before they are able to spillover and amplify in humans and other animals.

The United States Government will help selected countries establish multisectoral mechanisms and policies to minimize the transmission of zoonotic diseases, including vector-borne diseases, between animals and human populations. Activities could include helping these countries:

- prioritize and address zoonotic diseases of greatest national concern or risk;
- establish or strengthen surveillance systems in the animal health and public health sectors for zoonotic diseases/pathogens identified as of greatest national concern, and detect emerging pathogens;
- conduct multisectoral risk assessments for zoonotic disease events;
- develop multisectoral, risk-based prevention strategies and response plans for the priority zoonotic diseases; and
- establish functional multisectoral mechanisms to coordinate the prevention, detection, and response to zoonotic disease threats, including diseases that are vector borne.

Food Safety: The food safety technical area recognizes the requirements for surveillance and response systems to foodborne disease and food contamination risks, including indicator- and event-based disease surveillance with supporting laboratory analysis. It also acknowledges the need for a national food safety emergency plan. To support these efforts, the United States Government will help selected countries strengthen their defense against foodborne illness. Activities could include helping countries:

¹⁰ Emerging Infectious Diseases Journal. No 2. February 2018: Zoonoses. Retrieved from: <http://wwwnc.cdc.gov/eid/page/zoonoses-2018>.

- develop or adapt an existing coordination mechanism with clear terms of reference to facilitate communication among public health, agriculture, food inspection, veterinary, and laboratory entities; and
- adapt existing surveillance and monitoring systems to include priority foodborne diseases.

Biosafety and Biosecurity: The biosafety and biosecurity technical area aims to reduce the risk of both the deliberate and accidental spread of dangerous pathogens to human and animal populations. Using a whole-of-government approach, the United States Government will strengthen biosafety and biosecurity systems and oversight frameworks that identify, secure, and safely monitor and store dangerous pathogens. The United States Government will also provide essential training to and share best practices with professionals to advance the safe and responsible handling and management of dangerous pathogens, while strengthening the culture of biosafety, biosecurity, and responsible conduct in the life sciences.

The United States Government will help selected countries establish a comprehensive national oversight program for biosafety and biosecurity. Activities could include helping countries:

- develop a comprehensive national biosafety and biosecurity system that maintains pathogen inventories in a minimal number of facilities;
- develop a cadre of biological risk management experts to train staff at their respective institutions;
- develop instructional materials and training for national officials on biological risk assessment and management; and
- establish biological risk management policies and practices (regular laboratory assessments, inventories of lab specimens) and common educational materials.

Immunization: The WHO estimates that vaccines help prevent nearly 2–3 million deaths per year. A functional health system requires a national immunization program that delivers vaccines, reaches marginalized populations, sustains the cold chain, and ensures ongoing quality control. Epidemic-prone diseases such as measles, cholera, meningococcal disease, typhoid, polio, and yellow fever are all vaccine-preventable, resulting in saved lives, beneficial economic and social impacts, prevention of introduction of cases to neighboring countries, and prevention of epidemics.

The United States Government will help selected countries strengthen their national immunization systems to improve their response to existing and new infectious disease threats. Activities could include helping countries to strengthen:

- vaccination programs against epidemic prone vaccine-preventable diseases;
- vaccination systems for diseases that are transferable from cattle, poultry, and domesticated animals to humans, such as influenza, anthrax, and rabies;
- vaccine cold chain throughout the country; and
- effectiveness and acceptability of vaccination campaigns during outbreaks (e.g., Ebola).

National Laboratory Systems: Diagnostics and laboratory confirmation are essential for proper outbreak containment. The United States Government will help selected countries develop and use a nationwide laboratory system for the public health and animal sectors that can safely and accurately detect and characterize pathogens that cause significant morbidity, mortality, and epidemic disease. Activities could include helping countries:

- train laboratory technicians in standard operating procedures for microbiological methods and specimen collection/referral;
- conduct an increased number of WHO, FAO, and OIE core tests on identified and collected outbreak specimens that are safely transported from intermediate levels in the country;
- develop and implement national quality laboratory standards and systems;

- strengthen laboratory networks and a tiered national laboratory system that may incorporate nongovernmental laboratories; and
- strengthen vector monitoring capacity in laboratories, including resistance studies.

Surveillance: Understanding the burden of disease within human and animal populations (both domestic and wildlife), in addition to having systems to identify new or previously unknown pathogens is essential to preventing large-scale epidemics. Knowing the epidemiological trends and having real-time data can facilitate a quicker and more efficient response. The United States Government will help selected countries strengthen their public health and animal health surveillance systems so that they can assess risks and identify and prioritize threats to public health and health security. Activities could include helping countries develop or enhance:

- surveillance systems for priority public health and animal diseases, syndromes, and events, and disease vectors that link communities with national-level authorities;
- capabilities to transmit standardized and timely electronic surveillance data from community, district, and regional levels of government; and
- immediate and weekly reporting of the highest-risk infectious diseases from the local level, including community health workers, and on an ad hoc basis.

Reporting: The United States Government will help selected countries strengthen timely, transparent, and accurate disease reporting according to WHO and OIE requirements and obligations under the IHRs. Activities could include helping countries:

- strengthen reporting systems and establish interoperability agreements, protocols, processes, and regulations governing reporting of internationally reportable human, zoonotic, and animal diseases at local, intermediate, and national levels; and
- implement efficient and timely reporting (through designated focal points) of internationally reportable human, zoonotic, and animal diseases.

Human Resources/Workforce Development: Developing national and frontline capacity is one of the most critical components for keeping outbreaks from becoming large-scale epidemics. The United States Government will help selected countries train and sustain skilled and competent community health workers and professionals across health sectors (including animal health) using multisectoral approaches in pre- and in-service training. Activities could include helping countries:

- strengthen programs to train field epidemiologists and disease detectives at national, regional, and community levels;
- work with higher education entities to create and implement curricula to promote a multisectoral approach to infectious diseases; and
- expand in-service training programs that address zoonotic diseases and the multisectoral approach at both national and sub-national levels, including community health workers; and extend pre- and in-service training to under-represented-field staff, such as medical entomologists.

