

National Health Security Strategy Evaluation of Progress, 2015–2018







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ASPR

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EXECUTIVE SUMMARY

Every four years, the U.S. Department of Health and Human Services (HHS), Office of the Assistant Secretary for Preparedness and Response (ASPR) prepares an Evaluation of Progress (EOP) on the state of national health security in the United States. The EOP summarizes progress made during the implementation of the quadrennial National Health Security Strategy (NHSS) and informs the needs to be addressed in the subsequent NHSS.

Our nation has made **significant progress** in the past four years on many of the major dimensions of preparedness and response. This progress can be seen at all levels of government. However, it has not been uniform across all states or regions, nor has it occurred equally on all critical dimensions of preparedness and response.

As we conclude the 2015-2018 NHSS cycle, we must also prepare for risks on the horizon from an evolving, diverse threat landscape with the potential to disrupt our public health and health care systems and inflict injury and loss of life. These 21st century threats include severe natural disasters, emerging and pandemic infectious diseases, terrorism, and potentially catastrophic risks posed by nation-state actors, revisionist powers, and roque regimes.

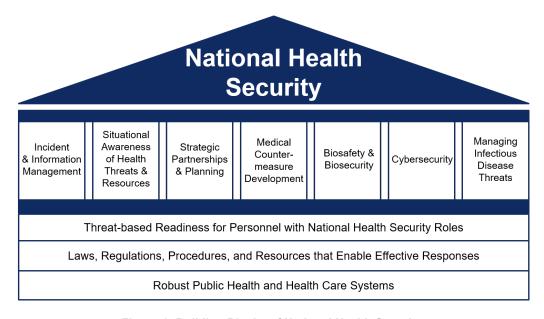


Figure 1: Building Blocks of National Health Security

Public health and medical preparedness and response is supported through all levels of government—federal, state, local, tribal, and territorial (SLTT), and in collaboration with the international community. This work relies on the many contributions made by private nonprofit and for-profit organizations. Through formal and informal collaborative relationships, the public and private sectors build preparedness and response capabilities within local communities, across states, and nationally.

Following are brief highlights of national health security progress areas, challenges, and threats:

Incident and Information Management: This capability area refers to federal, state, and local response leaders and groups understanding and adhering to standardized approaches, which allows them to expediently manage response efforts. The nation's incident and information management capability has become the strongest and most improved component of health

security over recent years.¹ Local health departments (LHDs) have increasingly emphasized medical countermeasure (MCM) and community preparedness activities such as emergency simulations, drills, and exercises to enhance the nation's incident management capabilities. Significant gains have also been made in public information and warning. An emergency alert test in 2016 showed more than 90 percent of the U.S. population was able to receive public information and warnings through commercial television, radio broadcast stations, and cable television systems.²

Due to several preparedness initiatives, more than 90% of the U.S. population was able to receive public information and warnings in 2016 through standard communication services.

However, leaders recognize further improvements must be made to effectively and securely deploy critical public information to targeted recipients and communities. For example, planning should ensure that all members of an impacted community have equal access to emergency support and services, including individuals with access and functional needs, such as persons with disabilities, as well as individuals with limited English proficiency and older adults, who are protected under federal law from discrimination in certain emergency situations.

Health Situational Awareness: Activities such as drills and exercises have made major contributions to federal and SLTT preparedness and response capabilities. The Centers for Disease Control and Prevention's (CDC) Public Health Emergency Preparedness (PHEP) grant funding is a means by which these national efforts have been better developed at the state and local levels for greater coverage and system effectiveness. They have also highlighted the need for refining epidemiological, laboratory, and health information systems, which can more immediately identify threats to national health and welfare. The United States will continue efforts to improve laboratory systems across the nation, including the territories and across the world's under-resourced countries.³ The United States will also continue efforts to improve situational awareness across the human, animal, and environmental sectors and their respective threats to human health.

Strategic Partnerships and Planning: Community collaboration, planning, and engagement improved significantly nationwide. The majority of LHDs have established partnerships with other emergency agencies in their respective locales, and local Emergency Medical System (EMS) teams are participating in Health Care Coalitions (HCCs) at increasing rates.⁴ Engagement of LHDs with local volunteer and private groups has also increased significantly. In

Since 2013, community partnerships for emergency preparedness have seen a significant improvement of **22.4%** nationally.

addition, the Combating Antibiotic Resistant Bacteria Accelerator (CARB-X) Program, which promotes the development of new antibacterial drugs, vaccines, and diagnostics, is a successful model for public-private partnerships.⁵

Personnel Training and Capabilities: CDC PHEP and ASPR's Hospital Preparedness Program's (HPP) support of integrating LHDs, health care personnel, and other key local groups into HCCs has advanced unified training and improved coordination efforts during emergency responses. While 82 percent of LHDs are currently members of HCCs, there has not been significant growth in recent years.⁶ As of 2016, only 10 states have developed or are developing a formal access program to enable private sector health care personnel and supplies to enter restricted areas during disasters.⁷ The National Disaster Medical System (NDMS) has adopted the "Total Team Concept" approach for HHS' deployable NDMS Teams. NDMS personnel who maintain jobs in the civilian sector during non-emergency times train together in the units in which they'll respond to emergencies. More HCCs are involving NDMS personnel in emergency exercises.

MCM Development and Management: New antibiotics, vaccines, therapeutics, and diagnostics are vital to our ability to respond to existing and developing threats. The Biomedical Advanced Research and Development Authority (BARDA), along with the National Institutes of Health's (NIH's), National Institute of Allergy and Infectious Diseases (NIAID), play a leading role in this effort by, for example, focusing MCM development on countering chemical, biological, radiological, and nuclear (CBRN) threats; antibiotic resistance; and pandemic influenza. Since 2015, BARDA and its partners have brought a total of eight new MCMs for CBRN threats for Food and Drug Administration (FDA) approval. Since 2014, CDC has submitted three Emergency Use Authorizations (EUAs) and three 510(k)s to FDA for approval of diagnostic tests to detect biothreats and emerging infectious diseases. These include diagnostic tests for Ebola virus, Zika virus, Variola virus (smallpox), Rickettsia virus, and Nonvariola orthopox virus.

Biosafety and Biosecurity: Life sciences research and biotechnology activities protect Americans from infectious diseases. Biosafety refers to the use of specific practices, safety equipment, and specially designed facilities to ensure that workers, the community, and the environment are protected from biological hazards. Biosecurity measures prevent unauthorized possession, loss, theft, misuse, diversion, manipulation, and intentional release of biological pathogens. Since 2015, the US Government's implementation of the Federal Experts Security Advisory Panel (FESAP) and Fast Track Action Committee on Select Agent Regulations (FTAC-SAR) recommendations have included actions, regulatory changes, and guidance to:

- Improve biosafety and biosecurity;
- Develop measures to increase material accountability and oversight;
- Strengthen security-awareness education and promotea culture of responsibility; and
- Optimize inspection processes and incident reporting.¹¹

According to the Trust for America's Health, 47 state laboratories provided biosafety training and/or information on training courses for their sentinel clinical laboratories, and 47 state laboratories, including the District of Columbia, reported having a biosafety professional during the past four-year period.¹²

Cybersecurity: Accidental or intentional disruption of a hospital's computer system can cause providers to lose the ability to access patient information, monitor patients' conditions, and control medical equipment. In 2016, a ransomware virus infected the network of a Maryland-based health system, impacting 10 hospitals and more than 250 outpatient centers. ^{13, 14} In May 2017, the WannaCry ransomware cyber-attack affected 200,000 computers in 150 countries.

To protect against future cyber-attacks, Congress passed the Cybersecurity Information Sharing Act (CISA) of 2015, which authorizes companies to develop and monitor methods to counter cyber threats and encourages them to voluntarily share cyber threat indicators and defensive measures with government, private entities, and other companies. In response, HHS has led the development of an inter-governmental effort to develop protective measures to deploy throughout the health care sector. Although CISA was enacted and work has been underway, the United States must continue to advance efforts to be prepared for evolving cyber threats.

Managing Infectious Disease Threats: Increasing globalization, coupled with the ease of international air travel, means an emerging pathogen from anywhere in the world can rapidly

become a public health emergency within the United States (e.g., Ebola virus and Zika virus outbreaks). In late 2014, the Global Health Security Agenda (GHSA) was launched to address these potential threats. The CDC and U.S. Agency for International Development (USAID) are working with international organizations to build capacity in select countries to improve the ability of these countries to prevent, contain, and stop infectious disease outbreaks before they spread to and threaten other countries. Additionally, over 50 countries have endorsed adoption of the GHSA goals and program objectives. CDC's Laboratory Response Network (LRN) enables the United States to detect biological threats and emerging infectious diseases quickly and accurately. LRN laboratories performed tests on over 67,000 specimens for Zika virus and nearly 3,000 specimens for other potential threat agents. Nearly 85% of the U.S. population lives within 100 miles of one of the 130 LRN laboratories located around the United States.

Challenges and New Threats – Informing the NHSS 2019–2022: Great progress has been made over the last four years. Nevertheless, our nation faces diverse and rapidly evolving health security threats, which are identified in the priorities of the NHSS 2019-2022.

Threats posed by **nation-state actors, revisionist powers, and rogue regimes** have the potential to disrupt our society and efficient delivery of health care.

Areas of concern include:

- Increased risk of inter nation-state conflict;
- Heightened threat of nation-state and non-nation-state use of weapons of mass destruction;
- Increased frequency and diversity of reported disease outbreaks, and greater risk of infectious diseases crossing international borders;
- Increased frequency and severity of cyber-attacks by adversaries, some specifically targeting health care;
- Increased risk of the use of chemical or biological weapons by state and non-state actors; and
- More frequent and severe extreme weather events within the United States.

An evolving threat landscape compels us to assess risks to national health security and prioritize actions in a strategic and comprehensive manner. As part of this process, the EOP will inform the NHSS 2019–2022 and Implementation Plan to ensure the nation continues to advance its capabilities to save lives and protect America.

1. NATIONAL HEALTH SECURITY EVALUATION OF PROGRESS

1.1 Introduction

Every four years, the U.S. Public Health Service (PHS) Act requires an evaluation of the nation's progress on public health emergency preparedness and response goals. ¹⁶ Each EOP informs the development of the next quadrennial NHSS and its priorities. Its findings are pivotal to identifying issues, threats, and concerns that need new or adjusted levels of investment.

Our nation's health emergency preparedness and response efforts are organized by federal and SLTT governments. They combine resources from multiple government sectors and work with community organizations and private nonprofit and for-profit health care organizations through an array of formal and informal collaborative relationships.

The EOP's findings inform the future direction of the nation's health security and goals later outlined in the

SLTT governments have the primary responsibility of responding to emergencies for their respective jurisdictions. The federal government provides complementing support to SLTTs, typically when SLTTs' resources are at risk of being overwhelmed by the emergency.

While federal agencies assist SLTTs with response efforts, a number of federal initiatives prepare SLTTs in advance to better respond to emergencies. By surveying emergency experiences across all SLTTs, federal agencies can accumulate and share lessons learned with SLTTs through these initiatives. These initiatives offer program funds as well as technical assistance.

Local and state government responses to disasters and emergencies can involve numerous public sector departments, including law enforcement, fire departments, EMS, local public health departments, and public hospital and trauma centers. They can also involve a range of volunteer or community groups such as the American Red Cross, community-based organizations serving older adults and people with disabilities, disability networks, and private for-profit organizations like hospitals and related health care service providers.

Other community organizations (public or private) may also volunteer to assist during emergencies, albeit with sometimes hard-to-quantify resources and capabilities since emergency response planning is not their first order of business. Bringing these organizations together to coordinate and exercise for emergency preparedness is a complex challenge for SLTT leaders, but one they address regularly to engage all potential partners that can help support a better coordinated and resourced response.

