International Health Regulations – Joint External Evaluation of the United States of America

Self-Assessment Report

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Abbreviations

Abbreviation	Full wording
AAVLD	American Association of Veterinary Laboratory Diagnosticians
ABSA	American Biological Safety Association
ACIP	Advisory Committee on Immunization Practices
AFHSB	Armed Forces Health Surveillance Branch (DoD)
AFRRI	Armed Forces Radiobiology Research Institute (DoD)
AHRQ	Agency for Healthcare Research and Quality (HHS)
AMR	antimicrobial resistance
APHIS	Animal and Plant Health Inspection Service (USDA)
APHL	Association of Public Health Laboratories
APIC	Association for Professionals in Infection Control and Epidemiology
APSED	Asia-Pacific Strategy for Emerging Infectious Diseases
ASPA	Assistant Secretary for Public Affairs (Office of)
ASPR	Assistant Secretary for Preparedness and Response (Office of)
ATSDR	Agency for Toxic Substances and Disease Registry (HHS)
BARDA	Biomedical Advanced Research and Development Authority (HHS)
BMBL	Biosafety in Microbiological and Biomedical Laboratories
BSAT	biological select agents and toxins
CARB	Combating Antibiotic-Resistant Bacteria (National Plan or National Strategy)
CBP	Customs & Border Protection (DHS)
CDC	Centers for Disease Control and Prevention (HHS)
CDRP	communicable disease response plans
CERC	Crisis and Emergency Risk Communication
CFR	Code of Federal Regulations
CLIA	Clinical Laboratory Improvement Amendments
CLSI	Clinical and Laboratory Standards Institute
CMS	Centers for Medicare & Medicaid Services (HHS)
CSTE	Council of State and Territorial Epidemiologists
DFWED	Division of Foodborne, Waterborne and Environmental Diseases (HHS)
DHS	Department of Homeland Security
DoD	Department of Defense
DoS	Department of State
DOE	Department of Energy
DOI	Department of Interior
DOT	Department of Transportation
DSLR	Division of State and Local Readiness (CDC)
DURC	dual use research of concern

Abbreviation	Full wording
EIP	Emerging Infections Program (CDC)
EIS	Epidemic Intelligence Service
EMP	Emergency Management Program
EOC	Emergency Operation Center
EPA	Environmental Protection Agency
EPCRA	Emergency Planning and Community Right-to-Know Act
ERLN	Environmental Response Laboratory Network
ESF	Emergency Support Function
ESSENCE	Electronic Surveillance System for the Early Notification of Community-based Epidemics
FAA	Federal Aviation Administration (DOT)
FAO	Food and Agriculture Organization
FBI	Federal Bureau of Investigation (Department of Justice)
FDA	Food and Drug Administration
FEMA	Federal Emergency Management Agency (DHS)
FERN	Food Emergency Response Network
FESAP	Federal Experts Security Advisory Panel
FIOP	Federal Interagency Operational Plans
FOOD Tool	Foodborne Outbreak Online Database
FRMAC	Federal Radiological Monitoring and Assessment Center
FSAP	Federal Select Agent Program
FSIS	Food Safety and Inspection Service (USDA)
FTAC-SAR	Fast Track Action Committee on Select Agent Regulations
GFI	Guidance for Industry
GHSA	Global Health Security Agenda
GHSI	Global Health Security Initiative
GOARN	Global Outbreak Alert and Response Network
GTD	Global Traveler's Diarrhea & Acute Gastroenteritis Study
GVAP	Global Vaccine Action Plan
HAN	Health Alert Network
HCAI	health care associated infections
EHR	electronic health record
HHS	Department of Health and Human Services
HICPAC	Healthcare Infection Control Practices Advisory Committee
HIPPS	HHS International Policy Group for Personnel Sharing
HPP	Hospital Preparedness Program
HRSA	Health Resources and Services Administration (HHS)
IAEA	International Atomic Energy Agency
IAS	International Assistance System
IATA	International Air Transport Association

Abbreviation	Full wording
ICAO	International Civil Aviation Organization
ICLN	Integrated Consortium of Laboratory Networks
IDCRP	Infectious Disease Clinical Research Program
IHR	International Health Regulations
IMAAC	Interagency Modeling and Atmospheric Assessment Center
INFOSAN	International Food Safety Authority Network
INTERPOL	International Criminal Police Organization
ISMPG	International Sharing of Medical Countermeasures Policy Group
ISO	International Organization for Standardization
IVD	*in vitro* (testing) devices
JEE	Joint External Evaluation
JIC	Joint Information Center
JTTF	Joint Terrorism Task Force
LRN	Laboratory Response Network
LRN-C	Chemical Threat Laboratory Response Network
MCM	medical countermeasures
MOU	memorandum of understanding
MERS-CoV	Middle Eastern Respiratory Syndrome Coronavirus
MMR	measles, mumps, rubella vaccine
MMRV	measles, mumps, rubella and varicella vaccine
MMWR	Morbidity and Mortality Weekly Report
MRSA	methicillin-resistant *Staphylococcus aureus*
MRSN	Multidrug-resistant organism Repository and Surveillance Network
NACCHO	National Association of County and City Health Officials
NAHLN	National Animal Health Laboratory Network
NAHRS	National Animal Health Reporting System
NAHSS	National Animal Health Surveillance System
NAPAPI	North American Plan for Avian and Pandemic Influenza
NAREL	National Analytical Radiation Environmental Laboratory
NARMS	National Antimicrobial Resistance Monitoring System
NBIC	National Biosurveillance Integration Center (DHS)
NDMS	National Disaster Medical System
NFP	National Focal Point
NHSN	National Healthcare Safety Network
NICCL	National Incident Communications Conference Line
NIH	National Institutes of Health
NIMS	National Incident Management system
NIOSH	National Institute for Occupational Safety and Health (CDC)
NIS	National Immunization Surveys
NLRAD	National List of Reportable Animal Diseases