Emergency Preparedness: Emergency preparedness is having the knowledge, capacities, and organizational systems to anticipate, respond to, and recover from emergencies. This includes a combination of planning, allocation of resources, training, exercising, and organizing to build, sustain, and improve operational capacities at national, intermediate, and local levels, based on strategic risk assessments. Activities could include helping countries:

- conduct risk assessments;
- develop multisectoral emergency response plans; and
- create standard operating procedures for effective multisectoral coordination.

Emergency Response Operations: All countries need coordination mechanisms, incident management systems, and emergency operations centers and procedures. These measures help countries shorten the time between early warning/detection to activation of response plans, and result in coordinated multisectoral responses and reduced health and societal consequences. Activities could include helping countries:

- develop standard operation procedures and train staff in emergency operations;
- establish and maintain national public health emergency operations centers or equivalent structures that can be activated in response to emergencies;
- conduct simulation exercises to test response operations capabilities at the national level, or activate national health response systems to respond to a major emergency;
- identify and train multi-disciplinary rapid response teams;
- strengthen emergency operations center integration with public health and animal health surveillance and laboratory information systems; and
- plan resilient communications for emergency response.

Linking Health and Security Authorities: It is critical that there are frameworks that outline the roles and best practices between and among human and animal health, law enforcement (LE), defense, and other personnel in times of infectious disease and health emergencies. Activities could include helping countries:

- establish protocols or agreements between human and animal health and security authorities that include roles, responsibilities, standard operating procedures, and information to be shared during emergencies;
- conduct public health emergency responses or exercises that include participation of security and LE authorities; and
- develop training opportunities and programs for security and LE personnel on topics related to prevention, detection, and response to infectious disease threats.

Medical Countermeasures and Personnel Deployment: The transfer of medical and non-medical counter-measures, as well as public health and medical personnel between international partners during a public health emergency is an important component of an effective response. In addition, countries need case management guidelines for priority epidemic-prone diseases and national-level medical countermeasure supply chain plans to codify how medical counter-measures (MCMs) are managed during emergencies. Activities could include helping countries:

- plan laws, regulations, and infrastructure, and deploy medical and non-medical counter-measures (e.g., personal protective equipment, disinfectant, sample collection kits);
- collaborate with other countries, and FAO, OIE, and WHO regional offices to facilitate cross-border resource deployment during emergencies;
- conduct simulation exercises to demonstrate sending or receiving MCM and health personnel;
- develop and make available case management guidelines for priority epidemic-prone diseases; and
- develop and test (through exercises or real-world events) national-level MCM supply chain plans.

Risk Communication: Countries need to build capacities in multisectoral and multifaceted risk communication to adequately respond to health emergencies. There must be real-time exchange of information and technical advice during outbreaks and emergencies so that communities and people can take protective and preventive actions. These measures comprise the full range of communication channels, including traditional and social media, mass awareness campaigns, health promotion, social mobilization, and community engagement. Activities could include helping countries:

- conduct rapid landscaping analyses before an emergency to assess systems that can support strategic behavior change communication, such as media, information and communication platforms, and existing community and social networks;

- develop emergency risk-communication plans based on existing data and prior simulated or actual testing in response to a health emergency;
- develop and disseminate risk-reduction messages, materials, and programs to mitigate the spread and impact of infectious disease outbreaks, including those caused by vector-borne disease; and
- implement community-based social mobilization during an emergency that engages local leaders in protective and preventive messaging and appropriate health-seeking behaviors.

Border Health Security: Ensuring that a country’s borders are protected from the importation or exportation of health threats is a vital security and LE consideration, both for the country and for the international community. A comprehensive approach to building border health security and mitigating the risk of international spread of infectious disease includes engagement at points of entry, in border regions, and among internationally mobile populations. Activities could include helping countries:

- improve capacities to prevent, detect, and respond to health events at air, sea, and ground points of entry, in accordance with the IHR;
- integrate points of entry into existing national public health surveillance systems and strengthen multisectoral point-of-entry partnerships for enhanced disease detection and response;
- enhance health security capacity in geographic areas at risk of international disease spread by understanding the movement of people and goods between countries; and
- build linkages with neighboring countries and across a region for public health information-sharing and collaboration, per the principles of the IHR.

b. Geographic Priorities

Through the end of Fiscal Year (FY) 2019, the United States Government will continue to principally support its 17 GHSA partner countries: Bangladesh, Burkina Faso, Cameroon, Cote D’Ivoire, Ethiopia, Guinea, India, Indonesia, Kenya, Liberia, Mali, Pakistan, Senegal, Sierra Leone, Tanzania, Uganda, and Vietnam. Limited United States Government funding may also be used to support other critical high-risk countries to fill key gaps in health security capacity. Beyond FY 2019, the United States Government will use an evidence-, risk-, and feasibility-based process to establish geographic priorities. Partnerships will change over time, with some countries reducing United States Government programs or transitioning from assistance, while other countries are added based on the availability of funds, health security risks, and other factors. The United States Government will consider the following factors when identifying geographic priorities:

- Human and animal health security gaps and risks, including progress made and progress possible.
- Partner-country willingness to engage in, contribute to, and sustain the implementation of health security capacities.
- United States diplomatic and national security priorities.
- Operational aspects of implementation, including safety and security of assets.

Multi-year Cost Estimates¹¹

\$ in millions	FY 2018	FY 2019	FY 2020¹²
CDC/Department of Health and Human Services			
Global Public Health Protection ¹³	108.2	108.2	149.8
Ebola Balances ¹⁴	80	50	-
USAID			
Global Health Security	72.6	100	90
Ebola Balances ¹⁵	100	38	TBD
Emergency Reserve Fund ¹⁶	35	2	-

CDC and USAID continue to obligate funding appropriated in FY 2015 (via Public Law 113-235) for Ebola Response and Preparedness to support global health security activities. Both agencies also have resources available that could be used to respond to an infectious disease emergency. For example, in FY 2019 (via Public Law 115-245), Congress established an Infectious Diseases Rapid Response Reserve Fund (IDRRRF) that CDC and certain other agencies within the Department of Health and Human Services (HHS) could use to contain an infectious disease threat.

c. Monitoring, Evaluation, Sustainability, and Transition to Country Ownership

Monitoring and Evaluation: The United States Government helps selected countries increase their capacities (and associated JEE scores) in priority technical areas outlined in the IHR Monitoring and Evaluation Framework,¹⁷ including as measured through the voluntary JEE and the mandatory IHR annual self-assessment, two quantifiable ways to measure a country's capacity.