1.2 Information Sources for the Evaluation of Progress Report

ASPR national health security staff analyzed information from carefully selected sources to provide a comprehensive overview of trends and identify factors behind the progress, gaps, and challenges observed. Four general sources of information were used:

- A review and synthesis of the more comprehensive National Health Security Preparedness Measurement Initiatives;
- A review of the key federal programs, drawing from program descriptions and progress reports;

- In-depth interviews, Delphi reviews, and listening sessions with subject matter experts from across the field, who were asked about current issues, progress, challenges, and emerging or changing priorities; and
- Extensive literature reviews of peer-reviewed journals, academic sources, news sources, response groups, and other respected groups to capture data trends and findings on significant developments in public health emergency preparedness.

The national health security/public health emergency preparedness measurement initiatives reviewed included:

- The National Health Security Preparedness Index (NHSPI);1
- CDC's annual "National Snapshot" Reports;¹⁷
- The National Association of County and City Health Officials' annual survey of preparedness coordinators;⁶
- The HHS Office of Disease Prevention and Health Promotion/Healthy People 2020 (HP2020) topic on "Preparedness"; 18 and
- Findings from GHSA and the World Health Organization's (WHO) Joint External Evaluation (JEE) mission reports, which are assessments of a country's ability to detect, report, respond to, and contain infectious disease outbreaks.^{3, 19}

The PHS Act requires that the NHSS evaluates progress on the five following preparedness programs and activities:

- ASPR's HPP;
- CDC's PHEP:
- ASPR's NDMS;
- Collective efforts for advancing influenza vaccine development, tracking, and security;
 and
- Alignment of the BARDA and NHSS strategic plans for MCM development.

This EOP also provides examples of *return on investments* (ROIs) or accomplishments achieved as a result of the public funds invested in these preparedness programs and activities.

2. NATIONAL-LEVEL PROGRESS AND ACCOMPLISHMENTS

Over the past four years, our nation has made significant progress on the critical elements of preparedness and response performance. This progress is demonstrated at all levels of government (federal and SLTT), although it is not uniform across all states nor is it uniform across all dimensions of performance.¹

A number of federal preparedness initiatives help champion, finance, and offer technical leadership for many of these efforts. Some assistance is provided by federal agencies

partnering with other federal agencies, and some is provided by federal-to-private sector collaborations. The large majority of support offered by federal preparedness programs is given directly to SLTTs.

In its latest annual update, the 2018 NHSPI found that while the United States saw improvement in the overall ability to respond to disasters and health emergencies on a national level over the past four years, these improvements were not evenly distributed across the 50 states. At present, there is a difference of 31 percent in preparedness capabilities between the most and least prepared states.¹

There is a 31% gap in preparedness capabilities between the most and least prepared states.

Many states have shown modest improvement on multiple measures. Some states, however, have declined. Twelve states, predominantly in the Deep South and Northern Mountain regions, have trailed or lost ground compared to the national average. States that exceed the national average are predominantly found in the Northeast, Upper Midwest, and Western Pacific regions.¹

The factors that influence and contribute to these trends are numerous and diverse. They include differences in state-by-state public revenue, socioeconomic conditions, federal funding, geographic location (which influences the types and severity of natural threats), population density, urbanization, subject matter experts (to advocate for and lead programs), health care resources, and the health care infrastructure.

2.1 Incident and Information Management Has Seen Significant Improvements

Incident and information management has seen significant improvements in recent years according to both the CDC and NHSPI.^{1, 17} This progress reflects an expanding appreciation for how critical this capability is, including the simulations and response exercises that help refine the capability.

More LHDs and HCCs are participating in these exercises, thereby thoroughly integrating groups into community response networks and providing better connectivity across the local, state, and federal jurisdictions.

As this work continues, the goal is to expand local participation in emergency simulation exercises to include more local community leaders, local organizations, schools, and other segments of the health care delivery field. The MCM assets of LHDs are also increasingly factored into response exercises.

Improvements have also been made in information management which is the ability to provide information to the public during disasters that can help them stay safe and protect their health. For example, the CDC's Health Alert Network (HAN) works with federal and SLTT partners to create an interoperable platform where important public health information is shared and disseminated. Over 90 percent of state populations are now covered by these state-based HAN programs.²⁰

2.2 Advances Have Been Made in Health Situational Awareness

When a new public health threat emerges, the first awareness of it may be provided by a variety of sources such as hospital health information systems, EMS/first responders, epidemiologists,

animal or public health laboratories, private physician offices, the military, and international organizations. Sifting through this vast sea of information to discern relevant phenomena from irrelevant or false alerts is a daunting task. Advancements have been made in epidemiological, laboratory, and health information systems at local, state, federal, and international levels to more immediately identify threats to public health and welfare as they emerge. Significant progress has been achieved through the use of various systems, tools, and methodologies. The various systems include the National Syndromic Surveillance Program, the CDC Epidemiology and Laboratory Capacity, the Advanced Molecular Detection, BioWatch drills and exercises, and the Laboratory Response Network – Chemical.

CDC's PHEP grant funding is a means by which these national efforts are better developed at the state and local levels for greater coverage and system effectiveness. As with the other capabilities, we find geographic variation in the implementation of these situational awareness programs, requiring increased effort in underperforming geographic regions to achieve better coverage and awareness capabilities across the entire country²¹.

2.3 New Strategic Partnerships Established and Community Engagement Expanded

There have been significant improvements at the national, state, and local levels in building community engagement, collaboration, and key strategic partnerships to advance public health emergency preparedness. As noted earlier, according to the NHSPI, there has been a 22.4 percent improvement between 2013 and 2017. Nearly every aspect of emergency preparedness and response relies on the extensive network of partnerships that exists between federal

An **extensive network of partnerships** is the foundation of virtually all facets of emergency preparedness and response.

and SLTT governments, non-government organizations (NGOs), and health care and related enterprises.

The HPP and PHEP grant programs have prioritized the formation of these partnerships through their support of HCCs. The HCCs—through which LHDs come together with hospitals, EMS, police and fire fighters, and NGOs—offer the means for communities to identify common concerns, conduct simulations and exercises, and respond more quickly and effectively.

The majority of HCCs now have LHDs and hospitals well-established among their memberships, with about 82 percent of LHDs being members of their local HCC.⁴ After a steady increase, the rate of participation has leveled off in the last two years, prompting the need for further attention. Attention has also been placed on improving participation rates of EMS/first responders in their local HCCs, as these rates are lower than those of LHDs.



Figure 2: National Participation Rate of HCC Core Members

Private sector groups can play significant roles in emergencies. Some states and locales are considering the use of private clinical provider groups as a way to help expand clinical care provisions during emergencies. Currently, only ten states are pursuing formal access programs

as a means for private sector personnel (and supplies) to enter disaster zones.⁶ Fortunately, this area has begun to receive greater attention. Examples of successful partnerships include:

- The NDMS program has supported its teams joining state and local joint-training exercises. This will give all parties insight into how personnel can complement each other during emergencies when NDMS teams are deployed.
- Federal agencies, in partnership with experts from professional organizations, industry, academia, and NGOs, developed educational resources and guiding principles for strengthening the culture of biosafety, biosecurity, and responsible conduct.
- Through the CARB-X Program (Figure 3), federal agencies came together and reached out to key private sector groups to create a partnership that leverages private sector funds to support the development of new antibacterial drugs, vaccines, and diagnostics.



Figure 3: CARB-X Initiative

While progress has been significant, challenges remain. An example of next-order challenges includes how to better supply community members with essential prescriptions in the period immediately following a disaster. Another example involves health departments and health care providers working together with emergency responders, pharmaceutical companies, and community organizations to better understand the problem of opioid misuse, thereby responding in a more effective way.

2.4 Investments Have Been Made in Building and Maintaining Response Personnel

Funding received from HPP and PHEP grant programs enables local health care organizations and personnel to train to better handle public health emergencies, including medical surge. In addition, the NDMS and Medical Reserve Corps (MRC) programs explicitly offer critical emergency personnel to SLTTs and contribute to building personnel capacity to advance national health security. NDMS teams consist of civilian health care personnel who can be mobilized as intermittent federal employees to provide direct patient care or help fill gaps in critical personnel needs. The MRC (Figure 4), a national



Figure 4: Medical Reserve Corps

network of professionals who volunteer to assist during emergencies, is also more frequently included in local-level exercises.

First responders, especially EMS, are key to the successful management of any emergency due to the critical importance of immediate care. They are actively recruited to join LHDs and hospitals in HCCs for comprehensive preparedness training. Policy initiatives work to reinforce these programmatic efforts. For example, an HP2020 objective involves increasing the number of states with state line protocols or triage guidelines for EMS during mass casualty situations. ¹⁸ This will enhance all response personnel's capabilities during a public health emergency.

2.5 Biosafety and Biosecurity Have Been Improving

Biosafety and biosecurity are longstanding priorities that receive considerable attention. With the advent of genetic engineering and synthetic biology, risks in the biological laboratory are changing. Biosafety and biosecurity are responding to protect workers, the public, and the environment while promoting responsible research using these novel technologies. Laboratories maintain a constant schedule of inspections, and most state laboratories require their staff to take laboratory biosafety and biosecurity training courses on a regular basis. 12 Regulatory programs, such as CDC's Import Permit Program and



Figure 5: Biosafety and Biosecurity

the Federal Select Agent Program, also help reinforce safe laboratory practices.²² Since 2015, federal government agencies involved in life sciences research have collaborated on innovative reforms to improve key aspects of biosafety and biosecurity.

Pursuant to the implementation of FESAP and FTAC-SAR recommendations, enhanced biosafety and biosecurity included:

- Implementing new training for Customs and Border Protection personnel to improve how packages being imported into the United States are handled when they contain a known or suspected select agent or toxin;
- The development of a Best Practices Checklist for Departments and Agencies to use when considering an expansion or construction of high containment laboratory space;
- Redesigning the National Select Agent Registry to include an online portal that allows registered entities to communicate and share information readily with the program; and
- Redesigning the S3: Science, Safety, and Security portal to provide a single, coordinated portal for scientists, laboratory staff, policy makers, and the public to locate and link to existing federal and non-federal resources on biorisk management.²³

In October 2015, HHS established the HHS Biosafety and Biosecurity Coordinating Council, an intradepartmental group established by the HHS Immediate Office of the Secretary, which provides a mechanism to share best practices, enhance visibility across HHS agencies, and coordinate biosafety and biosecurity policy development as well as oversight activities. The HHS Biosafety and Biosecurity Coordinating Council promotes strong biosafety and biosecurity systems which are of paramount importance for protecting the nation's health, conducting quality research, and upholding public trust.

In addition, HHS continues to work with scientific institutions around the country to improve biorisk management and to ensure research is conducted safely and securely. Efforts have been made to improve oversight of dual use research of concern (DURC). DURC is defined as life sciences research that, based on current understanding, can be reasonably anticipated to provide knowledge, information, products, or technologies that could be directly misapplied to pose a significant threat with broad potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security.

A new policy, the *HHS Framework for Guiding Funding Decisions about Proposed Research Involving Enhanced Potential Pandemic Pathogens* (HHS P3CO Framework) provides a mechanism for federal review and addresses a specific subset of dual use research. Together, the HHS P3CO Framework and the DURC Policies help preserve the benefits of life science research while minimizing potential biosafety and biosecurity risks.

The use of current best practices for biosafety, biosecurity, and biocontainment are essential for national and global health security, and for the safe and secure pursuit of life sciences research. The US Government participated in international outreach, bilateral engagements, and assistance activities aimed at implementing the United Nations Security Council resolution 1540 (UNSCR 1540) which addresses threats deriving from access to, or use of, chemical, biological, and nuclear weapons, related materials, and means of delivery by non-state actors. Domestically, through implementation of FESAP and FTAC-SAR recommendations, the U.S. Government strengthened the implementation of UNSCR 1540 obligations and required measures with regard to accounting, securing, and physically protecting biological agents and related materials. This is further supported by actions pursuant to obligations under the Biological Weapons and Toxins Convention and the G7 Global Partnership.

2.6 MCMs are Receiving Priority Attention

The development of new vaccines, therapeutics, and diagnostics is integral to the nation's ability to respond to existing and potential new threats. Equally important is the ability to rapidly deploy stockpiles of drugs and vaccines to disaster areas. ASPR plays a primary role in this process and is the designated lead for the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE). PHEMCE's core HHS members include the Director for the CDC, the Director of NIH's NIAID, and the Commissioner of the FDA. Other members include the Department of Defense (DoD), Department of Homeland Security, Department of Agriculture, and Department of Veterans Affairs.