Abbreviation	Full wording
NNDSS	National Notifiable Diseases Surveillance System
NMRC	Navy Medical Research Center (DoD)
NPHIC	National Public Health Information Coalition
NRC	Nuclear Regulatory Commission
NRF	National Response Framework
NRIA	Nuclear Radiological Incident Annex
NSABB	National Science Advisory Board for Biosecurity
NSAR	National Select Agent Registry
NSSP	National Syndromic Surveillance Program
NVAP	National Veterinary Accreditation Program
NVSL	National Veterinary Services Laboratories (USDA)
OCI	Office of Criminal Investigations (FDA)
OIE	World Organisation for Animal Health
OSHA	Occupational Safety and Health Administration (Department of Labor)
PAG	Protective Action Guides
PAHO	Pan American Health Organization
PAHPA	Pandemic and All Hazards Preparedness Act
PAHPRA	Pandemic and All Hazards Preparedness Reauthorization Act
PCR	polymerase chain reaction
PHEIC	public health emergency of international concern
PHEMCE	Public Health Emergency Medical Countermeasures Enterprise
PHEP	Public Health Emergency Preparedness cooperative agreement
PHL	public health laboratory
PICCL	Private Sector Incident Communications Conference Line
PoE	point/port of entry
PPD	Presidential Policy Directive
PPE	personal protective equipment
PT	proficiency testing
PVS	Performance of Veterinary Services
SAR	Select Agent Regulations
SARS	Severe Acute Respiratory Syndrome
SEDRIC	System for Enteric Disease Response, Investigation, and Coordination
SNRA	Strategic National Risk Assessment
SNS	Strategic National Stockpile
SOP	standard operating procedures
SSCC	Ship Sanitation Control Certificate
SSCEC	Ship Sanitation Control Exemption Certificate
TATFAR	Transatlantic Task Force of Antimicrobial Resistance
TIAS	Treaties and Other International Act Series
USAID	United States Agency for International Development

Abbreviation	Full wording
USAMRIID	United States Army Medical Research Institute for Infectious Diseases (DoD)
U.S.C.	United States Code
USCG	United States Coast Guard (DHS)
USDA	United States Department of Agriculture
USGS	United States Geological Survey (DOI)
USPHS	United States Public Health Service (HHS)
UST	United States Treaty
WHISPers	Wildlife Health Information Sharing Partnership – Event Reporting System
WHO	World Health Organization
WMD	Weapons of Mass Destruction

Executive Summary

This Self-Assessment Report for the Joint External Evaluation (JEE) describes the domestic U.S. capacities to prevent, detect, and respond to public health emergencies in alignment with the International Health Regulations (IHR). As a comprehensive overview, it sets the stage for the visit to the United States by external assessors on May 23-27, 2016. The JEE uses the evaluation methodology developed for the Global Health Security Agenda (GHSA), combining the infectious disease targets of GHSA with the all-hazards approach to public health preparedness and response required for implementation of the IHR. The Self-Assessment Report contains multisectoral descriptions of the U.S. public health system in the 19 capacity areas that are included in the JEE. The Office of the Assistant Secretary for Preparedness and Response (ASPR) in the U.S. Department of Health and Human Services (HHS) oversaw development of this report with considerable input from 23 U.S. departments and agencies. Using the Self-Assessment Report as reference material, the external assessors and U.S. Government subject matters experts will discuss the U.S. capacity levels during the external assessment visit. The external assessors will produce a final JEE report based on those discussions.

IHR Implementation and Coordination

Overall, the United States has legislation, policies and systems in place to meet the requirements for IHR implementation in all of the capacities included in the JEE. Implementation of the IHR began in 2007 when the 2005 amendments went into force, at which time most of the legislation and policy needed to support prevention, detection, assessment, response and reporting were in place in the United States. Through a series of interagency discussions and agreements, the U.S. federal government established the U.S. IHR National Focal Point (NFP) in ASPR. The U.S. IHR NFP role includes all of the essential NFP tasks – coordinating national risk assessments, officially communicating with the World Health Organization (WHO) regarding potential public health emergencies of international concern (PHEIC), and reporting the status of U.S. IHR implementation. As evidence of the success of multisectoral IHR implementation in the United States, the U.S. IHR NFP has notified the WHO of 77 potential PHEIC since 2007 (as of May 2016), including various types of communicable diseases, zoonoses, hazardous materials accidents, medical product defects, and foodborne infectious disease risks.