11 United States Government activities described under the Global Health Security Strategy are subject to the appropriation and availability of current- and future-year funding.

12 Fiscal Year 2020 President's Budget Request.

13 A subset of these funds are used to directly support capacity building as part of GHSA. Of the \$108.2 million provided for Global Public Health Protection in FYs 2018 and 2019, \$50 million will support GHSA each year. Of the \$149.8M requested for in the FY 2020 President's Budget, \$99.762M would support GHSA and related CDC global health security programs.

14 These funds expire at the end of FY 2019. The FYs 2018 and 2019 levels are outlined in the CDC GHSA spending plan.

15 The FY 2018 and FY 2019 appropriations bills repurposed Ebola balances for the GHSA (\$100M in FY 2018, \$38M in FY 2019). The \$90M requested for global health security in the FY 2020 President's Budget will support GHSA and USAID's Emerging Pandemic Threats program. The allocation of resources between GHSA and Emerging Pandemic Threats is to be determined.

16 The FY 2018 and FY 2019 appropriations bills repurposed Ebola balances for the Emergency Reserve Fund.

17 WHO IHR Monitoring and Evaluation Framework – <https://extranet.who.int/sph/ihrmef>.

The monitoring and evaluation plan will track: 1) United States Government-funded outputs (e.g., training, technical assistance, and commodity support); 2) the outcomes in JEE-relevant capacities that United States Government investments build (such as public or animal health institutions strengthened, national laboratory systems created or strengthened); and 3) the impact that these capacities have on improving detection of and response to new outbreaks and preventing future outbreaks. Indicators have been developed and will be built upon and tracked for United States Government investment outputs, outcomes, and impact across all partner countries. Progress will be evaluated by a United States Government monitoring and evaluation working group.

Sustainability and Transition to Country Ownership: The United States Government will work with partner countries to outline strategies and criteria for transition to host-country sustainment of global health security activities. While the ultimate goal is full country ownership and financing of programs, systems, and human resources necessary to maintain a high level of health security, it is understood that different technical areas have different transition timelines. The United States Government may use a phased process to decrease capacity-building programs in partner countries. In addition, there may be a need for technical assistance on a periodic basis.

The United States Government will help partner countries develop sustainable, tailored transition frameworks. Transition plans will be developed early in the partnership with the goal of self-reliance on health security capacities, and ensuring coordination and communication with all stakeholders throughout the partnership. The phasing out of United States Government assistance will be accompanied by key host-government actions including: 1) active and effective implementation and monitoring of national plans for health security; 2) promoting public-private partnerships in health security; 3) using international financial tools, credits, or loans in support of national plans (where appropriate to do so); and 4) promoting improved domestic resource mobilization for priority health-security activities. It is envisioned that the partnerships will transition to relationships of collaboration, information sharing, and exchange of technical expertise, as appropriate.

The following is an illustrative transition scenario that will vary by country, funding availability, and other factors:

- a. **Intensive Support:** The United States Government provides intensive financial and technical support to countries across multiple or all technical priorities to build capacity to prevent, detect, and respond to infectious disease threats in compliance with obligations under the IHRs. This assistance may increase over time, corresponding with increasing country commitment, staffing, and the availability of United States Government funds.
- b. **Targeted Support:** As countries begin to achieve improved JEE capacities (e.g., a Level 3 or 4) across key technical areas, the United States Government will transition to less-intensive efforts across priority technical areas focusing instead on prioritized gaps identified by the JEE or support for a reduced set of technical areas.
- c. **Emergency Support:** At this stage, a country has increased its JEE scores and is capable of maintaining those scores in the absence of United States Government support and/or resources. However, as health security emergencies occur, the United States Government may need to provide support as a part of global efforts to limit the spread of infectious disease.

The United States Government will further consider reducing or increasing financial support via regular assessments using the following criteria:

- Country JEE scores (self-reported and via formal JEE) and compliance with the reporting obligations under the IHRs.

- Effective implementation of United States Government-funded activities.
- Changes in high-level support from partner country for planned activities.
- Changes in commitments from other donors.
- Changes to safety and/or security in country.
- Additional criteria outlined under geographic priorities in Section V.

IV. UNITED STATES GOVERNMENT GLOBAL HEALTH SECURITY ACTIVITIES

In addition to partner-country capacity building, the United States Government engages in a number of activities that directly complement and strengthen overall global health security. The activities described below are examples from numerous departments and agencies, and reinforce the United States’ multisectoral approach.

a. Response to International Outbreaks

Because an infectious disease can spread rapidly to all parts of the world, endangering lives and economies, the United States Government will continue to monitor and respond to international outbreaks through several mechanisms, including CDC’s Global Disease Detection Operations Center (GDDOC), CDC’s IDRRRF, and USAID’s Emergency Reserve Fund for infectious disease outbreaks (ERF). The GDDOC will continue to monitor disease outbreaks and other health emergencies of potential international importance, historically providing verification and early warning of more than 300 outbreaks per year. The IDRRRF, established by the Congress in FY 2019, is an emergency fund that CDC and other parts of HHS could use to rapidly mobilize in the early stages of an infectious disease threat. The ERF will be considered for use in response to an outbreak that is in the national interest to respond to an emerging health issue that poses severe threats to human health. Established in the FY 2017 Congressional Appropriation, the ERF was used for the 2017 Madagascar plague outbreak and the 2018 Democratic Republic of Congo Ebola outbreak in Equateur province. The United States will continue to work in partnership with other donors and international organizations to respond to outbreaks, including WHO, GAVI, CEPI, the World Bank, and the International Federation of the Red Cross and the Red Crescent Societies.

The United States Government will continue to deploy scientific experts to support outbreak response or support requests for technical expertise (e.g., antimicrobial resistance, Zika, monkeypox, and yellow fever). For example, the CDC may deploy technical experts through its Global Rapid Response Team (GRRT) and the WHO Global Outbreak and Response Network (GOARN). Since 2015, the GRRT has provided more than 17,000 person-days of emergency support in more than 75 countries. Separately, with support from USAID’s Emerging Pandemic Threats (EPT) program, WHO and FAO manage a stockpile of emergency non-medical commodities that includes items such as personal protective equipment, disinfectants, and laboratory supplies; and a small outbreak response fund for immediate use, if needed. In addition, USAID and CDC facilitate the work of the GOARN through technical and financial support. Finally, the United States and other partners support the FAO Emergency Management Center-Animal Health to plan and deliver emergency responses to zoonotic disease investigations and outbreaks, upon request from host countries.

b. Infectious Disease Response in Humanitarian Emergencies

Infectious disease outbreaks, such as water and vector-borne diseases, can occur during humanitarian disasters due to the breakdown of health services; the disruption of water, sanitation, and hygiene systems; the movements of people; the formation or expansion of internally displaced persons and/or refugees; and the overall lack of governance and security. Sometimes, infectious disease events, if serious enough (like the 2014–2015 West Africa Ebola outbreak), can provoke a humanitarian crisis by themselves.