ASPR through BARDA also forms strong partnerships within the industry to facilitate new development and ensure adequate manufacturing capabilities of key products. This collaboration has produced 35 FDA-approved or -cleared products and has significantly expanded pandemic influenza domestic vaccine production capacity.²⁴ In addition, the CARB-X Program vetted 168 proposals and selected the 11 most promising for funding, in which three entirely new classes of antibiotics were created.⁵

Within ASPR, MCM development is a top priority and BARDA has taken the lead on this effort.

Since the beginning of the 2015 NHSS, a total of eight new MCMs for CBRN threats have been brought for FDA approval.²⁵ Research funded since fiscal year (FY) 2015 by BARDA has already led to significant progress in MCM development and procurement or new FDA approval of critical products. This is a lengthy process, involving multiple partners, including NIAID and BARDA. NIAID is the lead on pre-clinical and early clinical development and evaluation of

MCMs, while BARDA assumes advanced development and stockpiling responsibilities prior to receiving FDA approval. Progress in MCM development includes:

Anthrax

- In November 2015, the FDA approved BioThrax®, a new anthrax vaccine that can also be used as a post-exposure treatment;
- In June of 2018, the Advisory Committee for Immunization Practices expanded guidelines on how to optimize use of the vaccine in case of a mass-exposure event, expanding the coverage of vaccination in case of logistical or supply issues;
- Expiring stockpiles of existing anthrax antitoxins used to treat inhalational anthrax were replenished;
- After researching years of data on anthrax cases, clinicians at CDC developed an evidence-based treatment algorithm and checklist for use of intravenous antibiotics;

Smallpox

- Stockpiles of an investigational smallpox vaccine have been acquired to augment
 existing stockpiles of smallpox vaccine doses. The investigational smallpox vaccine uses
 a strain of the modified vaccinia Ankara (MVA) virus and is being developed to provide
 improved capability and increased capacity to vaccinate larger segments of the
 population, including at-risk individuals such as, those with HIV and atopic dermatitis and
 to include all age ranges and nursing and pregnant women.;
- CDC is evaluating the use practices and effectiveness of this MVA vaccine in health care
 workers at risk for monkeypox, a deadly relative of the smallpox virus which re-emerged
 in several countries in 2017. Responses to both the standard liquid-frozen product and a
 freeze-dried formulation are currently being tracked in nearly one thousand medical
 professionals;
- FDA approved TPOXX, a therapeutic, in July 2018; two million oral capsule doses have been delivered to the stockpile;

Radiological and Nuclear

- The FDA approved three new products specifically for the treatment of acute radiation syndrome;
- In 2018, NIAID initiated a pivotal large animal study to assess efficacy of a licensed product that prevents bleeding as a way to treat radiation-induced thrombocytopenia, with FDA approval for acute radiation syndrome targeted for early 2020;

Biodosimetry

 BARDA continues to support five biodosimetry candidates—products intended to measure the amount or dose of radiation exposure;

- Since FY 2016, four biodosimetry candidates have transitioned to support under Project Bioshield (PBS):
- NIAID continues to conduct discovery research on novel methods to determine dose of radiation exposure received, having already transitioned several approaches to BARDA for further development;

Cutaneous Burns

- BARDA is focusing on procuring MCMs that can expedite and improve burn treatment. A burn dressing to manage sulfur mustard skin burns is in the final stages of laboratory testing, and a dressing for radiation burns has completed preliminary animal studies:
- NIAID continues to study radiation burns and the impact of radiation exposure on thermal burn injuries by developing animal models to study the process and supporting early stage research on MCMs to treat the damage;
- Additionally, BARDA purchased and stockpiled the product Silverlon® (Argentum Medical, LLC); a long-acting, silver-based burn dressing that has an extensive track record in U.S. military practice;²⁶

Influenza

- In 2017, the CDC released its <u>Pandemic Influenza Plan Update</u>, which further enhanced pandemic influenza preparedness and response planning;²⁷
- BARDA has continued to advance vaccine, diagnostic, and therapeutic capabilities to address pandemic influenza and emerging infectious diseases. Improvements in vaccine manufacturing and effectiveness have led to an expanded influenza vaccine production capacity;
- CDC has established plans for pandemic influenza vaccine distribution that allow for optimal vaccine distribution and access. This system, which includes private sector partnerships, was successfully used to distribute pandemic vaccine during the 2009 H1N1 response.
- In 2018, CDC released <u>Interim Updated Planning Guidance on Allocating and Targeting Pandemic Influenza Vaccine during an Influenza Pandemic to assist with effective allocation and administration of pandemic influenza vaccine.</u>
- BARDA sponsored the BRITE Study, a randomized double-blind Phase II clinical trial, to assess the long-term safety and efficacy of a stored H5N1 influenza vaccine and demonstrated that vaccines currently stored long-term in stockpiles remain safe and effective for use, if needed, beyond their current noted shelf life;²⁸
- As a result, BARDA is now working closely with the FDA to develop innovative approaches to extend the usability of adjuvants and pre-pandemic bulk vaccine stockpiles;
- Since 2017, NIAID has launched multiple clinical trials to evaluate universal influenza vaccine approaches aimed at increasing breadth and durability of influenza vaccines;

- NIAID conducted multiple clinical trials to evaluate candidate vaccines against prepandemic influenza viruses H3N2v, H5N8, and H7N9. Through its Vaccine and Treatment Evaluation Units, Respiratory Pathogen Research Center, and other clinical trial resources, NIAID supported 12 clinical trials, enrolling more than 2,000 volunteers. An additional trial is expected to begin by the end of 2018;
- In 2018, NIAID released <u>A Universal Influenza Vaccine: The Strategic Plan for the National Institute of Allergy and Infectious Diseases</u>, to guide research investments in this area;
- In accordance with its Universal Influenza Vaccine Strategic Plan, in 2018, NIAID released two funding opportunities:
 - Collaborative Influenza Vaccine Innovation Centers
 - Impact of Initial Influenza Exposure on Immunity in Infants

Improved Diagnostics

BARDA is supporting novel technologies to drive diagnostics to in-home use, which
could help detect influenza much faster to improve timely, effective use of antivirals and
promote social distancing to reduce disease spread;

Ebola Virus

- In the midst of the response to the 2014-2015 Ebola virus outbreak in West Africa, BARDA redirected early stage MCM candidates into a new Ebola portfolio and engaged industry partners to expedite advancement of these products. As a result, four candidates transitioned to PBS support in FY 2017: two Ebola vaccines and two Ebola therapeutics. The goal is to support the licensure or approval of these candidates;²⁹
- NIAID is advancing the development of diagnostics capable of detecting Ebola. In addition, NIAID is supporting the development of several candidate therapeutics, including small-molecule anti-virals, and monoclonal antibodies, such as Z-Mapp and MAb114, and several vaccine candidates;

Zika Virus

- CDC confirmed that Zika virus causes birth defects and deployed Zika virus diagnostics domestically and internationally. CDC established long-term surveillance to better evaluate the long-term health effects from Zika virus.
- As Zika virus cases were being diagnosed in South America, the Caribbean, and Southeastern United States, HHS identified a need to have a more rapid diagnostic test. In response, BARDA funded a project to coordinate with the CDC and LHDs to collect blood samples from people with a confirmed Zika virus infection.³⁰ This effort increased access to Zika virus antibodies, which could be used to validate testing of new methodologies to reduce diagnostic time from days to hours;
- BARDA is currently supporting the development of two Zika virus vaccine candidates, four diagnostic tests (all available under EUA), and two blood screening assays (one FDA approved);

- NIAID is supporting several vaccine candidates for Zika virus including three in clinical trials. NIAID is also supporting efforts to develop improved molecular assays for Zika virus RNA in different bodily fluids, identify biosignatures of Zika virus, and develop point-of-care tests for the early detection of active Zika virus infection. In addition, NIAIDsupported researchers are developing therapeutics for Zika virus, including a broadspectrum antiviral that also has activity against Ebola virus, and polyclonal and monoclonal antibody immunotherapeutics; and
- NIAID is supporting large natural history studies of Zika virus in Latin America to
 elucidate virological and immunological factors in pregnant women that correlate with
 congenital disease. The results of these studies should help inform the development of
 vaccines and therapeutics for Zika virus.

2.7 Cybersecurity: There Has Been Some Progress but Threats Have Been Increasing

Cybersecurity is recognized as a serious issue requiring much more attention. Health care is a target for hackers, as evidenced by the 2016 Maryland-based health care system and 2017 WannaCry cyber-attacks. ¹³ In support of CISA, HHS has led the development of a federal interagency effort to develop protective measures for the health care sector that health care providers, federal health care programs, and others can deploy. ¹⁵ HHS also conducted a number of forums to reach out to, and partner with, the health care sector to better understand their challenges and help support their cybersecurity efforts.

3. CHALLENGES AND GAPS

3.1 There Have Been Struggles to Replenish the Preparedness Workforce

The public health sector has seen a long, slow, and steady decline in its workforce. From 1980 to 2000, the ratio of public health workforce personnel to the U.S. population has decreased from 220 to 158 per 100,000 people. Retirement and job turnover pose significant challenges to maintaining technical expertise and leadership at a time when experience and leadership is desperately needed to guide the country through an evolving and challenging threat landscape.

3.2 Extreme Weather Events Have Been Increasing in Frequency and Severity

Hurricanes, tornadoes, strong winter storms, regional droughts, and other destructive weather events constitute the longest-appreciated category of threats among emergency preparedness programs. In recent decades, and especially in the most recent years, there has been an increase in the frequency, intensity, and destructive impact of adverse weather events of all types.

In 2017, three Category 4 and/or 5 hurricanes swept through the Caribbean and Southeastern United States. Even hundreds of miles away, potential storm surges and flooding imperiled

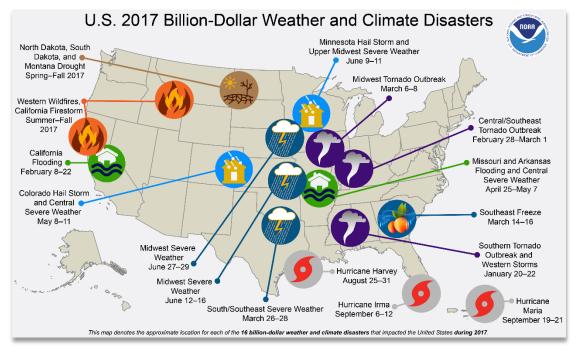


Figure 6: U.S. Billion-Dollar Weather and Climate Disasters

lives, homes, and cities. Simultaneously, extreme drought conditions were driving forest fires in numerous areas of the Western United States, and continue to do so in 2018. These three storms, in addition to the other weather events listed in **Figure 7** above, each caused over \$1 billion in damages and contributed to an annual record cost of over \$300 billion in 2017. The Emergency preparedness groups will need to adjust to this new reality and prepare for more intense and destructive storms that may come in quick succession or concurrently, requiring simultaneous emergency response efforts.

3.3 Infectious Disease Outbreaks and Pandemic Threats Continue

In recent years, the U.S. population has been threatened by a number of highly pathogenic, emerging infectious diseases, including Ebola virus, Zika virus, Middle East respiratory syndrome Coronavirus (MERS-CoV), chikungunya virus, Chagas disease (*Trypansoma cruzi* parasite infection), and pandemic influenza. Many originate outside of the United States. Factors contributing to outbreaks include greater international travel and commerce, population

pressure on habitats, and environmental degradation. Reducing the risk of these threats requires consistent, systematic application of preventive practices in transportation, commerce, and environmental management, as well as at each stage of the commercial food production and delivery chain.