Disease prevention and health protection

The U.S. Centers for Disease Control and Prevention (CDC) within HHS is the nation's public health agency, with myriad offices that support every aspect of human health. Those offices collaborate extensively with other departments and agencies where their authorities and program areas intersect. The U.S. Food and Drug Administration (FDA) within HHS, is the primary regulatory authority for most food, food ingredients, animal feed/feed ingredients, and all medical products in the United States. The

U.S. Department of Agriculture (USDA) is the national lead for animal health, and has unique regulatory authorities over meat, poultry, egg products, and catfish as well as animal vaccines and other veterinary biologics for treating or preventing animal diseases. The Department of the Interior (DOI) oversees the health of wildlife in the extensive National Park System. The Department of Defense (DoD) is responsible for protecting the health and welfare of the military and military-associated populations, both within the United States and overseas, independently maintaining many public health programs and services.

Immunizations are a key component of disease prevention in the United States. U.S. states have compulsory rules for the vaccination of children who attend schools, though there are allowable exemptions for medical or personal reasons that vary by jurisdiction. As an indicator of the effectiveness of the U.S. system, 91.5 percent (± 0.9%) of children ages 19-34 months in 2014 had received the recommended vaccinations for measles.

In the Department of Labor (DOL), the Occupational Safety and Health Administration (OSHA) develops and promotes standards that protect almost all U.S. workers, including standards that afford protections to many health care and laboratory personnel. The CDC, USDA, FDA, and the Department of Homeland Security (DHS) collaborate to ensure the compliance of food and medical products passing through international air-, land-, and seaports in the United States. Additionally, the Department of Transportation (DOT), Department of State (DoS), and DHS play a supporting role in preventing the introduction of infectious diseases into the United States. The Department of Energy (DOE), the Nuclear Regulatory Commission (NRC) and the Environmental Protection Agency (EPA) are responsible for overseeing radiation protection regulations in the United States, though other agencies with a role in public health have radiation hazard-specific controls and plans in place. Similarly, EPA and other agencies have developed the Protective Action Guide (PAG) Manual for radiation emergencies. The PAG Manual contains radiation dose guidelines that would trigger public safety measures, such as evacuation or staying indoors, to minimize or prevent radiation exposure during an emergency. EPA also oversees the safe manufacture, usage and storage of chemicals. The Federal Bureau of Investigation (FBI) in the Department of Justice (DOJ) is a critical federal law enforcement partner for health security, maintaining relationships with all other departments and agencies, as well as with the international security community, to prevent threats and prosecute intentional or irresponsible actions that endanger the health of Americans.

Public health laboratories and surveillance systems

In the United States, the individual states, territories and other local-level jurisdictions bear most of the responsibility for overseeing the public health, health care, and veterinary systems, food production and processing, environmental sanitation, disease prevention, outbreak surveillance and responses to health emergencies. Numerous private health systems and practitioners provide the majority of human and veterinary medical care and laboratory services, with a federally coordinated network of state and local

laboratories providing the bulk of public health testing and confirmation using devices regulated by the FDA. Quality assurance schemes apply universally to public and private clinical laboratory services, and there are special, wide-ranging federal biosafety and biosecurity regulations. Numerous federal and state agencies provide oversight and enforcement of local biosafety and biosecurity policy implementation, complemented by the roles and responsibilities of other national organizations and academic institutions, to protect against misuse and mishandling of hazardous biological material.

High quality microbiology (including culture), rapid diagnostic testing, and biochemical assays for routine clinical diagnosis and public health screening are widely available for use by licensed medical providers. The United States has a highly regulated and closely monitored medical supply system, ensuring that there are safe pharmaceutical products and other medical treatments. CDC, USDA, DOI, DHS, FDA, and DoD maintain various components of an extensive laboratory network with designated human and veterinary laboratories around the country. Specific to the scope of the JEE, those networks provide widespread clinical, sentinel and syndromic surveillance data for a multitude of diseases, including zoonoses, that must be notified to the federal government, as well as antimicrobial resistant bacteria. The CDC Laboratory Response Network (LRN), the USDA National Animal Health Laboratory Network (NAHLN), and the DoD Laboratory Network ensure that states and jurisdictions have emergency access to testing for biological threat agents and toxins, chemicals, and radiological material. These laboratories, along with the USDA National Plant Diagnostic Network, the FDA/USDA Food Emergency Response Network (FERN), the FDA Veterinary Laboratory Investigation and Response Network, and the EPA Environmental Response Laboratory Network, comprise the U.S. Integrated Consortium of Laboratory Networks (ICLN) under the advisement of the DHS Joint Leadership Council.

Early warnings and alerts for human diseases and outbreaks of public health importance in the United States flow from local providers and laboratories to state and jurisdiction health departments based on jurisdiction-specific reportable disease lists. Through agreements with the federal government, those jurisdictions notify the CDC regarding the occurrence of a specified set of diseases and conditions. When outbreaks occur, the states and local health departments ensure that suitable investigations are completed with assistance from the federal government if needed. To varying degrees, states also use systems for event-based surveillance and syndromic surveillance that complement federal programs that are in the process of being expanded to cover the entire U.S. population. Systems for the surveillance of diseases in animal populations, whether as pets, a part of agriculture, or wildlife, are also present throughout the country under programs overseen by USDA or DOI.