When the Chief of Mission issues a disaster declaration, USAID's Office of United States Foreign Disaster Assistance (OFDA) assumes the lead United States Government coordination role for an international humanitarian response. When an infectious disease outbreak becomes a humanitarian response, OFDA serves as the lead coordinator for United States Government response efforts, with technical support from CDC and USAID's Global Health Bureau, and other departments and agencies as needed. OFDA may activate a response management team (RMT) based in Washington, D.C., and disaster assistance response teams (DART) in the affected locations to support the United States Government response.

Going forward, the United States Government, in partnership with other countries and international organizations, will strengthen country capacity for components of global health security to limit the spread of outbreaks in humanitarian crises, including workforce development, epidemiologic investigation, infection prevention and control, case management, risk communication, community engagement, surveillance, laboratory systems in both the public health and veterinary sectors, emergency operations, and ensuring that supply chains for emergency supplies reach high-risk and affected communities.

c. Research

Research is essential for understanding how pathogens spread and cause disease, and to generate safety and efficacy data to support regulatory decisions on MCM clearance, approval, licensure, and emergency use. Recent outbreaks of diseases such as Lassa fever, Ebola, Zika, and Nipah have highlighted gaps in the knowledge base needed to optimally stem the outbreak. These gaps can be addressed through the integration of infectious disease research into global preparedness and response activities. To close these gaps, the United States supports ongoing research into many infectious diseases and will plan, where feasible, for emergency response research, such as expeditiously implementing clinical trials of MCM for such epidemics. Research during an emergency response is often the only available and most effective opportunity for determining the safety and efficacy of a vaccine, therapeutic, or diagnostic (which may expedite licensure and access to safe, effective countermeasures).

Since 2015, global institutions such as the WHO and the World Bank, and public-private partnerships have been responding to deficiencies in research by ensuring integration of research into global health security preparedness and response efforts. The 2015 World Health Assembly-mandated WHO reform included the development of a WHO Research and Development Blueprint for pathogens with epidemic and pandemic potential.

The United States has an extensive scientific and technical research enterprise and emergency response research experience that can be leveraged to advance global health security preparedness, prevention, detection, and response. Where feasible, the United States Government will work with international partners to support an interdisciplinary, multisectoral approach to integrate epidemiological, diagnostic, clinical, and social science research into outbreak response. Specifically, the United States Government will support research in global health security to advance, for example:

- Preparedness: Work during inter-epidemic periods to enhance understanding of pathogens with pandemic potential and applied biosafety and biosecurity practices and procedures; support selected countries to develop research capacity and regulatory and ethical oversight and implementation in support of potential collaborative response research.
- Prevention: Develop vaccines or other mitigation methods against identified diseases with epidemic potential, including efforts to accelerate vaccine development processes, and communications and social sciences research to guide prevention messaging and behavior change initiatives.
- Detection: Improve or enhance diagnostic tests, laboratory equipment, and training to improve laboratory detection; strengthen resistance monitoring to identify research needs; and integrate surveillance networks into the health care system and at the human-animal interface.
- Response: Accelerate development and assessment of vaccines and therapeutics against outbreak pathogens as well as public health and outbreak mitigation measures. Plan rapid implementation of an emergency response research agenda to develop data to assess the safety and efficacy of medical countermeasures to reduce morbidity and mortality, accelerate the end of the outbreak, and support regulatory decision-making.

d. Strengthening International Biosafety and Biosecurity

Disease outbreaks can devastate the health of populations, diminish the food supply, overwhelm economies, destabilize political environments, and threaten national security. Such weakened states present the dual-risk of ungoverned spaces serving as incubators for terrorist organizations that may have access to dangerous pathogens. Disease outbreaks are usually natural occurrences; however, a less likely but potentially devastating scenario occurs when an outbreak is caused by the accidental release of dangerous pathogens or intentional dissemination of lethal agents. It is important to ensure that pathogens are safe from accidental release or from misuse by those intending to cause harm.

The United States approach to mitigating these vulnerabilities is carried out by its extensive support for global biosafety and biosecurity, which is a whole-of-government effort seeking to:

- ensure that especially dangerous pathogens are identified, held, secured, and monitored in a minimal number of facilities;
- strengthen biosafety and biosecurity best practices and operations at facilities housing dangerous pathogens;
- reduce the threat of terrorist acquisition and use of biological weapons;
- reduce the risk of unintentional exposure or release of pathogens and toxins using appropriate containment practices, safety equipment, and facility design and construction;
- reduce the risks posed by dual-use technology; and
- strengthen the culture of biosafety, biosecurity, and responsible conduct in the life sciences.

Biosafety and biosecurity are fundamental to human, animal, and environmental health. It is critical to employ biosafety and biosecurity in hospitals and other health care settings; food and agriculture; research and development; and drug and pharmaceutical and trade and transport industries. Recognizing the critical role for laboratory biosafety and biosecurity, the United States Government will continue to support global threat reduction programs that strengthen biosafety and biosecurity to prevent accidental release or intentional misuse of biological material.

V. COORDINATION, ROLES, AND RESPONSIBILITIES

The United States recognizes the importance and value of employing a multisectoral approach to prevent, detect, and respond to infectious disease threats. For the United States, actions to strengthen global health security are coordinated both domestically and internationally, leveraging the expertise of numerous departments and agencies.

a. Interagency Coordination

Global Health Security Agenda Interagency Review Council: In November 2016, Executive Order 13747¹⁸ established a GHSA Interagency Review Council (Council), consisting of representatives serving at the Assistant Secretary level or higher, from all relevant departments and agencies to carry out the responsibilities described in the executive order. The responsibilities of the Council include, but are not limited to issuing guidance on GHSA goals, objectives, and implementation; facilitating interagency multisectoral engagement; providing a forum for raising and resolving interagency disagreements on GHSA policy or implementation; reviewing progress in achieving GHSA commitments; and developing annual GHSA progress reports.