Antibiotic-resistant infections are a growing health concern. More than two million Americans develop antibiotic-resistant infections each year, leading to more than 23,000 deaths, \$20 billion in direct medical costs, and more than \$35 billion in lost productivity.³²

Figure 7: 2014-2016 Ebola Response

Foodborne disease outbreaks remain a problem. An estimated 48 million Americans get sick, 128,000 are hospitalized, and 3,000 die from contaminated food annually. In 2017, *Salmonella* infection linked to imported papayas sickened over 200 people, while a *Listeria* outbreak in soft raw cheese killed two of eight people infected. Nearly 600 non-travel-associated cases of cyclosporiasis were reported in 2017. A brand of soy nut butter contaminated with Shiga toxin-producing *E. coli* caused illness in 12 people in five states, with six of the patients requiring hospitalization.³²

3.4 Emergency Plans Need to Better Address MCM Development, Delivery, and Dispensing

The MCM enterprise contributions have been significant but challenges remain. One challenge is how to more effectively link the Strategic National Stockpile (SNS) inventory and delivery pods with the end-users in SLTT governments, LHDs, medical centers, pharmacies, and community members during actual emergencies. The topic of how to rapidly deploy or distribute MCMs from the SNS is receiving more attention in response exercises and simulations. This issue—commonly referred to as "The Last Mile"—will receive even more attention going forward.

Other MCM challenges include improving MCM dispensing during catastrophic emergencies, creating a seamless integration of SNS distribution with SLTT dispensing, and support for jurisdictions that are particularly vulnerable to CBRN threats and terrorist attacks. Plans are also needed to address dispensing of MCMs under investigational new drug protocols, particularly for vulnerable populations, and to evaluate safety and efficacy of MCMs developed under the animal rule.

3.5 New CBRN Threats to the United States Have Been Emerging

Global geopolitical hostilities with select countries have raised the risk of CBRN attacks against the United States. New threats from individuals and groups, both internal and external, continue to mount. New technologies, chemical and biologic agents, and weapon delivery devices are more easily available, which could be unleashed by terrorist for destructive purposes. While there has been some progress, preparedness gaps still exist for CBRN and

New threats continue to mount, as advancements in science, technology, and transport become probable means for terror and destruction.

influenza threats. MCMs are also needed to treat newly emergent viral hemorrhagic fevers and a range of chemical exposure threats. Chemical threats are a high priority for BARDA in the near term, along with gaining licensure and approval of Ebola products and improving treatment of Marburg and Sudan viruses.

Synthetic biology experiments such as the recent re-creation of horsepox virus using commercially available synthetic DNA, molecular biology tools, and reagents, may lead to vaccines and therapeutics that are safer and more effective. However, there are biosafety and biosecurity risks associated with undertaking such research that must be appropriately considered and mitigated in order to realize the potential benefits and not create additional vulnerabilities. The U.S. Government will need to continue to engage with industry and other non-governmental partners to assess the impact of recent advances in science and technology to the HHS Screening Framework Guidance for Providers of Synthetic Double-Stranded DNA and provide regulatory interpretation regarding synthetically created DNA sequence.

3.6 States Face Difficult Decisions During Emergencies

When unexpected and large-scale public health emergencies arise, the funds needed to address them can easily outstrip public health agencies' steady-state budgets. The recent Ebola virus and Zika virus outbreaks are examples of this phenomenon. In the early weeks and months of an outbreak, public health agencies may be forced to make decisions about how to allocate their limited existing resources. These agencies may be forced to exhaust resources and draw from other non-emergency public health programs, thereby disrupting those efforts as well

3.7 The United States Health Care System's Capacity is Strained

Americans turn to the U.S. health care system for their everyday medical care and personal emergency needs, and also rely on this system during disasters and emergencies. There are 5,534 registered hospitals in the United States, of which 4,840 are community hospitals. Roughly two-thirds are nonprofit facilities, and a third are investor-owned or for-profit. There are 956 hospitals run by local or state governments and 209 hospitals run by the federal government.³³

The 2018 NHSPI that health care providers have been obliged to contend with rapid shifts and declines in their patients' health insurance coverage, while also needing to contend with an increasingly uncertain health policy environment. These obligations minimize the amount of attention and resources available for national health security needs within hospitals, HCCs, and communities.¹

Furthermore, many hospitals have moved to just-in-time inventory management, meaning that stock levels of pharmaceuticals and medical supplies are kept to minimums (often just a few days' worth for non-emergency operations).³⁴ A surge of supply needs will quickly drain these resources.

3.8 The United States' Critical Infrastructure is Aging

Aging critical infrastructure (roads, bridges, electrical grids, water systems, rail transports, communications, etc.) pose increased challenges during emergencies and disasters. These systems are less resilient and more easily damaged when storms and floods occur. When we also consider other aspects like older model railroad cars used to transport dangerous chemicals, the potential scale and impact of this issue extends even wider still. With cyberattack threats now targeting our infrastructure, older systems can be more vulnerable. When infrastructure fails under the additional strains of an emergency, there is the potential to compound the injuries and deaths. For example, the catastrophic damage to Puerto Rico's power grid during Hurricane Maria is one of the most dramatic recent cases of infrastructure failure complicating an existing disaster.

Aging infrastructure also has a direct effect on our ability to respond to medical disasters. National disaster plans call for the delivery of medical supplies and health care personnel into affected disaster areas. Some of these plans also call for the redistribution of patients out of the disaster areas and into other regions of the country. Both depend on roads and runways that are intact and usable.

3.9 Cybersecurity is an Area of Increasing Concern

As previously mentioned, society is increasingly computer-based and internet-connected, creating both new efficiencies and new vulnerabilities. This is particularly evident in the health care sector, where the use of electronic health records has become the standard of care. These systems are potentially vulnerable to wide-scale accidental and intentional disruptions that can complicate patient care.

The 2016 Maryland-based health care system and 2017 WannaCry cyber-attacks are examples of intentional attacks.¹³ While hospital systems are the main area of concern, other health care organizations, such as outpatient care centers, doctors' offices, and medical supply companies, may be less equipped to develop adequate cybersecurity measures needed to respond to a cyberattack.

Appreciating these challenges, and in support of CISA, HHS began developing strategies for supporting the health care sector. This has led to an inter-governmental effort to develop protective measures that can be deployed by government groups, health care providers, and others. As the Federal Emergency Management Agency's *National Preparedness Report* found, the need for improvement in cybersecurity is growing and will require increased attention.³⁵

3.10 Environmental Health Remains a Concern from a Complex Array of Threats

The field of environmental health includes the safety of water and food supplies, security, environmental hazard testing, and workforce protection from environmental hazards. The recent Flint, Michigan lead contamination of the municipal water system is an example of an environmental health threat. As public infrastructure ages, these threats will increase. Studies have reported estimates in the United States of nearly 82,000 annual hospitalizations, 477,000 annual emergency department visits, and nearly 7,000 deaths each year from diseases transmitted by unsafe water.³⁶

An environmental disaster can rapidly result from many threats including the spread of toxic chemicals following an industrial explosion or flood, derailment of railroad cars carrying hazardous chemicals, or a coal slurry pond spill. Managing and reducing these threats requires a combination of multi-sector coordination, policy development and enforcement, infrastructure development, and disease surveillance across agriculture, commercial industry, government, public health, and health care.

4. SUCCESS STORIES – PREPAREDNESS PROGRAMS MAKE A DIFFERENCE

The federal programs that receive preparedness funds, along with partnering SLTT governments, are continually working to improve the nation's preparedness and response capabilities. In this section, we highlight some of these accomplishments, improved approaches, and ROIs on the public funds put to use. These particular examples illustrate the wide variety of public health emergencies that occur and the range of programs that must be prepared to respond.

4.1 Examples of Success at the National Level

Example 1. ASPR Develops Means to Reach and Safeguard Medically Vulnerable Populations: ³⁷ As the intensity of storms and hurricanes increases, the chance of longer power outages during and after these storms also increases. This puts all residents who rely on electricity-dependent durable medical equipment and devices at risk. Identifying this need, ASPR collaborated with the Centers for Medicare & Medicaid Services on a solution: the HHS emPOWER Program. Central to emPOWER is an interactive public map, which ASPR launched in 2015.

The <u>HHS emPOWER Map</u> shows all Medicare beneficiaries who use (or more precisely, submit claims for) electricity-dependent durable medical equipment, such as ventilators, oxygen concentrators, enteral feeding machines, and wheelchairs. The map can show these beneficiaries down to the smallest zip code zone. The map combines this data with real-time severe weather tracking information from the National Oceanic and Atmospheric Administration. This tool is publicly available to all partners, so they can anticipate, monitor, and plan for potential at-risk population needs in emergencies.

Public health authorities are also provided with more detailed monthly de-identified datasets of certain Medicare electricity and health care dependent populations to support emergency planning. In the event of an emergency they can request additional information, such as names and addresses, to support potential life-saving outreach activities. To date, over 40,000 individuals in local and state governments across the nation use the publicly available HHS emPOWER Map to inform preparedness, response, and recovery decision-making activities.

During the 2017 hurricane responses, NDMS personnel and the DoD's Urban Search and Rescue teams utilized emPOWER data to locate dialysis patients whom authorities were unable to reach during the initial evacuation in Florida and St. Thomas.³⁸

- **Investment:** ASPR's development of datasets and interactive public maps, known as the HHS emPOWER Program
- **Use of Investment:** enhanced situational awareness of electricity and health care dependent populations and hazards that may adversely impact them
- ROI: nationwide use of interactive maps for preparedness, response, and decision-making; increased situational awareness about resources and logistics; information exchange between states and municipalities; ability to easily geo-locate people using electricity-dependent devices; identify nearest health care facility

Example 2. Advancing the Development, Manufacturing, and Distribution of Influenza Vaccines, and Monitoring Their Use, Safety, and Effectiveness:³⁹ To encourage greater involvement from private vaccine manufacturers, federal agencies began proactively communicating their long-term influenza program goals and meeting with private manufacturers regularly to expand these goals. This has incentivized manufacturers, increasing the number of companies that can supply vaccines to the United States from just two in the 2004–2005 influenza season to six in the 2016–2017 influenza season.

In 2009, the CDC pandemic influenza vaccine distribution program focused on increasing access to vaccine through pharmacies in addition to other provider settings. This initiative was a catalyst in expanding the types of providers and settings in which vaccines can be given. In the

last decade expansion of pharmacist practice has more than tripled the number of U.S. adults who report receiving a seasonal influenza vaccine at a pharmacy or retail setting (from 6 percent in 2007 to almost 25 percent in 2015).

Private providers have improved the capability of electronic health records (EHR) to directly populate immunization information systems, thereby improving both vaccine ordering and vaccine coverage data. Implementation of CDC's Vaccine Tracking System, done through the 64 CDC-funded local and state immunization programs, modernized HHS' ability to manage vaccine orders and distribution logistics across the United States. More broadly, federal public health programs have engaged with health care delivery partners to improve the overall national capacity to monitor vaccine distribution and effectiveness, as well as the safety of influenza vaccines and MCMs throughout influenza pandemics.

- **Investment:** proactive communication by federal agencies with vaccine manufacturers about influenza vaccine goals;
- **Use of Investment:** increased manufacturer interest in vaccine production; improve EHR capacity
- ROI: increased vaccine development, distribution, coverage rates; higher coverage rates lead to lower infection rates, which lowers the need for medical care and reduces costs incurred by health care systems; enhanced knowledge about vaccine safety and effectiveness

Example 3. NDMS Improves Training for Deployments: ⁴⁰ Before and during disasters when catastrophic events can overwhelm SLTT resources, ASPR's NDMS teams can assist local and state coordinators and medical care providers to fill gaps by supplementing health and medical systems and supplying response coordination. This can include serving behind the scenes at large-scale national events, like the Presidential Inauguration or Republican and Democratic national conventions. To better prepare for these deployments, the NDMS program has adopted a number of new training opportunities to accelerate medical team readiness.