Public health emergency response

There are several key legislative elements of the U.S. system for public health emergencies. The U.S. Public Health Service Act of 1944 provides specific quarantine and inspection authorities to HHS and gives the Secretary of HHS the authority to declare a public health emergency. The Federal Emergency Management Agency (FEMA) was created by Reorganization Plan No. 3 (43 FR 41943) which went into

effect on April 1, 1979. The Disaster Relief Act of 1974, amended in 1979, expanded the authorities of the Federal Emergency Management Agency (FEMA) to better assist individuals, states, and local communities. The Robert T. Stafford Disaster Relief and Emergency Assistance Act of 1988 provides the President of the United States with the authority to declare an emergency or major disaster, typically at the request of a state governor, that are subsequently managed by FEMA. The Stafford Act has been amended numerous times in an effort to remedy gaps in federal emergency response and recovery, including in 2006 by the Post-Katrina Emergency Management Reform Act and in 2013 by the Sandy Recovery Improvement Act. The U.S. Public Health Service Act has also been amended numerous times. For example, in 2004, the Project BioShield Act significantly increased the U.S. Government's investment in medical countermeasures against biological, chemical, radiological, and nuclear threats; and in 2006, the Pandemic and All-Hazards Preparedness Act created ASPR within HHS.

In addition to the examples of legislation cited above, multiple Presidential Policy Directives (PPD) and Homeland Security Policy Directives (HSPD) issued by the National Security Council (NSC) or the Homeland Security Council have established requirements and standards for the U.S. Government's multisectoral planning and preparedness. The United States has developed and implemented a comprehensive, crosscutting, multihazard system to prepare for and respond to public health emergencies. The existing planning frameworks – one each for prevention, protection, mitigation, response, and recovery – guide federal and state-based agencies as they plan for specific risks and hazards. Pursuant to the Homeland Security Act and Presidential directive, the Secretary of Homeland Security is the principal federal official for domestic incident management. As the national lead for human health, HHS is also the lead for public health emergency preparedness and response. For significant international public health events with potentially domestic impacts, the DoS has an important coordinating role during the U.S. response. By policy, the Attorney General of the United States, generally acting through the Director of the FBI, leads and coordinates the operational law enforcement response, on-scene law enforcement, and related investigative and appropriate intelligence activities related to imminent terrorist threats and incidents, including, but not limited to, weapons of mass destruction (WMD) or those that have public health consequences. Depending on the type of emergency and its consequences, HHS coordinates with other agencies as described by the National Response Framework (NRF) Emergency Support Functions (ESFs), Incident Annexes and related Federal Interagency Operational Plans (FIOPs) that comprise the elements of the National Preparedness System. All of the departments and agencies with a responsibility for a component of public health have an emergency operations center (EOC) that maintains situational awareness in their respective domains and that supports the coordination of activities during response operations. The DHS National Operations Center (NOC), the HHS Secretary's Operations Center (SOC), and the CDC EOC provide the broadest spectrum of awareness and oversight of activities during domestic public health emergencies, with the DoS Operations Center providing complementary coordination for an international event. The FBI-led WMD Steering Group, an interagency crisis action team, is activated within the FBI Strategic Information and Operations Center for WMD situations. It supports information exchange and de-

confliction of counterterrorism activities to prevent imminent WMD terrorist threats while simultaneously coordinating with the nationwide effort to save lives and protect property. The HHS SOC is part of the U.S. IHR NFP and serves as the official IHR point-of-contact with the WHO.

Challenges and Opportunities

Although the United States has systems to reduce the risks and impacts of major public health emergencies, and actively participates in the global health security system established by the IHR, there are still areas for improvement. In general, the U.S. Government seeks to be ready for both anticipated and unanticipated threats. The country's geographic size and spread, economic and social diversity, and legal complexity require ongoing refinement of existing plans and systems. Ongoing planning, capacity sustainment, partnership development and reinforcement, and integration of lessons learned account for the dynamic nature of human populations, international travel and trade, and the evolution of human pathogens and other threats to health security. Coordinating within and among federal departments and agencies, and maintaining functional relationships with state and other jurisdictional authorities, is a process constantly exercised and evaluated during real-world and simulated emergency responses. In some areas within the complex government structure, the implementation of IHR in the United States could be strengthened through the education of a variety of stakeholders across the country. While the United States maintains a robust National Level Exercise program for multiple types of disasters, more frequent exercises specific to public health emergencies, such as pandemics of influenza and other communicable diseases, could be useful in assessing aspects of both preparedness and response. As has been noted during past events, complexities of the federal system, with its numerous state and local jurisdictions, has the potential to result in delayed notification of potential PHEIC.