In the executive order, the heads of departments and agencies are tasked with making the GHSA and its implementation a high priority, including GHSA-related activities within their respective department and agencies' strategic planning and budget processes, and keeping the Council apprised of their GHSA-related activities. Departments and agencies are responsible for coordinating with one another on their programmatic functions with host governments, and GHSA country teams, implementers, and donors in host countries. The National Security Council (NSC) staff serves as the chair of the Council and regularly convenes departments and agencies to coordinate policy and programs and maintain awareness of GHSA implementation and diplomatic engagements.

United States Embassy Teams for Partner Country Capacity Building: At the country level, the ambassador convenes an interagency team that implements GHSA and develops and executes annual work-plans. This team reports progress on specific JEE metrics on a semi-annual basis to the Interagency Review Council and NSC staff. The progress reported informs the GHSA annual report. The Department of State and NSC staff convene the GHSA country teams, including the Ambassadors, at least once year to discuss work-plans, priorities, challenges, and successes.

b. Agency Roles and Responsibilities

Executive Office of the President Staff:

- NSC Staff: Coordinate and review global health security policy, including during outbreak response, through the process described in National Security Presidential Memorandum-4 of April 4, 2017 to provide strategic input and facilitate policy integration.
- Office of Management and Budget: Oversee budget development, execution, and implementation of budget policy and resource allocation for global health security activities across the Executive Branch.
- Office of Science and Technology Policy: Lead interagency science and technology policy coordination efforts and serve as a source of scientific and technological analysis and judgment for the President with respect to major policies, plans, and programs of the Federal Government.

¹⁸ Executive Order 13747 on Advancing the Global Health Security Agenda to Achieve a World Safe and Secure from Infectious Disease Threats.

Department of State:

- Lead diplomatic outreach in conjunction with other relevant departments and agencies to promote global health security with countries, regional and international organizations, development banks, multilateral bodies, nongovernmental stakeholders, and other relevant actors.
- Engage Chiefs of Mission, country teams, regional and functional bureaus to promote global health security with international and bilateral partners and facilitate GHS implementation and reporting.
- In emergencies, facilitate requests of assistance from the host government.
- Respond to requests for biocontainment transport for infected mission personnel, affected United States persons, and other eligible personnel.
- Advise Chiefs of Mission who retain Chief of Mission authority.

Department of the Treasury:

- Provide technical input on issues of health financing and sustainable financing for global health security.
- Engage in bilateral policy dialogue with ministries of finance on sustainable financing for health, which includes health security.
- Leverage equities with the multilateral development banks (e.g., the World Bank) and international financing institutions to advance policies that promote the health security agenda and investments in health security by beneficiary countries.

Department of Defense (DOD):

- Facilitate implementation and coordination of relevant DOD programs and activities that align with GHS and other global health security goals, particularly biosurveillance, biosafety, and biosecurity, military-to-military or military-to-civilian capacity-building efforts, and relevant research and development including that coordinated through the United States Government Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) priorities.
- In conjunction with other relevant agencies, coordinate and communicate with defense ministries on GHS and GHS needs and priorities, and work with partner-nation defense ministries and others to increase defense-sector representation in the GHS Multilateral Initiative. Advance global norms on the role of militaries and military-civilian collaboration in Global Health Security.
- For an emergency responder provide assistance and support in coordination with USAID's OFDA or HHS's Assistant Secretary for Preparedness and Response. In general, this involves providing unique response capabilities, such as logistics, transport, security, and medical evacuation and treatment, when critical capacity gaps cannot otherwise be easily filled by other departments and agencies.

Department of Interior:

- Implement and coordinate DOI programs to build capacity relevant to global health security, with a focus on the human-wildlife interface.
- Provide technical expertise on antimicrobial-resistant pathogens, and vector-borne and zoonotic diseases including plague, rabies, West Nile virus, Lyme disease, and avian influenza.
- Provide technical expertise on field and laboratory techniques for investigations of wildlife morbidity and mortality events as well as surveillance of wildlife diseases.

Department of Agriculture:

- Implement and coordinate USDA programs to build capacity relevant to global health security in the animal and wildlife sectors.
- Lead, in conjunction with other relevant departments and agencies, international engagement with ministries of agriculture and other government officials.
- Lead, in conjunction with other relevant departments and agencies, engagement with the OIE and the FAO on GHS targets and GHS issues.
- Conduct research and analyses and provide expertise on food safety and animal health, veterinary infrastructure, global animal disease-tracking, and risk management.

- Lead, in conjunction with other relevant departments and agencies, the United States Government research response to zoonotic diseases when the source of infection includes livestock and poultry, and work collaboratively with USAID, DOS, DOD, DHS, CDC, and NIH to lead development and implementation of a United States Government agricultural research agenda, such as development of veterinary MCM and vector control.
- Engage with international research institutions and global alliances to establish strategic research collaborations that help developing countries control and prevent diseases at the source.

Department of Health and Human Services:

- Lead, in conjunction with other relevant departments and agencies, international engagement with ministries of health and other relevant health security partners, and advise on bilateral and multilateral partnerships.
- Represent, in conjunction with other relevant departments and agencies, the United States in policy and diplomatic engagement with the World Health Organization.
- Engage domestically and internationally with other governments, industry, academia, professional organizations, and other nongovernmental entities to strengthen health security and respond to health emergencies of all types.
- Manage assessment, notification, and information-sharing through the IHR National Focal Point for potential public health emergencies of international concern and other events of international interest and emergency communications.
- In collaboration with other United States Government partners, accelerate development, procurement, and distribution of medical and non-medical countermeasures through the PHEMCE.

Department of Transportation:

- Facilitate the safe and efficient movement of people and goods in transportation, including the operation of the National Air Space.
- Facilitate and coordinate the safe transport of hazardous materials, including pathogens capable of causing disease.

Department of Homeland Security:

- Implement and coordinate DHS programs to contribute to domestic and global health security, with a focus on ports of entry, real-time biosurveillance, emergency response, and risk communications.
- Lead, in conjunction with other relevant departments and agencies, United States Government measures to protect against global health threats at United States borders and ports of entry.
- Provide regular biosurveillance updates and spot reports to federal, state, and local decision-makers to enhance awareness and early warning of emerging infectious diseases and acute biological events.
- Provide assessments of the impacts of global health threats on homeland security operations.