- NDMS has adopted the Total Team Concept, where NDMS personnel attend trainings together in the same units in which they will respond during a disaster to familiarize themselves, as intact units, with new equipment, policies, and practices.
- ASPR's NDMS has revised its training priorities to align with the ASPR's recently updated Threat and Hazard Identification and Risk Assessment.
- NDMS trainings now involve not only NDMS teams but also the MRC, U.S. Public Health Service Commissioned Corps (USPHS) Officers, and SLTT officials—essentially all the key leadership and operative personnel that lead and coordinate disaster responses.
- Starting in April 2017, 100 percent of new NDMS intermittent staff hired within the year will have completed Psychological First Aid training.
- Roughly 30 percent of NDMS teams are trained annually on a rotating basis.
- As a result of the recent Ebola virus and Zika virus outbreaks, a Health and Infectious Diseases training module was developed and will be implemented in NDMS trainings.

 In 2017, the U.S. Army Medical Research Institute of Infectious Diseases began training NDMS and USPHS health care providers to manage and treat highly contagious (e.g., Ebola) patients. In 2018, the U.S. Air Force School of Aerospace Medicine began training NDMS and USPHS health care providers to become critical care air transport teams. Both efforts are expanding federal response capabilities for emerging infectious diseases and/or events requiring critical care patient transport.

Together, these new training initiatives have resulted in an updated and prepared NDMS medical personnel force.

- Investment: adoption of new training initiatives by NDMS teams
- **Use of Investment:** improved NDMS team readiness



Figure 8: NDMS in Action

ROI: updated and prepared NDMS medical personnel workforce; increased team
readiness for rapid deployment across the United States; enhanced subject matter
expertise by NDMS team members; reduced morbidity and mortality during future
emergencies due to quick response by NDMS teams

Example 4. HHS Mobilizes Development of MCMs for Ebola Virus and Zika Virus:⁴¹ In the midst of the 2014 Ebola virus and 2016 Zika virus outbreaks, BARDA, NIAID, CDC, and other PHEMCE partners were able to rapidly develop and advance products for use in the field. In response to the Ebola outbreak in West Africa, BARDA redirected early-stage MCM candidates into its new Ebola portfolio and fully engaged industry partners to expedite advancement of these products. As a result, multiple Ebola vaccine and therapeutic products are in the development process, with four candidates transitioned to PBS support in FY 2017. The goal is to support the licensure or approval of these candidates. Similar efforts advanced Zika vaccines, diagnostics, and blood screening assays during the Zika virus outbreak.

- Investment: rapid development of MCMs for emerging disease threats
- Use of Investment: ability to use early stage MCMs to treat Ebola patients
- ROI: increased industry partner engagement; further investment in MCM development; MCM stockpiling more feasible; stockpiled MCMs ready for use during future emergencies and outbreaks; quick treatment with MCM therapeutics can lower t



Figure 9: Ebola Virus Structure

quick treatment with MCM therapeutics can lower the health care costs of long-term patient care

Example 5. GHSA Helps Focus on the Most Essential National Capacities for Building Preparedness for International Disease Outbreaks: ⁴² By identifying and stopping dangerous disease outbreaks before they reach U.S. borders, we avoid the major issues that come with such cases. Many developing countries are poorly prepared in this area. This was made very clear in 2014, when Ebola swept through a handful of West African nations and threatened to spread to other parts of the world. Similarly, dangerous outbreaks of Severe Acute Respiratory Syndrome (SARS) and MERS-CoV have impacted other parts of the world. The United States,

along with other nations and the three lead animal and human health international organizations, launched the GHSA to focus on this crucial global vulnerability.

The GHSA provides nations with guidance and support to establish the most essential and urgent policy and program actions needed to better prepare themselves to detect and quickly contain infectious disease outbreaks. By taking these steps, countries can reduce the threat of such outbreaks going beyond their borders and threatening other nations. An important component of GHSA is attention to the "One Health" approach for disease surveillance, which recognizes the need to track diseases in the environment, animals, and humans, given that some animal infectious diseases can also infect and threaten humans.

One key outcome of GHSA has been the WHO's adoption of the JEE process as a mechanism to independently evaluate and facilitate the strengthening of countries' domestic capacities under the International Health Regulations (IHR) of 2005⁴³. Recognizing the value of the JEE process and the need to further improve U.S. health security, the United States completed a JEE in 2016, identifying strengths and critical gaps in U.S. capacities to prevent, detect, and respond to public health emergencies based on the "Joint External Evaluation Tool: International Health Regulations (2005)" (JEE Tool). Based on the 2016 findings, ASPR has been leading the development of the National Action Plan to Strengthen Implementation of the IHR (2005) in the United States in close collaboration with over 40 federal departments and agencies with a role in human, animal, and environmental health across the 19 technical areas of the JEE Tool.

- Investment: identify and asses gaps in national and foreign public health capacity areas
- **Use of Investment:** fill gaps in national capacity; supports efforts to address international gaps
- ROI: improved public health capacity domestically; better public health practices incountry reduces odds of future outbreaks; fewer diseases crossing into U.S. borders; reduced health care costs spent treating infectious disease patients

Example 6. CDC's Laboratory Response Network for Biological Threats. During the Ebola outbreak in West Africa in 2014, CDC worked with partners at DoD and FDA to develop EUAs and deploy Ebola diagnostic tests to 57 LRN labs. The LRN is a national laboratory network that provides a rapid response structure to detect biological threats and emerging infectious diseases quickly and accurately. Due to the substantial biosafety and biosecurity needs associated with Ebola testing, CDC provided guidance to LRN labs for specimen collection, inactivation, reporting, and waste management. As a result of these efforts, LRN labs have enhanced biosafety practices, including training, and supporting biosafety officers in labs.

Over the course of the outbreak, the CDC worked with LRN partners to ensure that Ebola testing was performed for suspected cases. The LRN provided critical coordination and communication to sentinel laboratories and public health officials to ensure that the public received timely and accurate information to address concerns.

- Investment: rapid and accurate detection of biological threats and emerging infectious diseases nationwide
- **Use of Investment:** widespread ability to accurately detect unusual and highly lethal diseases, such as Ebola in the United States

• **ROI:** robust network of diagnostic laboratory testing capacity among partners at local, state and federal government, as well as across clinical laboratory and industry

4.2 Examples of Success at the SLTT and Regional Levels

Partnerships between federal grant programs and SLTTs enabled SLTT and regional bodies to develop preparedness and response programs that yielded positive results when faced with disasters and emergencies. The federal support to SLTTs extends beyond funding to include a variety of types of technical assistance.

Example 1. Ebola – CDC PHEP Grant Supports Nebraska's Ebola Response:³⁸ The University of Nebraska Medical Center – a member institution of the National Ebola Treatment and Education Center – was one of only three locations to receive Ebola-infected patients during the 2014-2015 outbreak. PHEP program support meant the response infrastructure could be put in place and exercised before Ebola patients arrived in Nebraska. During the actual response, PHEP funds were used to support public health collaboration with medical responders to ensure there was no danger to the public when treating patients with suspected and/or confirmed Ebola infection. In addition, public health departments played a critical role in monitoring signs and symptoms of Ebola virus in medical responders and high-risk quarantine patients. As a result, there were no cases of Ebola infection in Nebraska nor were there any missed diagnoses or threats to the public.

- Investment: CDC PHEP grant funding and technical assistance
- Use of Investment: public health collaboration with medical responders to mitigate Ebola virus transmission to medical personnel and the public



Figure 6: National Ebola Treatment and Education Center Logo

ROI: no Ebola virus transmission in Nebraska;
 no additional health care costs for treating new infections; no additional provider labor required to treat additional infections

Example 2. Ebola – CDC PHEP Grant-Funded Lab Ensures Rapid and Secure Testing of New York Ebola Patient:³⁸ After helping to fight the Ebola virus outbreak in West Africa, a physician returned home to New York City and subsequently developed symptoms of the disease. After arriving at New York City's Health and Hospitals Bellevue Hospital, a specimen was obtained from the patient. Hospital staff, working closely with the New York City Health Department's Public Health Laboratory (PHL), facilitated the delicate transfer of the specimen from the hospital to the PHL. Supported by PHEP funds, this lab and others like it are prepared to test highly infectious disease specimens, such as Ebola on an emergency basis, 24 hours a day, 7 days a week.

- Investment: CDC PHEP grant funding and technical assistance
- **Use of Investment:** expanded local laboratory capacity to run appropriate diagnostic assays
- **ROI:** costs of treating new infections were avoided by quick specimen transfer and identification by a local laboratory; the local laboratory has the capacity to perform in

future outbreaks; more laboratory staff can be trained to run tests, adding to local subject matter expertise

Example 3. CDC PHEP Supports Georgia's Ebola Response:³⁸ Georgia is home to the CDC headquarters and many of its staff traveled to West Africa during the Ebola outbreak. It also has an international airport that received travelers from West Africa. Both of these factors put Georgia at an increased risk for Ebola cases. To meet this need, a PHEP-funded CDC Career Epidemiology Field Officer (CEFO) assigned to Georgia worked with the state health department to create an electronic surveillance system, the Ebola Active Monitoring System (EAMS), within the existing State Electronic Notifiable Disease Surveillance System (SendSS). Within six days, EAMS was a fully automated patient tracking system that allowed two epidemiologists to monitor more than 100 patients per day and quickly follow up with those who were beginning to show possible symptoms of the disease.

- Investment: CDC PHEP grant funding and technical assistance (CDC epidemiology personnel)
- Use of Investment: creation of state-level electronic disease surveillance system
- ROI: patient tracking limited disease spread; fewer costs treating new patients; tracking system can be used for future Ebola surveillance; system can be expanded to monitor other emerging threats ("all-hazards approach"); increased situational awareness; other states can create their own version

Example 4. ASPR HPP Grant – Ebola and Infectious Disease Regional Approach for Health Care System Preparedness:⁴⁴ Following the 2014 Ebola outbreak and using emergency supplemental funding, ASPR and CDC worked with health care centers through the HPP grant program to develop a regional approach to care for future Ebola patients. HPP provided awardees with Ebola emergency supplemental funding to establish a nationwide, regional treatment network for Ebola virus and other infectious diseases. This approach balances geographic need, differences in institutional capabilities, and accounts for the potential risk of needing to care for an Ebola-infected patient.

This network consists of ten regional Ebola and other special pathogen treatment centers that can be ready within a few hours to receive patients with confirmed diagnoses from their regions, or medically evacuated from outside of the United States. It established 64 state or local jurisdiction Ebola treatment centers that can safely care for patients in the event of a cluster of Ebola patients that might overwhelm a regional Ebola treatment center.

- **Investment:** Ebola emergency supplemental funding, ASPR HPP grant funding, and ASPR and CDC technical assistance
- Use of Investment: establishment of a regional network to treat infectious diseases
- ROI: increased situational awareness; coordination between health care facilities; partnerships can be leveraged in future emergencies for patient movement, and information sharing

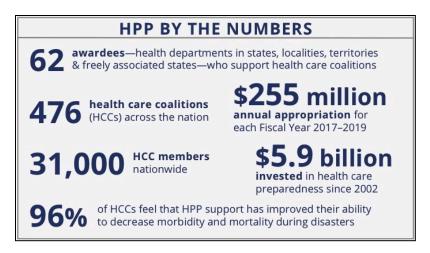


Figure 7: HPP by the Numbers

Example 5. ASPR HPP Grant – Ft. Lauderdale Mass Shooting Response: When a shooter opened fire on January 6, 2017 at the Fort Lauderdale-Hollywood, Florida International Airport, killing five people and injuring many more, the Broward County HCC was ready to respond. The HCC and Florida International Airport have been close partners since 2007, performing multiple disaster drills together every year. Thanks to years of exercising together, the HCC and Florida International Airport had formalized plans placing representatives at both the airport's Emergency Operations Center (EOC) and in local hospitals, greatly enhancing information sharing during the response.

This shared coordination enabled effective, real-time communication between health care responders, transit authorities, and law enforcement as the incident unfolded. Within seven minutes of shots fired, the HCC EOC liaison at the airport was coordinating patient distribution with first responders on the scene, while providing real-time updates to local hospitals and HCC members. As a result, local hospitals were able to suspend scheduled surgeries and accommodate over 50 incoming patients.