An area that deserves further evaluation is the development of triggers for national actions in situations that fall below the threshold for a public health emergency declaration. Events with significant public health implications to which the United States responds domestically and internationally, such as the 2010 earthquake and cholera outbreak in Haiti, the 2011 earthquake that destroyed the Fukushima Daiichi nuclear reactor, the Ebola virus disease outbreak in West Africa, and the Zika virus outbreak in the Americas, often fall below the legal threshold for an emergency declaration, yet require significant resources and multiagency coordination. Similarly, multiple and prolonged emergency responses require increased and sustained levels of coordination and the ability to "surge" beyond the traditional public health emergency scenarios. The federal government could evaluate models for an intermediate "emerging event" response status that enhances implementation of a shared, multiagency coordination mechanism even when it seems unlikely that a full emergency declaration will be needed.

With respect to the U.S. laboratory system, while the networks are extensive and efficient, there is a need for better coverage in some parts of the country and overseas territories. Components of the laboratory system that could be improved include surveillance for antimicrobial resistant bacteria,

testing for food contamination, and the detection of potentially dangerous microbes for human health in animal agriculture. Efforts are underway to develop and expand the use of new technologies, such as advanced molecular detection, to improve surge capacity for testing. The federal government could expand the existing systems, to include working with states and other jurisdictions, to establish greater local support systems for their designated public health laboratories (PHL) and to install technologies to link sub-systems across the entire country. Systems for human and animal health surveillance, as well as systems for environmental surveillance for chemicals and radiation, have grown in parallel, but not in concert with one another. Although linking and making optimal use of multisectoral, multilevel, multimedia surveillance data is an ongoing effort, full interoperability may be achievable only with development of new technologies.

There are other challenges related to the complexity and size of the U.S. public health system. For example, there is a modern, very productive biomedical research sector in the United States that is helping to create new countermeasures and diagnostics against biological threats. A number of recent laboratory incidents involving the mishandling of dangerous pathogens highlight the need for improvements to the national biosafety and biosecurity scheme, many of which are already underway. Federal and independent working groups have identified a number of specific opportunities, and the U.S. Government is considering greater efforts to achieve full implementation and evaluate the effectiveness of changes.

Lastly, developing and sustaining a qualified workforce is a critical part of a comprehensive strategy for public health security. The United States could focus on developing a better understanding of the types and numbers of personnel needed in national and subnational jurisdictions based on models that support current, local risk assessments. Based on recent studies and expert opinion, it seems that there are potentially significant gaps among risk communicators, radiation professionals, chemical emergency experts, emergency response coordinators, biosafety/biosecurity specialists and laboratorians of many types. The U.S. Government could consider options for developing a public health workforce model that is adaptable to local risk assessments, takes into account the ability of some personnel to have multiple qualifications, and the need for various types of experts and specialists in emergency situations that are most likely to occur.

Introduction to the United States Joint External Evaluation

Background

➢ Assessment Methods for IHR Implementation

The 58th World Health Assembly adopted amendments to the IHR in 2005 that fundamentally changed the way that States Parties would coordinate and collaborate to strengthen global health security. Entering into force on June 15, 2007, the purpose of the revised IHR was "to prevent, protect against, control, and provide a public health response to the international spread of disease in ways that are commensurate with and restricted to public health risks, and which avoid unnecessary interference with international traffic and trade."[1] The IHR amendments established explicit requirements and standards for the rapid and transparent communication of potential PHEIC by States Parties and assigned responsibility to the WHO to facilitate communication, ensure appropriate capacity building, and coordinate international responses to public health threats. An annual self-assessment and reporting by States Parties on their core public health capacities – another important new feature of the IHR – was intended to ensure that all countries met their IHR obligations by the June 2012 deadline originally established by agreement among the 196 IHR States Parties.

The primary method for evaluating IHR implementation introduced in 2012 was the IHR monitoring and evaluation framework and related annual questionnaire. The questionnaire required national authorities in each country to respond to a series of questions for 13 "core capacities." The framework included rank-ordered capacity levels informed by the annual questionnaire to describe the State Party's progress towards implementation of full capacities. In practice, the results of those State Party self-assessments were sent to their respective WHO Regional Offices and aggregated into regional statistics that were reported annually at the World Health Assembly. Despite the comprehensiveness of the IHR monitoring and evaluation framework, concerns about it centered around a lack of transparency in the respective national processes to obtain information, the lack of correlation between a country's stated capacity levels (based on self-assessment) and objective evidence, and a general disconnect between the outcomes of the evaluations and further planning for capacity building.

[1] WHO. International Health Regulations. 2005. 3rd edition.

Nearly 10 years after the update to the IHR, the Ebola virus outbreak in 2014 revealed how poorly prepared many countries still were to handle significant public health emergencies. The *IHR Review Committee on Second Extensions for Establishing National Public Health Capacities and on IHR Implementation*[2] (November 13-14, 2014) recommended that "…the Secretariat should develop through regional consultative mechanisms options to move from exclusive self-evaluation to approaches that combine self-evaluation, peer review and voluntary external evaluations involving a combination of domestic and independent experts. These additional approaches should consider, amongst other things, strategic and operational aspects of the IHR, such as the need for high-level political commitment, and whole -of -government/multi-sectoral engagement…"

➢ The Global Health Security Agenda External Evaluation Process

Launched on February 13, 2014, as a multilateral, multisectoral collaboration framework among 28 countries, the WHO, the Food and Agriculture Organization (FAO) and the World Organisation for Animal Health (OIE), GHSA has set the joint goal of accelerating progress toward full global IHR implementation. In addition to the 11 capacity building "action packages" for infectious disease prevention, detection and response, GHSA introduced a functional model for an independent, external evaluation process for participating countries. The GHSA Assessment Tool, piloted in Uganda, Georgia, Peru, Portugal, and the United Kingdom, provided a series of targets and structured indicators for each of the action packages designed to assist countries to develop their own capacity building "roadmaps."