Environmental Protection Agency:

- Lead, in conjunction with other relevant departments and agencies, international engagement with ministries of environment and other government officials in this sector.
- Engage foreign governments and international organizations on improving drinking water and wastewater treatment; and pesticides, pesticide policy, and integrated pest management practices for vector control.

United States Agency for International Development:

- Implement and coordinate USAID programs to build capacity relevant to global health security.
- Lead, in conjunction with other departments and agencies, animal health, community preparedness, response, antimicrobial stewardship and infection prevention and control, emergency supply chain, risk communication, and multisectoral training (especially pre-service), including programming, technical assistance, and capacity building.

- Lead, in conjunction with other departments and agencies, in addressing infectious disease outbreaks through USAID programming (e.g., risk communication, supply chain, the Emergency Reserve Fund, and other relevant activities), technical assistance, and targeted commodity support.
- In the event that a large-scale public health emergency becomes a humanitarian emergency, USAID, through OFDA, will lead and coordinate the United States Government's response efforts, including providing response support (including but not limited to case management, coordination, logistics, and social mobilization).
- In crises of sufficient scale, deploy a Disaster Assistance Response Team, supported by a response management team at headquarters, to lead and coordinate United States Government's international response.

Federal Bureau of Investigation:

- Facilitate, with other relevant departments and agencies, efforts to identify and investigate potential covert biological threats.
- Establish protocols for joint investigations and information sharing among public health and law enforcement, including relevant threat information, domestic disease reporting, and health surveillance information.
- Engage international partners in developing protocols in respective countries to better identify when an infectious disease outbreak may be the result of a deliberate or malicious act.

Centers for Disease Control and Prevention:

- Implement and coordinate CDC programs to build capacity relevant to global health security.
- Lead, in conjunction with relevant departments and agencies, public health surveillance, laboratory, workforce, antimicrobial stewardship, infection prevention and control, and emergency-management capacity development, including technical expertise, training, and capacity building.
- Provide technical and scientific expertise to measure and evaluate infectious disease preparedness, including for vector-borne disease, and response capacity in countries.
- During an outbreak, leverage technical expertise and public health emergency leadership to ensure the efficiency and efficacy of the partner country, WHO, and the United States Government response.
- Engage with international research institutions and global alliances to establish strategic research collaborations to control and prevent diseases at the source.

National Institutes of Health:

- Lead, with other relevant departments and agencies, the preparedness, development, and implementation of the United States Government research agenda, including development of MCM.
- Provide, through Fogarty International Center and other NIH Institutes and Centers, research capacity in countries around the world through training fellowships, research grants, and experience working in/collaborating with NIH research programs.
- Advance, in conjunction with other departments and agencies, global response research initiatives, including the WHO R&D Blueprint and the World Bank Group program for strengthening clinical research capacity to prevent epidemics.
- During an outbreak, define and implement a research agenda, with other relevant departments, agencies, and international organizations.

Food and Drug Administration:

- Provide scientific technical support to the World Health Organization, and support regulatory authorities of affected countries to facilitate efficient development and expediting emergency use of investigational medical countermeasures, such as an Investigational New Drug and Emergency Use Authorization.
- Provide assistance as necessary with other relevant departments and agencies and working closely with manufacturers, to facilitate the development and availability of biologics (including vaccines), drugs, and devices (including diagnostic tests and personal protective equipment).

ANNEX I: PROGRESS TO DATE AND LESSONS LEARNED

a. Progress to Date

Multiple programs have supported the United States Government's global health security objectives for more than 15 years, through both bilateral activities and multilateral initiatives. As a result, outbreaks of Marburg virus, Ebola virus, dengue fever, and cholera, as well as clusters of initially unexplained illnesses and deaths were detected, assessed, and responded to in a timely and efficient manner.

A specific subset of bilateral capacity-building activities are linked to the United States Government's commitments to the GHSA. Since the launch of the GHSA, the United States Government has worked with 17 partner countries to strengthen capacity through programs and technical assistance, as measured by internationally accepted metrics. Through these partnerships, countries have developed and implemented 5-year action plans that address specific gaps in health security capability across 11 technical focus areas, ultimately reducing the likelihood of a disease outbreak and strengthening the capacity of partner countries to contain outbreaks when they do occur.

United States technical assistance to these countries helped to prevent or curtail the spread of numerous infectious disease outbreaks. In 2017, there were more than 25 reported public health emergencies in United States-assisted GHSA countries as well as other serious disease outbreaks and events. In most cases, partner countries led the responses to these outbreaks with the improved capacities built with the help of GHSA member countries, the United States, and other partners.

In Liberia, for example, health officials detected a cluster of unexplained illness among attendees at a funeral in April 2017. Within 24 hours, Liberia's Ministry of Health mobilized disease detectives to investigate the report and collect laboratory samples. The National Reference Laboratory quickly ruled out Ebola as the cause, and with assistance from United States Government partners, confirmed an outbreak of meningitis. Because Liberia built the ability to respond rapidly and effectively, the outbreak was controlled within a matter of weeks, limiting the toll to 31 cases and 13 deaths.

Examples of the outcomes achieved with United States Government investments in GHSA partner countries include:

- 16 countries detected dangerous pathogens using laboratory equipment and recently built capabilities.
- 13 countries enhanced surveillance systems for zoonotic diseases in humans, wildlife, and domesticated animals.
- 11 countries improved the ability to report public health threats internationally in a timely manner and/or expanded their geographic coverage to detect and report public health threats.
- 10 countries improved the ability of their public health workforce to prevent, detect, and respond to infectious disease outbreaks.

In addition to the specific country capacities built across all technical areas, achievements include but are not limited, to:

- Development and implementation of 5-year road-maps for achieving the GHSA targets and strengthening coordination among country partners.
- Development and implementation of an iterative monitoring and evaluation framework, including annual reports by GHSA country teams, so that the United States Government can demonstrate progress and identify areas of remaining need.
- Provision of technical expertise to key capacity-building lines of effort, including WHO JEEs and country-owned National Action Plans for Health Security (NAPHS).

- Support to complete JEEs in 16 of 17 GHSA-partner countries.
- Support for 8 of 17 partner countries to develop NAPHS, with 6 more plans currently being drafted.