- **Investment:** ASPR HPP grant funding and technical assistance
- **Use of Investment:** formed EOCs to partner with hospitals for real-time information exchange
- ROI: efficient and coordinated response so local hospitals could prioritize trauma
 patients to mitigate loss of life; increased situational awareness; can serve as a model
 for other locales; partnership formed between health care and non-health care entities;
 real-time communication

Example 6. CDC PHEP Grant Assists Vulnerable Populations During Winter Storms:³⁸ PHEP funds helped provide access to medications and critical information during emergencies. In early 2015 and 2016, two major winter storms named Octavia and Jonas led to a state of emergency in many counties in Kentucky. Road closures left residents stranded on interstate highways and vulnerable in case of a health emergency. In 2016, PHEP-funded health department staff built a HAN to identify stranded residents in need of care and to work with EMS to transport them to nearby hospitals. As a result, stranded residents in future emergencies will be ensured continuity of care and access to needed medications.

Additionally, medical status information can now be provided to emergency coordinators to help coordinate care, which helped save many lives during these storms. Winter Storm Jonas brought almost 30 inches of snow, high winds, and coastal flooding, which forced Maryland to declare a state of emergency. Through planning supported by PHEP, the state established an incident command structure, staffed the state EOC, coordinated with EMS, and communicated with vulnerable groups in the state to ensure their medical needs were met during the storm. As a result, the state was able to mitigate cold weather-associated deaths and injuries during the storm.

- Investment: CDC PHEP grant funding and technical assistance
- **Use of Investment:** expanded infrastructure to allow access to health care needs during storms
- ROI: fewer weather-associated deaths (reduced loss of life); infrastructure in place to respond during future storms; continuous health care access during weather emergencies; enhanced situational awareness

Example 7. ASPR HPP Grants Support Patient Evacuations and Care during Hurricane Matthew in Georgia: 42 As Hurricane Matthew approached Georgia, local HCC members applied the well-developed coastal evacuation plan that had been built on lessons learned through years of HPP-funded exercises. It also used numerous agreements between health care providers and other partners that are essential for moving patients across the state. These formalized, cross-functional partnerships enabled sharing of information on staffing, capacity, and resource availability before and during the response. Five days before hurricane landfall, the HCC began coordinating situational awareness among members and partners, allowing ample time for collaborative, informed decision-making. In the critical 24 hours before landfall, the HCC evacuated over 1,200 hospital inpatients—some just out of surgery—without any loss of life.

The HCC turned to its strong partnerships, including with law enforcement, to ensure all patients were relocated around the state. Appropriate transportation, which included helicopters from neighboring states, was used to evacuate the most critical patients to safety. One HCC member shared that, "HPP enables critical partnerships to be formed and tested before a disaster. By exercising and planning together, our HCC ensured that everyone knew their role during the response. We could not have successfully evacuated over a thousand patients in 24 hours without our HCC and HPP."

- **Investment:** ASPR HPP grant funding and technical assistance
- Use of Investment: patient evacuation exercises
- ROI: mass patient evacuation; no loss of life; partnerships formed between health care and non-health care entities; partnerships formed that can be leveraged to respond during future emergencies; cooperation between states eases burden on federal government during response

Example 8. ASPR HPP Grants Enable Coordinated Response Capabilities during Republican National Convention Preparations in Ohio:⁴² An estimated 50,000 visitors converged in Cleveland, Ohio for the Republican National Convention (RNC) in July 2016. The Northeast Ohio Regional HCC, a network of hospitals, EMS, public health departments, and

emergency management services, was critical for coordinating the city's yearlong medical preparations for the convention. The HCC reached out to 27 hospitals and specialty medical facilities across Ohio and neighboring states to prepare medical surge support. Before and during the Convention, the HCC coordinated closely with HHS and the Secret Service and led information management efforts by surveying health care facilities daily to ensure inventories of specialized equipment, contact information, blood inventories, and hospital bed availability were up to date. "Without the Northeast Ohio Regional HCC, there would have not been a centralized body to coordinate all of the different players and information sources involved with the Convention." noted an HCC member.

- **Investment:** ASPR HPP grant funding and technical assistance (with HHS and Secret Service support)
- **Use of Investment:** developed coordinated statewide and regional response plans in the event of an emergency at the RNC
- ROI: ready to handle hospital surge capacity; sufficient stocks of needed resources in place

Example 9. CDC PHEP Supports SLTT Teams for the Zika Virus and Other Emergencies in 2016:³⁸ PHEP-funded staff served on the incident management team for Florida's Zika virus response, meeting daily through the busy summer of 2016, and coordinated the distribution of Zika virus preparedness kits, flyers, and mosquito repellants. The PHEP-supported team also oversaw mosquito control efforts, which were paid for with PHEP funds, in Florida. In Chicago, between January and December 2016, more than 2.3 million people from countries with endemic Zika virus traveled through Chicago's airports, resulting in thousands of requests for Zika virus testing and evaluation in the Chicago area. From the time that the city activated its EOC for Zika virus in January 2016, the Chicago Department of Public Health has conducted more than 2,400 Zika virus-testing requests at its PHL, which is partially funded by PHEP.

PHEP funding also supported the development and implementation of Zika virus family preparedness campaigns, Zika virus media campaigns, and a CDC CEFO, who serves as the city health department's Zika virus Coordinator. In Puerto Rico, to address the Zika virus outbreak, the Department of Health activated its EOC under an incident command system structure for 510 days. The response was managed and supported by more than 700 PHEP-trained personnel. PHEP also supported laboratory testing and community outreach, testing over 95,000 blood samples and providing more than 30,000 people with insect repellent and educational materials. The number of Zika virus cases in Puerto Rico decreased from about 35,000 in 2016 to about 500 in 2017.

- **Investment:** CDC PHEP grant funding and technical assistance (laboratory support)
- Use of Investment: supplied staff to Florida's Zika virus incident management team; processed Zika virus testing requests in Chicago; laboratory testing and community outreach in Puerto Rico
- ROI: fewer health care costs treating Zika virus-infected patients; expansion in local laboratory capacity; better educated public; fewer new infections due to prevention and control efforts

Example 10. ASPR and CDC Support for the Flint, Michigan Water Crisis:³⁸ In Flint, Michigan in 2016 after the state changed the source of the city's drinking water, residents became exposed to unsafe levels of lead. Michigan's governor declared a state of emergency,

and Flint residents were instructed to use only bottled or filtered water. ASPR assumed responsibility for coordinating the federal assets that were needed, which quickly expedited response efforts.

CDC's PHEP grant supported the establishment of a bloodtesting clinic to check for lead exposure. Free blood tests were made available to people who could not otherwise afford them, connecting the community's most vulnerable residents with the care and treatment they needed. The health department also educated residents on how to stay safe and supported



Figure 8: Flint Water Plant

behavioral health teams to establish crisis-counseling services, including a crisis hotline. PHEP grants funded this testing, a crisis phone hotline, and community education activities which helped mitigate the negative health effects of water contamination.

- Investment: CDC PHEP grant funding and CDC and ASPR technical assistance
- Use of Investment: support of local blood testing clinic; community education and outreach
- **ROI:** mitigation of health effects from the contaminated water; funds saved on treating cases; greater access to blood tests; more educated public that was better able to avoid illness; more health-conscious community behavior

Example 11. CDC PHEP Grant Funds Help Reduce Risk of Zika Virus Transmission among Pregnant Women:³⁸ PHEP funds were used to conduct mosquito control activities and staff a response team to address the immediate spread of the Zika virus in states with documented cases. PHEP funds were also used to purchase Zika virus prevention kits, conduct Zika virus outreach to pregnant women, and fund the removal of more than 90 tons of solid waste, including tires where water had accumulated, which are known breeding sites for the type of mosquitoes that carry the Zika virus.

- **Investment:** CDC PHEP grant funding and technical assistance (outreach and education expertise)
- **Use of Investment:** vector control activities; reduced mosquito breeding sites; purchased Zika virus prevention kits; community outreach
- **ROI:** fewer babies born with the Zika virus (thus reduced loss of infant life); fewer health care costs of treating Zika virus-infected patients; reduction in mosquito breeding sites yielded better community sanitation overall

5. CONCLUSION

The many groups responsible for the nation's public health and health care emergency preparedness have made considerable progress during the four-year period reviewed for this EOP. Progress has been particularly noteworthy in select preparedness and response capabilities. For example, innovative types of new public-private partnerships have helped bring

into existence new antibiotic options, enhanced biosafety and biosecurity, improved situational awareness for emergencies, and better ways to serve those with special medical needs. Persistent efforts to improve incident management through exercises that engage key groups in communities have resulted in marked improvement in this area. And a number of potentially critical MCMs—in the conceptual state only a few years ago—have been brought into existence.

Along with this success in some of the critical preparedness capabilities, national reviews show areas of concern as well—some persistent and showing no improvement, others becoming worse. Some regions of the country are consistently lagging behind their neighbor regions, and an increasing portion of the nation's population is residing in these struggling areas.¹

The broader threat landscape includes the risk of more frequent and severe extreme weather events. Society's ever-increasing reliance on infrastructure and technology brings with it novel vulnerabilities and interdependencies. An array of new and evolving threats to the nation's health and wellbeing include the rise of emerging diseases and the risk of terrorist or nation-state actors employing new CBRN threats.

Re-doubled efforts and new strategies will be required to address these 21st century threats. The NHSS provides the mechanism to learn the lessons described in this EOP, re-assess our risks, and revise the strategies needed to better prepare the nation, save lives, and protect the health of Americans.

APPENDIX A: FY 2003- FY 2010 HOSPITAL PREPAREDNESS PROGRAM (HPP) FUNDING

FY 2003- FY 2010 HPP Cooperative Agreement State Funding Award Amounts (dollars shown in thousands)

AWARDEES	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007	FY 2008	FY 2009	FY 2010
Alabama	7,762	7,762	7,326	7,155	6,330	6,073	5,529	5,959
Alaska	1,959	1,959	1,484	1,458	1,349	1,312	1,233	1,295
American Samoa	602	602	350	335	323	320	313	319
Arizona	9,030	9,030	8,964	8,754	8,317	7,973	7,242	7,820
Arkansas	5,078	5,078	4,634	4,531	4,063	3,906	3,574	3,837
California	38,774	38,774	39,203	38,325	34,107	32,626	29,486	31,967
Chicago	5,069	5,069	4,596	4,738	4,104	3,945	3,608	3,874
Colorado	7,705	7,705	7,402	7,222	6,526	6,260	5,698	6,142
Connecticut	6,197	6,197	5,783	5,652	4,943	4,747	4,332	4,660
Delaware	2,205	2,205	1,740	1,709	1,582	1,534	1,433	1,513
District of Columbia	2,868	2,868	1,854	1,824	1,737	1,708	1,590	1,683
Florida	25,776	25,776	26,311	25,638	23,433	22,422	20,280	21,973
Georgia	13,719	13,719	13,671	13,330	12,371	11,848	10,739	11,615
Guam	738	738	486	492	457	448	429	444
Hawaii	2,857	2,857	2,407	2,346	2,130	2,058	1,906	2,026
Idaho	2,998	2,998	2,572	2,522	2,359	2,277	2,103	2,241
Illinois	15,876	15,876	15,578	14,951	13,164	12,606	11,423	12,358
Indiana	10,271	10,271	9,897	9,661	8,504	8,151	7,403	7,994
Iowa	5,437	5,437	4,965	4,847	4,280	4,114	3,761	4,040
Kansas	5,089	5,089	4,631	4,526	4,004	3,850	3,522	3,781
Kentucky	7,157	7,157	6,745	6,585	5,832	5,597	5,099	5,493
Los Angeles County	15,583	15,583	15,582	15,084	13,111	12,556	11,378	12,309
Louisiana	7,765	7,765	7,319	7,139	5,936	5,696	5,188	5,590