In the GHSA process, the countries used the GHSA Assessment Tool to conduct a self-assessment and write a report for review by a team of independently selected "external assessors" prior to an in-country visit. During the visit, the national team and the external assessors discussed the self-assessment report and arrived at a capacity-level score based on the pre-selected indicators. The rank-ordered scoring system in the GHSA Assessment Tool was similar to the capability indicator system used in the IHR evaluation framework. In October 2015, members of a WHO consultation meeting concluded that the existing IHR evaluation framework (which reflected the all-hazards approach to emergency preparedness and response) should be merged with the GHSA external evaluation methodology.[3] Adapting the GHSA methodology, including all of its targets and indicators, for the evaluation of IHR capacities resulted in the development of the JEE Tool and process.

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[2] WHO. Report by the Director-General: Executive Board, 135th Session/Agenda Item 22/Addendum 1. 16 January 2015.

[3] WHO. Technical consultation on monitoring and evaluation of functional core capacity to implement the International Health Regulations (2005). 20-22 October 2015.

➢ The Joint External Evaluation Tool

The JEE Tool combines the GHSA targets for each action package with the IHR core capacities for a total of 19 capacity elements or technical areas. Each capacity element, or Technical Area, is associated with a "target statement," one or more indicators, and a rank-ordered scoring system for each indicator. Some of the 48 JEE indicators are derived from the original IHR framework and some are from the GHSA Assessment Tool. In the JEE Tool (and this Report), the indicators are grouped into the "Prevent" (P), "Detect" (D), and "Respond" (R) categories (e.g., P1, P2, R1, R2, etc.). The Other IHR-Related Hazards and Points of Entry indicators are distinct, and labeled as "Points of Entry" (PoE), "Chemical Events" (CE), and "Radiation Emergencies" (RE).[4] **The targets and indicators throughout this report have been taken verbatim from the JEE Tool and retain their labels.**

For quick reference, Tables 1 through 4 (below) showe the arrangement of JEE sections, the capacity elements and the indicator labels from the JEE Tool.

Table 1. Technical areas within the PREVENT section of the JEE Tool.

Technical Area (Capacity)	Labels
National Legislation, Policy, and Financing	P.1.x
IHR Coordination, Communication, and Advocacy	P.2.x
Antimicrobial Resistance	P.3.x
Zoonotic Disease	P.4.x
Food Safety	P.5.x
Biosafety and Biosecurity	P.6.x
Immunization	P.7.x

Table 2. Technical areas within the DETECT section of the JEE Tool.

Technical Area (Capacity)	Labels
National Laboratory System	D.1.x
Real-Time Surveillance	D.2.x
Reporting	D.3.x
Workforce	D.4.x

[4] In the May 2016 (original) version of this report that was provided to the external assessors only, the indicator labels were based on a version of the JEE Tool that was released in January 2016. Since then, an updated version of the JEE Tool was released and is now the official JEE Tool. This September 2016 revision (released to the public) reflects the changes to the labeling of the indicators.

Table 3. Technical areas within the RESPOND section of the JEE Tool.

Technical Area (Capacity)	Labels
Preparedness	R.1.x
Emergency Operation Centers	R.2.x
Linking Public Health and Security Authorities	R.3.x
Medical Countermeasures and Personnel Deployment	R.4.x
Risk Communication	R.5.x

Table 4. Technical areas within the OTHER IHR HAZARDS AND POINTS OF ENTRY section of the JEE Tool.

Technical Area (Capacity)	Revised Labels
Points of Entry	PoE.1 & PoE.2
Chemical Events	CE.1 & CE.2
Radiation Emergencies	RE.1 & RE.2

Process & Methodology for the United States JEE Self-Assessment

In preparation for the JEE of the United States, ASPR coordinated a comprehensive self-assessment of U.S. IHR capacities using the JEE Tool (see the full list of participating agencies below). The relevant federal departments and agencies identified a lead person or team to be responsible for coordinating their respective contributions to the JEE. Originally planning to use the GHSA assessment tool, ASPR and the HHS Office of Global Affairs hosted a series of teleconferences starting in December 2015 to establish a U.S.-specific process for the self-assessment. Based on the release of the JEE Tool in January 2016, the White House NSC Staff hosted an interagency "Town Hall" meeting on January 27 to introduce the new JEE Tool and facilitate the adoption of the combined IHR-GHSA evaluation system.