Other achievements resulting from GHSA investments across each of the 11 technical areas (also known as “Action Packages”) in partner countries are summarized in the United States Government’s 2016 and 2017 GHSA annual reports.

b. Lessons Learned

Despite considerable progress, the United States Government has encountered challenges in the implementation of global health security activities. Based on these experiences, the following lessons have been documented to guide future implementation:

- The United States Government should conduct country-specific planning for health security activities based on capacity gaps.
- Activity implementation should be country-led and consider each partner country’s commitment to supporting sustainable capacity-building efforts, including through domestic financing and in-kind contributions.
- Regional initiatives and approaches can be leveraged to improve health security capacities, including regional networks of entomological surveillance.
- Successful partnerships with host countries, international organizations, other donor countries, and nongovernmental organizations are necessary to build health security capacity. These same partnerships are critical to ensure an effective, coordinated response to health emergencies.
- Clearly defined metrics, such as those outlined in the JEE, are important for measuring progress in global health security.
- The United States Government should take a multisectoral approach to global health security, including the linking of human, animal, and environmental health, and engagement of sectors such as security and finance ministries.
- Country planning should account for challenges in operational feasibility, including safety, security, and mobility of United States personnel and partners.

ANNEX II: RELATED UNITED STATES GOVERNMENT GLOBAL HEALTH PROGRAMS THAT SUPPORT GLOBAL HEALTH SECURITY OBJECTIVES

While not considered core global health security programs, the ongoing United States Government programs described below investment in and support activities that contribute to strengthening global health security. Controlling malaria, HIV, and tuberculosis, and eradicating polio are critical to reducing the burden of infectious diseases worldwide. Moreover, these global health programs strengthen laboratory capacity, surveillance, and increase human resource and other capacities, all of which support the objectives of the Global Health Security Strategy.

Pandemic influenza: Beyond the considerable harm wrought by seasonal influenza, an influenza pandemic could place extraordinary demands on public health and health care systems globally, causing millions to be affected by illness, hospitalizations, or death. Preparing for such a threat is an important priority for the United States Government, the World Health Organization, and countries around the world. To prepare for the threat of an influenza pandemic and continually respond to seasonal influenza disease, the United States Government works with partner countries to establish, expand, and maintain multisectoral influenza surveillance and laboratory capacity, helping develop global and local pandemic plans and influenza-prevention policies, supporting targeted research projects to address critical needs, building the evidence base for decisions on influenza vaccine program expansion, and ensuring timely detection, reporting, and sample-sharing of viruses that have pandemic potential. These efforts contribute to improved influenza vaccine strain selection and diagnostic tests for both pandemic and seasonal influenza, and strengthen laboratory capabilities to manage influenza and other respiratory viral pathogens.

Polio: The United States Government provides technical and programmatic assistance to the global polio laboratory network, including critical diagnostic services and genomic sequencing of polioviruses to help guide disease-control efforts in many countries. This includes support for implementation of laboratory procedures that have increased sensitivity to detect and confirm new polio infection. Other new laboratory procedures help countries overcome specific operational challenges, enable more rapid detection of wild poliovirus, and accelerate response to importations or spread of virus. Additional efforts include technical assistance to laboratories implementing environmental surveillance for polio detection. The United States Government funds facility and community-based surveillance for polio (and other diseases), including support of surveillance medical officers (SMO) who investigate outbreaks of polio and other diseases at the district level and who are often the first responders in emergencies. Polio diagnostics, vaccine programs, data systems, and case investigation are key aspects of broader health security aims. Through networks of nongovernmental organizations, community volunteers are trained to identify cases of acute flaccid paralysis and rapidly report them to SMOs, thus reducing the time from onset of disease to investigation and response. The volunteers, who have the trust of their communities, are also trained in community mobilization and given skills to convince parents to vaccinate (e.g., convert refusers to acceptors) and to conduct risk communication and promote safe health behaviors.

Tuberculosis: Tuberculosis (TB) is the leading cause of death from an infectious disease, and drug-resistant (DR) TB is the leading cause of death among all antimicrobial-resistant pathogens. As drug resistance evolves and spreads, global gains in combatting TB are at risk. Efforts to strengthen the diagnosis, treatment, and prevention of TB and DR-TB also support broader global health security goals. The United States Government

helps countries develop comprehensive networks capable of diagnosing and monitoring all forms of TB, including DR-TB and TB in people living with HIV (PLHIV). With United States Government support, these networks develop and use appropriate diagnostic tools; strengthen functional specimen transport and referral networks; implement high-quality laboratory management systems; support logistics and supply chains; and strengthen monitoring and evaluation systems. United States Government programs aim to ensure that all individuals at risk for TB and DR-TB are screened, diagnosed, and cured. This is accomplished through screening approaches based on risk prioritization, expanded access to rapid diagnostic technologies able to detect DR-TB, and patient-centered care with better and shorter treatment regimens. In addition, the United States Government builds the capacity of countries to collect, manage, and use high-quality data that link laboratory and TB and DR-TB surveillance systems and promote rapid diagnosis and initiation of treatment. To prevent TB and DR-TB transmission and infection, the United States Government supports facility-based interventions that reduce the risk of infection for health care and laboratory workers, patients, and visitors, and community-based approaches to limit transmission among households and within provider settings. Infection control interventions are prioritized in antiretroviral therapy (ART) clinics and other facilities where TB preventive therapy is a routine part of HIV care and people with active TB may come into contact with PLHIV. PEPFAR-supported programs include TB screening and treatment and provision of TB preventive therapy for patients on ART.

President's Emergency Plan for AIDS Relief: PEPFAR was designed with a clear beginning, middle, and end to its direct foreign assistance investments as it accomplishes its outcomes-based mission in partnership with the host country and community, controlling the HIV/AIDS pandemic one community, one country, and one region at a time. The United States Government has invested more than \$80 billion in the global HIV response and saved more than 17 million lives, prevented millions of new HIV infections, transformed the global HIV response, and created the roadmap to controlling the pandemic as countries contribute more and more to their responses. By focusing resources where the HIV burden is the heaviest and the potential impact the greatest, the United States Government, through PEPFAR, has accelerated progress toward HIV epidemic control and delivered remarkable results. PEPFAR has also built health infrastructure and capacity to promote the Global Health Security Agenda and has been leveraged for response for many outbreaks since its inception. PEPFAR has helped train nearly 270,000 health care workers to deliver and improve HIV care and other health services, creating a lasting infrastructure that enables partner countries to confront current and future health challenges. In 2017–2018, PEPFAR invested nearly \$900 million on horizontal, above-site health systems strengthening (HSS), including more than \$141 million for laboratory systems promoting a strong platform of health security. These efforts have strengthened the ability of countries with high HIV prevalence to manage other outbreaks, such as Ebola, avian influenza, and cholera, ultimately enhancing global health security and protecting America's borders.