AWARDEES	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007	FY 2008	FY 2009	FY 2010
Maine	2,944	2,944	2,480	2,434	2,175	2,102	1,945	2,069
Marshall Islands	582	582	331	333	322	318	312	317
Maryland	9,150	9,150	8,855	8,646	7,619	7,306	6,640	7,166
Massachusetts	10,686	10,686	10,257	9,984	8,661	8,301	7,539	8,141
Michigan	16,141	16,141	15,788	15,395	13,298	12,735	11,539	12,484
Micronesia	704	704	451	410	387	381	368	378
Minnesota	8,543	8,543	8,173	7,983	7,050	6,762	6,150	6,633
Mississippi	5,327	5,327	4,870	4,760	4,190	4,027	3,682	3,955
Missouri	9,530	9,530	9,152	8,951	7,907	7,581	6,889	7,435
Montana	2,370	2,370	1,892	1,857	1,698	1,645	1,533	1,621
Nebraska	3,603	3,603	3,138	3,067	2,742	2,643	2,434	2,599
Nevada	4,174	4,174	3,899	3,818	3,664	3,524	3,229	3,462
New Hampshire	2,906	2,906	2,453	2,404	2,167	2,093	1,938	2,061
New Jersey	13,879	13,879	13,601	13,270	11,560	11,073	10,040	10,856
New Mexico	3,771	3,771	3,343	3,277	2,978	2,869	2,637	2,820
New York	18,020	18,020	17,748	16,938	14,561	13,942	12,628	13,666
New York City	12,858	12,858	12,350	12,445	10,914	10,455	9,482	10,251
North Carolina	13,417	13,417	13,251	12,949	11,728	11,233	10,184	11,013
North Dakota	1,963	1,963	1,461	1,436	1,306	1,271	1,195	1,255
N. Marianas Islands	613	613	362	363	347	342	333	340
Ohio	18,235	18,235	17,844	17,397	15,051	14,410	13,050	14,125
Oklahoma	6,250	6,250	5,826	5,681	5,037	4,838	4,414	4,749
Oregon	6,256	6,256	5,899	5,768	5,192	4,985	4,547	4,893
Palau	529	529	279	279	275	274	272	273
Pennsylvania	19,617	19,617	19,254	18,777	16,271	15,576	14,103	15,267
Puerto Rico	6,808	6,808	0	500	5,479	5,260	4,795	5,162

AWARDEES	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007	FY 2008	FY 2009	FY 2010
Rhode Island	2,603	2,603	2,132	2,090	1,853	1,794	1,667	1,767
South Carolina	7,147	7,147	6,790	6,632	5,978	5,737	5,225	5,629
South Dakota	2,147	2,147	1,659	1,630	1,491	1,448	1,355	1,428
Tennessee	9,700	9,700	9,360	9,139	8,156	7,818	7,103	7,668
Texas	33,338	33,338	34,045	33,177	30,301	28,988	26,204	28,404
Utah	4,448	4,448	4,066	3,979	3,733	3,590	3,288	3,527
Vermont	1,928	1,928	1,439	1,415	1,291	1,256	1,182	1,241
U.S. Virgin Islands	685	685	0	250	388	382	369	379
Virginia	11,890	11,890	11,702	11,387	10,189	9,762	8,857	9,572
Washington	10,069	10,069	9,799	9,563	8,608	8,251	7,493	8,092
West Virginia	3,725	3,725	3,246	3,176	2,805	2,704	2,488	2,659
Wisconsin	9,180	9,180	8,800	8,589	7,544	7,234	6,576	7,096
Wyoming	1,747	1,747	1,260	1,242	1,153	1,124	1,063	1,111
Total	497,998	497,998	470,755	460,215	415,031	398,061	362,017	390,497

Table 1: FY 2003- FY 2010 HPP Funding

APPENDIX A1: FY 2011- FY 2018 HOSPITAL PREPAREDNESS PROGRAM (HPP) FUNDING

FY 2011- FY 2018 HPP Cooperative Agreement State Funding Award Amounts (dollars shown in thousands)

AWARDEES	FY 2011	FY 2012	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017	FY 2018
Alabama	5,868	5,422	5,119	3,237	3,232	3,213	3,316	3,265
Alaska	1,282	1,231	1,186	913	949	947	952	921
American Samoa	318	318	314	278	278	279	278	278
Arizona	7,698	7,082	6,676	4,007	3,986	3,803	3,931	4,952
Arkansas	3,781	3,503	3,318	2,004	2,015	2,022	2,003	2,024
California	31,445	28,752	27,010	23,324	23,204	23,405	23,397	23,315
Chicago	3,818	3,276	3,105	2,696	2,737	2,763	2,736	2,679
Colorado	6,049	5,679	5,360	3,223	3,231	3,019	3,119	3,163
Connecticut	4,591	4,181	3,954	2,478	2,468	2,352	2,331	2,360
Delaware	1,496	1,425	1,368	1,068	1,061	1,058	1,049	1,020
District of Columbia	1,663	1,120	1,081	951	952	949	944	943
Florida	21,617	19,861	18,667	11,649	11,662	11,834	11,823	11,824
Georgia	11,431	10,476	9,861	5,970	5,941	6,010	5,973	7,256
Guam	441	436	425	353	353	358	375	363
Hawaii	2,001	1,901	1,814	1,218	1,221	1,253	1,261	1,259
Idaho	2,212	2,114	2,015	1,219	1,217	1,253	1,248	1,234
Illinois	12,161	10,937	10,293	8,743	8,868	8,882	8,773	8,602
Indiana	7,870	7,177	6,765	4,116	4,128	3,974	3,935	4,134
Iowa	3,981	3,637	3,444	2,084	2,091	2,126	2,130	2,125
Kansas	3,727	3,438	3,257	2,078	2,069	2,053	2,117	2,108
Kentucky	5,410	4,969	4,693	2,874	2,901	2,798	2,760	2,855
Los Angeles County	12,113	10,611	9,987	9,156	9,197	9,262	9,264	9,190
Louisiana	5,505	5,168	4,880	3,150	3,137	2,899	2,896	3,008

AWARDEES	FY 2011	FY 2012	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017	FY 2018
Maine	2,043	1,868	1,784	1,077	1,079	1,081	1,066	1,046
Marshall Islands	316	318	314	267	267	268	268	268
Maryland	7,055	6,446	6,079	4,944	4,916	4,912	4,865	4,860
Massachusetts	8,014	7,243	6,827	4,229	4,241	4,373	4,316	4,284
Michigan	12,285	10,678	10,050	6,066	6,087	6,173	6,158	6,074
Micronesia	376	360	354	276	275	277	277	277
Minnesota	6,532	5,962	5,625	3,526	3,520	3,547	3,518	3,555
Mississippi	3,898	3,556	3,367	2,169	2,174	2,166	2,176	2,143
Missouri	7,320	6,667	6,287	3,780	3,767	3,621	3,677	3,776
Montana	1,603	1,519	1,456	918	911	927	921	908
Nebraska	2,564	2,381	2,265	1,373	1,377	1,362	1,373	1,363
Nevada	3,413	3,281	3,109	1,928	1,917	1,930	1,911	2,393
New Hampshire	2,035	1,856	1,772	1,113	1,104	1,102	1,090	1,066
New Jersey	10,684	9,554	8,995	5,821	5,836	5,460	5,634	5,652
New Mexico	2,782	2,621	2,490	1,518	1,508	1,537	1,527	1,516
New York	13,448	12,037	11,325	9,825	9,618	9,758	9,640	9,531
New York City	10,089	8,919	8,399	7,841	7,928	8,033	7,941	7,896
North Carolina	10,838	10,319	9,714	6,183	6,145	5,908	6,113	6,110
North Dakota	1,242	1,193	1,150	875	877	886	879	874
N. Marianas Islands	339	300	297	270	271	271	270	274
Ohio	13,898	12,380	11,647	7,443	7,459	7,210	7,450	7,445
Oklahoma	4,678	4,363	4,125	2,606	2,602	2,613	2,602	2,587
Oregon	4,820	4,445	4,202	2,534	2,524	2,580	2,577	2,544
Palau	273	272	270	255	255	255	255	255
Pennsylvania	15,022	13,581	12,774	8,118	8,132	8,194	8,094	8,135
Puerto Rico	5,085	4,337	4,100	2,503	2,507	2,589	2,576	2,608

AWARDEES	FY 2011	FY 2012	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017	FY 2018
Rhode Island	1,746	1,584	1,517	952	969	945	941	920
South Carolina	5,554	5,263	4,969	3,107	3,091	3,121	3,118	3,118
South Dakota	1,413	1,338	1,287	860	859	854	848	847
Tennessee	7,549	7,035	6,632	4,049	4,060	4,062	4,041	4,215
Texas	27,941	26,394	24,797	15,859	15,822	16,294	16,177	16,309
Utah	3,477	3,346	3,171	1,918	1,926	2,288	2,271	2,494
Vermont	1,228	1,144	1,105	900	898	782	780	775
U.S. Virgin Islands	377	363	356	340	339	306	306	305
Virginia	9,422	8,739	8,231	6,189	6,295	6,117	6,075	6,129
Washington	7,966	7,425	6,998	4,212	4,220	4,292	4,279	4,251
West Virginia	2,623	2,408	2,290	1,384	1,381	1,411	1,406	1,392
Wisconsin	6,986	6,356	5,995	3,642	3,612	3,639	3,635	3,597
Wyoming	1,101	1,080	1,045	841	836	843	838	829
Total	384,513	351,645	331,762	228,500	228,500	228,500	228,500	231,500

Table 2: FY 2011- FY 2018 HPP FUNDING

APPENDIX B: FY 2003-2010 PUBLIC HEALTH EMERGENCY PREPAREDNESS (PHEP) FUNDING

FY 2003-FY 2010 PHEP Cooperative Agreement State Funding Award Amounts (dollars shown in thousands)

AWARDEES	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007	FY 2008	FY 2009	FY 2010
Alahawa	45 500	40.044	40.040	40.400	40.050	40.044	0.005	40.040
Alabama	15,599	12,911	12,810	16,408	12,952	10,241	9,985	10,049
Alaska	6,503	5,205	5,210	6,768	5,839	5,015	5,015	5,165
American Samoa	576	444	448	735	548	386	383	390
Arizona	17,586	16,470	17,067	21,710	17,682	14,228	13,658	14,048
Arkansas	11,391	9,339	9,302	11,995	9,390	7,655	7,280	7,394
California	64,204	59,319	61,339	78,752	65,303	50,962	49,342	4,931
Chicago	11,378	12,563	12,817	15,255	15,703	12,002	10,700	10,640
Colorado	15,509	13,654	13,938	17,500	14,010	11,943	10,637	10,875
Connecticut	13,146	10,829	10,802	14,016	11,324	9,298	8,704	8,720
Delaware	6,889	5,519	5,596	7,263	5,911	5,000	5,000	5,150
District of Columbia	11,361	11,985	11,931	8,198	9,898	6,699	6,461	6,616
Florida	43,832	37,584	39,221	51,714	42,468	34,233	32,907	33,482
Georgia	24,936	21,575	22,322	28,600	23,156	19,467	18,146	18,482
Guam	680	516	551	1,009	772	555	547	545
Hawaii	7,910	6,385	6,381	8,268	6,418	6,611	5,145	5,250
Idaho	8,132	6,588	6,630	8,657	6,637	5,406	5,330	5,495
Illinois	28,316	23,719	24,044	30,467	24,576	20,709	19,986	19,497
Indiana	19,531	16,263	16,461	21,111	16,966	14,135	12,979	12,996
Iowa	11,954	9,817	9,725	12,466	9,779	7,961	7,540	7,565
Kansas	11,409	9,354	9,297	12,182	9,549	7,598	7,447	7,530
Kentucky	14,650	12,105	12,049	15,591	12,441	9,751	9,511	9,456
Los Angeles	27,857	27,070	27,933	34,079	30,712	22,852	22,523	22,220
Louisiana	15,602	12,914	12,790	16,530	13,243	10,396	9,756	9,999