The U.S. Government's departments and agencies that provided an agency lead during the development of this report included:

Department of Health and Human Services

- Office of the Assistant Secretary for Preparedness and Response
- U.S. Centers for Disease Control and Prevention
- U.S. Food and Drug Administration
- Health Resources and Services Administration
- National Institutes of Health
- National Vaccine Program Office
- Office of the Assistant Secretary for Global Affairs
- Office of the Assistant Secretary for Public Affairs

Department of Agriculture
- Animal and Plant Health Inspection Service
- Food Safety Inspection Service

Department of Defense
Department of Energy
Department of Justice
- Federal Bureau of Investigation

Department of Homeland Security
Department of the Interior
- U.S. Geologic Survey
- Fish and Wildlife Service

Department of Labor
- Occupational Health and Safety Administration

Department of State
Department of Transportation
Department of Veterans Affairs
Environmental Protection Agency
Nuclear Regulatory Commission
U.S. Agency for International Development
White House Executive Office
- Office of Management and Budget
- National Security Council Staff

Based on the JEE Tool, ASPR created a template that the agency leads used to organize their agency's inputs; in some cases, subject matters experts consulted with their counterparts in other agencies to align their inputs. ASPR organized a small team of volunteers from within ASPR, CDC, USDA, DoD and FDA (see *Acknowledgements* in Appendix 5) to help analyze the inputs from the U.S. departments and agencies, compile their responses, and compose sections of the first draft of the JEE self-assessment report. Following several rounds of technical review and revision, the final draft was cleared through existing interagency processes and sent to the external assessors.

This U.S. JEE Self-Assessment Report follows the same general structure as the JEE Tool. In brief, the self-assessment contains four major **sections** (Prevent, Detect, Respond, and Other IHR Related Hazards and Points of Entry.). Each section contains a number of **capacity elements** (e.g., *National Legislation, Policy, and Financing, Antimicrobial Resistance, Radiation Events,* etc.) for a total of 19 elements. Each capacity element has a **target** statement (taken verbatim from the JEE Tool), a high-level **summary of the U.S. capabilities**, and a more detailed description of the capabilities under one or more **indicators** (also taken directly from the JEE tool). Following each indicator, subtitles help to organize related themes or activities. At the end of each capacity element, there are paragraphs on **Best Practices,**

Gaps, Challenges, and Recommendations based on the analysis of the information provided and on the expertise of the U.S. departments and agencies that contributed to this self-assessment report.

Results from the United States International Health Regulations Joint External Evaluation Self-Assessment

PREVENT

National Legislation, Policy, and Financing

Prevent 1 (P1)

JEE Target

States Parties should have an adequate legal framework to support and enable the implementation of all of their obligations and rights to comply with and implement the IHR (2005). In some States Parties, implementation of the IHR (2005) may require new or modified legislation. Even where new or revised legislation may not be specifically required under the State Party's legal system, States may still choose to revise some legislation, regulations or other instruments in order to facilitate their implementation and maintenance in a more efficient, effective or beneficial manner. State parties should ensure provision of adequate funding for IHR implementation through national budget or other mechanism.

Level of Capabilities in the United States

➢ **Summary**

In 2007 and 2008, leading up to and following immediate implementation of the IHR in the United States, legislative and policy reviews led by ASPR resulted in the development of a national IHR policy and organizational framework. Before that, the U.S. Public Health Service Act (1944), the Disaster Relief Act (1974), Stafford Act (1988), and the Project BioShield Act (2004), among many other laws, regulations and policies, had already established many of the foundational elements for health surveillance, early event detection and warning, and multisectoral coordination and emergency response in the United States. Individual agencies with a role in public health were involved in the policy process to implement the IHR in the United States through a series of workshops and interagency dialogue. Public health in the United States is a multiagency task, with complementary authorities, roles and responsibilities. CDC leads the nation's human public health system, with complementary responsibilities in USDA for animal health and FDA for most food and medical products. Many other agencies contribute to public health protection through water and environmental surveillance activities, research and development, oversight of the natural and built environments, and control of international borders. All of the agencies that have defined roles in national health security coordinate with U.S. state and local authorities in various ways, where appropriate.

The policy, programmatic, and logistical infrastructure for national health security has grown considerably in the last 10-15 years as a result of real-world experiences and challenges, with a number

of executive policies and strategic plans that describe an appropriate role for the U.S. IHR NFP and IHR processes. Designated points of contact for the IHR in each agency form the list of "U.S. IHR Stakeholders." Those stakeholders inform the U.S. IHR NFP of potential health events, conduct risk assessments, and participate in multiagency consultation in preparing official IHR notifications. They also serve as subject matter experts for the annual IHR core capacity assessments. Successful IHR implementation in the United States has led to 77[5] potential PHEIC notifications to the WHO since 2007.