Malaria: United States Government programs that help prevent, diagnose, and treat people who have malaria also support broader global health security objectives. Under PMI and consistent with other federal malaria programs, the United States Government's objective is to work with partner countries and organizations to reduce malaria deaths and substantially reduce malaria morbidity, toward the long-term goal of elimination. Under the PMI, the United States Government directly contributes to the scale up of proven malaria prevention and control tools, including insecticide-treated mosquito nets, indoor residual spraying, intermittent and preventive treatment for pregnant women, seasonal malaria chemoprevention, and diagnosis by malaria microscopy or rapid diagnostic test with treatment for confirmed malaria cases with artemisinin-based combination therapies. Under PMI, important investments are also made in operations research; country capacity to collect and use information; insecticide and anti-malarial drug resistance; behavior change, communication, and social mobilization; and building country capacity and health systems. In countries approaching elimination of the disease, the United States Government works with national malaria programs to deploy evidenced-based elimination tools and approaches. Complementary to country programming, the United States Government also supports upstream malaria research, including malaria vaccine development, new insecticides and insecticide-based tool development, and new antimalarial drug development.

Health Systems Strengthening: Well-performing health systems are responsive, resilient, and adaptive to a wide range of challenges, including natural and man-made disasters. The United States Government’s work in HSS complements and contributes to the core elements of global health security. For example, HSS efforts help develop the information systems required for effective surveillance and reporting, including the organizational and behavioral responsibilities that promote timely use of data and information. HSS supports health workforce systems that hire and manage all cadres of health workers, including those (such as epidemiologists) that may be needed to improve health security. HSS builds the pharmaceutical regulatory and management systems required for combating antimicrobial resistance, including practices that promote stewardship and rational use of medicines, and ensure product quality such as secure supply chains and drug-quality surveillance. In addition, the United States Government’s HSS work helps health financing systems optimize resources, including those required to address infectious disease threats. United States Government HSS efforts develop quality improvement processes that ensure that health staff are competent and that facilities have the resources (equipment, supplies, personnel, and funds) to deliver high-quality services and prevent infections. Quality improvement programs also enable teams to identify and solve issues to prevent and respond to emergencies more effectively. Finally, building strong community health systems has proven critical for health security as communities are on the frontlines to prevent, detect, and respond to the public health threats affecting their members.

ANNEX III: REFERENCES AND RELATED TERMS

Action Packages: A concept developed to facilitate regional and global collaboration toward specific GHSA objectives and targets. The purpose of Action Packages and the underlying prevent-detect-respond framework is to: 1) focus international discussion on specific, coordinated actions in support of the GHSA; 2) highlight measurable approaches that countries can adopt to accelerate, monitor and report GHSA progress; and 3) provide a mechanism by which countries can make specific commitments and take leadership roles in the GHSA. The Action Package concept has been updated for GHSA 2024 (2019–2023), distinguishing between Action Package technical areas, all of which remain priority areas for capacity building, and Action Package working groups, which are working groups convened by multiple GHSA members to address specific technical areas, which may overlap with Action Package technical areas.

Biological Weapons Convention: The first multilateral disarmament treaty banning the development, production and stockpiling of an entire category of weapons of mass destruction, which entered into force on March 26, 1975.

Global Health Security: The capacity to prepare for, detect and respond to infectious disease threats and reduce or prevent their spread across borders. At the core of global health security are strong health systems with the resources and personnel needed to identify threats, respond quickly and prevent the spread of infectious diseases.

Global Health Security Agenda: A growing partnership of more than 65 nations, international organizations, and nongovernmental stakeholders to help build countries' capacity to create a world safe and secure from infectious disease threats and elevate health security as a national and global priority.

Global Health Security Agenda Consortium: A voluntary and open collective of nongovernmental entities that are dedicated to promoting values of collaboration, excellence, innovation and commitment in implementing the Global Health Security Agenda and promoting adherence to the IHR and the World Organization for Animal Health Performance of Veterinary Services Pathway, the Alliance for Country Assessments for Global Health Security and IHR Implementation, and the BWC and United Nations Security Council Resolution 1540.

International Health Regulations (IHR) 2005: A legally binding instrument of international law that has its origin in the International Sanitary Conventions of 1851, concluded in response to increasing concern about the links between international trade and the spread of disease (cross-border health risks).

Joint External Evaluation: A voluntary, collaborative, multisectoral process to assess country capacity to prevent, detect and rapidly respond to public health risks occurring naturally or due to deliberate or accidental events.

National Action Plan for Health Security: A country owned, multi-year planning process that can accelerate the implementation of IHR core capacities, and which captures national priorities for health security, brings sectors together, identifies partners and allocates resources for health security capacity development.

Next Generation Network: The NextGen engages and facilitates contributions by emerging scholars, scientists and professionals from government and nongovernmental institutions to the Global Health Security Agenda and other global health security projects.

Performance of Veterinary Services Tool: A tool created by the World Organisation for Animal Health to assist veterinary services to establish their current level of performance; identify gaps and weaknesses in their ability to comply with OIE international standards; form a shared vision with stakeholders (including the private sector); and establish priorities and conduct strategic initiatives.

Private Sector Roundtable: The mission of the Global Health Security Agenda PSRT is to mobilize industry to help countries prevent, detect and respond to health-related crises and strengthen systems for health security. The PSRT serves as the focal point for companies seeking to address these challenges.

Public Health Emergency of International Concern: An extraordinary event that is determined, as provided in the IHR to: 1) constitute a public health risk to other nations through the international spread of disease and; 2) potentially require a coordinated international response.

United Nations Security Council Resolution 1540: In 2004, the United Nations Security Council decided that all states shall refrain from providing any form of support to non-state actors that attempt to develop, acquire, manufacture, possess, transport, transfer, or use nuclear, chemical, or biological weapons and their means of delivery, in particular for terrorist purposes.