AWARDEES	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007	FY 2008	FY 2009	FY 2010
Maine	8,046	6,601	6,607	8,504	6,527	6,723	5,183	5,259
Marshall Islands	562	434	446	737	550	390	387	388
Maryland	17,774	14,757	15,291	19,974	16,047	13,038	12,690	12,721
Massachusetts	20,181	17,640	17,872	22,259	18,040	15,367	14,324	15,230
Michigan	28,732	26,897	27,106	33,292	26,993	22,492	20,124	20,143
Micronesia	653	498	497	860	649	461	456	450
Minnesota	16,822	14,702	15,004	18,722	15,592	14,831	12,055	12,912
Mississippi	11,782	9,671	9,608	12,350	9,722	7,630	7,468	7,527
Missouri	18,370	15,953	16,322	20,586	16,566	13,029	12,476	12,572
Montana	7,147	5,776	5,752	7,452	5,983	5,023	5,019	5,166
Nebraska	9,079	7,377	7,347	9,470	7,324	6,851	5,774	5,876
Nevada	9,975	8,928	9,268	11,785	9,340	7,652	7,293	7,512
New Hampshire	7,987	6,465	6,527	8,422	6,448	6,182	5,244	5,349
New Jersey	25,186	21,047	21,953	27,697	22,338	18,789	18,248	18,016
New Mexico	9,342	8,803	8,810	11,070	8,691	7,588	6,853	7,644
New York	31,676	28,494	28,293	35,407	28,875	22,519	22,171	22,932
New York City	23,586	25,875	26,070	31,208	28,823	23,609	20,674	20,603
North Carolina	24,462	20,433	20,547	26,604	21,306	16,696	16,224	16,552
North Dakota	6,510	5,223	5,194	6,718	5,840	5,203	5,023	5,022
N. Mariana Islands	585	450	466	790	593	423	419	377
Ohio	32,013	27,627	27,902	35,469	28,838	21,982	21,312	20,948
Oklahoma	13,229	10,899	10,840	13,905	11,102	8,740	8,537	8,487
Oregon	13,238	10,907	11,155	14,499	11,469	10,646	8,885	8,871
Palau	522	407	411	642	472	331	330	329
Pennsylvania	34,179	30,735	30,977	38,373	31,307	24,209	22,975	22,809
Puerto Rico	14,103	11,641	11,574	14,611	11,445	8,868	8,666	8,514
Rhode Island	7,513	6,048	6,240	7,947	6,074	5,686	5,000	5,150

AWARDEES	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007	FY 2008	FY 2009	FY 2010
South Carolina	14,634	12,092	12,109	15,644	12,549	9,969	10,097	11,035
South Dakota	6,798	5,441	5,426	7,033	5,879	5,000	5,000	5,150
Tennessee	18,636	15,488	15,459	20,080	16,418	12,845	12,496	12,711
Texas	55,685	51,804	53,590	67,920	56,223	44,155	42,817	43,195
Utah	10,404	8,502	8,561	11,210	8,879	7,444	7,019	7,329
Vermont	6,454	5,199	5,187	6,703	5,844	5,041	5,043	5,193
U.S. Virgin Islands	639	488	497	861	651	462	457	453
Virginia	22,068	19,925	20,475	26,207	21,301	18,587	16,614	17,063
Washington	19,214	16,979	17,351	21,957	17,736	14,193	13,562	13,732
West Virginia	9,271	7,540	7,499	9,624	7,412	5,933	5,839	5,898
Wisconsin	17,821	14,812	14,975	19,199	15,869	12,188	12,178	13,276
Wyoming	6,171	4,909	4,907	6,372	5,748	5,000	5,000	5,000
TOTAL	970,000	849,595	862,779	1,091,437	896,740	728,878	688,914	653,889

Table 3: FY 2003-2010 PHEP FUNDING

APPENDIX B1: FY 2003-2018 PUBLIC HEALTH EMERGENCY PREPAREDNESS (PHEP) FUNDING

FY 2003- FY 2018 PHEP Cooperative Agreement State Funding Award Amounts (dollars shown in thousands)

AWARDEES	FY 2011	FY 2012	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017	FY 2018
Alabama	8,634	9,103	8,610	8,943	8,896	8,896	8,758	8,758
Alaska	5,178	4,198	3,988	4,185	4,204	4,204	4,183	5,026
American Samoa	374	380	374	364	363	363	361	361
Arizona	11,895	11,931	11,209	11,813	11,828	11,828	11,818	11,818
Arkansas	6,470	6,741	6,439	6,655	6,627	6,627	6,809	6,549
California	41,662	42,840	39,704	42,354	42,551	42,795	42,417	43,562
Chicago	10,410	9,847	9,578	9,820	9,793	9,793	9,651	9,651
Colorado	9,398	9,811	9,260	9,768	9,800	9,800	10,095	9,835
Connecticut	7,553	7,917	7,519	7,767	7,724	7,724	7,835	7,575
Delaware	5,423	4,410	4,309	4,390	4,386	4,386	4,325	5,026
District of Columbia	6,731	6,337	6,278	6,347	6,389	6,389	6,380	6,380
Florida	27,688	29,548	27,467	29,286	29,487	29,871	29,578	30,150
Georgia	15,654	16,225	15,156	16,049	16,013	16,013	15,917	15,917
Guam	501	519	501	487	485	485	484	484
Hawaii	5,260	4,918	4,763	4,887	4,890	4,890	4,864	5,048
Idaho	5,182	5,072	4,905	5,036	5,035	5,035	5,291	5,048
Illinois	16,846	17,315	16,172	16,860	16,717	16,717	16,315	16,315
Indiana	11,147	11,642	10,943	11,449	11,399	11,399	11,619	11,219
Iowa	6,596	6,889	6,588	6,786	6,779	6,779	6,714	6,714
Kansas	6,595	6,871	6,558	6,771	6,745	6,745	6,923	6,663
Kentucky	8,276	8,665	8,207	8,501	8,465	8,465	8,342	8,342
Los Angeles	20,405	20,059	19,078	19,842	19,739	19,739	19,556	19,296
Louisiana	8,632	9,047	8,558	8,927	8,899	8,899	9,045	8,785

AWARDEES	FY 2011	FY 2012	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017	FY 2018
Maine	5,206	4,776	4,646	4,723	4,706	4,706	4,924	5,048
Marshall Islands	3,200	380	373	380	381	381	384	384
Maryland	11,057	11,448	10,765	11,284	11,267	11,267	11,376	11,116
Massachusetts	13,460	13,216	12,467	13,011	13,119	13,669	12,967	13,540
Michigan	16,544	17,123	16,057	16,674	16,672	17,222	16,332	17,477
Micronesia	421	430	419	425	423	423	417	417
Minnesota	10,843	11,303	10,710	11,161	11,263	11,813	11,143	11,716
Mississippi	6,565	6,826	6,530	6,731	6,697	6,697	6,860	6,600
Missouri	10,718	11,189	10,527	10,947	10,886	10,886	11,104	10,704
Montana	5,179	4,366	4,269	4,346	4,343	4,343	4,591	5,048
Nebraska	5,179	5,421	5,225	5,373	5,365	5,365	5,592	5,332
Nevada	6,586	6,825	6,516	6,756	6,763	6,763	6,777	6,777
New Hampshire	5,399	4,881	4,743	4,830	4,813	4,813	5,036	5,048
New Jersey	16,185	16,033	14,993	15,671	15,593	15,593	15,545	15,285
New Mexico	6,526	6,717	6,495	6,651	6,751	7,301	6,674	6,674
New York	19,285	19,927	18,688	19,787	19,805	20,114	19,585	20,730
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New York City North Carolina	19,244	18,658	17,841	18,535	18,478	18,478	18,046	18,046
	14,020	14,977	14,008	14,927	14,918	14,918	14,815	14,815
North Dakota	5,180 358	4,198 358	3,988 354	4,185 360	4,204 359	4,204 359	4,183 358	5,026 358
N. Mariana Islands								
Ohio	17,609	18,538	17,282	18,044	17,904	17,904	17,527	17,527
Oklahoma	7,510	7,895	7,500	7,806	7,801	7,801	7,739	7,739
Oregon	7,830	8,146	7,730	8,052	8,034	8,034	8,013	8,013
Palau	323	325	323	325	324	324	324	324
Pennsylvania	19,775	20,201	18,810	19,685	19,524	19,524	19,472	19,072
Puerto Rico	7,474	7,505	7,141	7,271	7,158	7,158	7,167	6,907
Rhode Island	5,302	4,574	4,447	4,516	4,503	4,503	4,460	5,048

AWARDEES	FY 2011	FY 2012	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017	FY 2018
South Carolina	9,309	9,765	9,290	9,713	9,832	10,382	9,813	9,813
South Dakota	5,170	4,198	4,075	4,185	4,147	4,147	4,183	5,026
Tennessee	10,846	11,424	10,743	11,289	11,253	11,253	11,146	11,146
Texas	37,546	37,552	34,758	37,455	37,664	37,664	37,887	37,887
Utah	6,464	6,664	6,368	6,637	6,656	6,656	6,664	6,664
Vermont	5,192	4,198	3,988	4,185	4,204	4,204	4,583	5,026
U.S. Virgin Islands	424	433	422	423	421	421	415	415
Virginia	14,484	15,099	14,188	14,931	15,050	15,541	14,883	16,028
Washington	11,711	12,243	11,495	12,128	12,133	12,133	12,375	12,115
West Virginia	5,337	5,426	5,243	5,356	5,328	5,328	5,518	5,258
Wisconsin	11,236	11,728	11,129	11,521	11,588	12,077	11,417	12,562
Wyoming	5,170	4,198	3,988	4,185	4,204	4,204	4,183	5,026
TOTAL	613,606	619,449	584,698	611,751	611,750	616,419	611,750	620,250

Table 4: FY 2003- FY 2018 PHEP FUNDING

ACRONYM LIST

Table 1: Acronym List

Acronym	Definition
ASPR	Office of the Assistant Secretary for Preparedness and Response
BARDA	Biomedical Advanced Research and Development Authority
CARB-X	Combating Antibiotic Resistant Bacteria Biopharmaceutical Accelerator
CBRN	Chemical, Biological, Radiological, and Nuclear
CDC	Centers for Disease Control and Prevention
CEFO	Career Epidemiology Field Officer
CISA	Cybersecurity Information Sharing Act of 2015
DoD	Department of Defense
DURC	Dual Use Research of Concern
EAMS	Ebola Active Monitoring System
EHR	Electronic Health Records
EOC	Emergency Operations Center
EOP	Evaluation of Progress
EMS	Emergency Medical Services
EUA	Emergency Use Authorization
FDA	Food and Drug Administration
FESAP	Federal Experts Security Advisory Panel
FTAC-SAR	Fast Track Action Committee on Select Agent Regulations
FY	Fiscal Year
GHSA	Global Health Security Agenda
HAN	Health Alert Network
HCC	Health Care Coalition

Acronym	Definition
HHS	U.S. Department of Health and Human Services
HHS P3CO Framework	HHS Framework for Guiding Funding Decisions about Proposed Research Involving Enhanced Pandemic Potential Pathogens
HPP	Hospital Preparedness Program
HP2020	Healthy People 2020
IHR	International Health Regulations
JEE	Joint External Evaluation
JEE Tool	Joint External Evaluation Tool: International Health Regulations (2005)
LHD	Local Health Department
MCM	Medical Countermeasure
MERS- CoV	Middle East Respiratory Syndrome Coronavirus
MRC	Medical Reserve Corps
MVA	Modified Vaccinia Ankara
NDMS	National Disaster Medical System
NGO	Non-Governmental Organization
NHSPI	National Health Security Preparedness Index
NHSS	National Health Security Strategy
NIAID	National Institute of Allergy and Infectious Diseases
NIH	National Institutes of Health
PBS	Project Bioshield
PHEMCE	Public Health Emergency Medical Countermeasures Enterprise
PHEP	Public Health Emergency Preparedness
PHL	Public Health Laboratory
PHS	Public Health Service
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Acronym	Definition
ROI	Return on Investment
SARS	Severe Acute Respiratory Syndrome
SendSS	State Electronic Notifiable Disease Surveillance System
SLTT	State, Local, Tribal, and Territorial
SNS	Strategic National Stockpile
UNSCR 1540	United Nations Security Council resolution 1540
USPHS	U.S. Public Health Service Commissioned Corps
WHO	World Health Organization

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