➢ **Indicators**

■ ***Legislation, laws, regulations, administrative requirements, policies or other government instruments in place are sufficient for implementation of IHR*** ***P1.1***

Primary U.S. laws and regulations for public health emergency preparedness and response

- The Robert T. Stafford Disaster Relief and Emergency Assistance Act (Public Law 93-288, as amended, 42 U.S.C. §5121 et seq.). This Act constitutes the statutory authority for most federal disaster response activities, especially as they pertain to FEMA and its programs. Importantly, the Stafford Act also provides the President of the United States with the authority to declare emergencies and major disasters, making available additional federal resources, including incident management.
- The U.S. Public Health Service Act, first passed into law in 1944 as Chapter 6A of Title 42 (The Public Health and Welfare) of the U.S. Code (specifically 42 U.S.C. § 201-300), contains numerous subchapters that authorize federal activities to protect and preserve the health of the United States.
    - The Project BioShield Act of 2004 amended the U.S. Public Health Service Act (section 201) to better prepare the United States for potential terrorist attacks and created authorities for the acquisition of medical countermeasures for the Strategic National Stockpile (SNS).
    - In 2006, Congress enacted the Pandemic and All-Hazards Preparedness Act (PAHPA, Public Health Law No. 109-417), which amended the U.S. Public Health Service Act to establish ASPR . ASPR became the national lead for policies, planning, and operations related to strengthening U.S. health systems and public health capacities. As a coordinating entity within HHS and among the other departments, ASPR supports all levels of emergency preparedness and response, from the needs of individual families and communities, to advanced medical

[5] Official notifications provided to WHO under Article 6 (PHEIC) of the IHR as of May 3, 2016. This number does not include numerous other notifications under other Articles and innumerable informal communications with WHO.

countermeasures development and the global deployment of resources. ASPR also provides leadership within HHS in international and global health security through several strategic partnerships (described in detail below) and maintains the functions of the U.S. IHR NFP. Importantly, PAHPA also reauthorized the funding for the Hospital Preparedness Program (HPP) and the Public Health Emergency Preparedness (PHEP) cooperative agreements . These two federal programs, described in detail throughout this report, remain critical in supporting state and local preparedness capacities.

- The Pandemic and All-Hazards Preparedness Reauthorization Act (PAHPRA, Public Health Law No. 113-5) reauthorized PAHPA in 2013.
- The U.S. Public Health Service Act also authorizes the Secretary of HHS to declare a public health emergency, increasing the ability of the Secretary and HHS component to mobilize and coordinate HHS resources to prevent and mitigate the consequences of the event.
- Additional legislation, regulation, and plans related to national emergency systems are described in the sections on *IHR Coordination, Communication, and Advocacy, Preparedness,* and *Workforce Development*, along with many other references to specific components of national health security as required in other sections where relevant.

- The United States ratified participation in the IHR on July 25, 1969 (Boston, 21 United States Treaty [UST] 3003; Treaties and Other International Acts Series [TIAS] 7026; 764 United Nations Treaty Series 3) and subsequent amendments in 1973 (25 UST 197; TIAS 7786) and in 1981 (33 UST 4436; TIAS 7786). In December 2006, the United States accepted the 2005 amendments to the IHR, subject to one reservation and three understandings, through a Presidential *Executive Agreement*.

Policies and strategies for public health emergency preparedness and response

- The U.S. Government has many national policies that provide a strong foundation for all planning and programming efforts. Table 5 below lists and describes several foundational national polices from 2001 to 2011 that explains their respective mandates related to supporting U.S. health security efforts.
- Highlighting a few policies:
  - *Presidential Policy Directive 2: National Strategy for Countering Biological Threats* (November 2009) specifically committed the United States to fulfilling its obligations under the IHR and the Biological Weapons and Toxins Convention, United Nations (UN) Security Council Resolution 1540, and guidelines established by the Organization for Animal Health (OIE).
  - *Presidential Policy Directive 8: National Preparedness* (March 2011) directed the establishment of a national preparedness system that links all levels of government with the public and private sectors in a coordinated effort to strengthen the security and resiliency of the United States against all forms of disasters, including pandemics .

Table 5. Major U.S. policy directives guiding and supporting national health security.

Year	Policy Title	Mandate
2001	HSPD 1: Organization and Operation of the Homeland Security Council	Coordination of all homeland security-related activities among departments and agencies
2003	HSPD 4: National Strategy to Combat Weapons of Mass Destruction	Applies new technologies, intelligence collection and analysis, strengthens alliance relationships, and establishes new partnerships with former adversaries to counter this threat
2003	HSPD 5: Management of Domestic Incidents	Directed the Secretary of Homeland Security to develop and administer a **National Incident Management System** to manage domestic incidents
2004	HSPD 9: Defense of United States Agriculture and Food	Establishes national policy to defend the agriculture and food system against terrorist attacks, major disasters, and other emergencies
2004	HSPD 10: Biodefense for the 21st Century	Provides a comprehensive framework for biodefense based on Threat Awareness, Prevention and Protection, Surveillance and Detection, and Response and Recovery
2007	HSPD 18: Medical Countermeasures against Weapons of Mass Destruction	Establishes national policy guidelines for the public and private sectors to address medical countermeasures for chemical, biological, radiology and nuclear threats
2007	HSPD 21: Public Health and Medical Preparedness	Plans and enables the provision for the public health and medical needs of the American people in the case of a catastrophic health event
2009	PPD 2: Implementing National Strategy for Countering Biological Threats	Defines the approach to reducing the risks of biological weapons proliferation and terrorism
2011	PPD 8: National Preparedness (Expanded HSPD 8 from 2003)	Strengthens security and resilience of the United States through preparation for threats to national security (terrorism, cyberattacks, pandemics, and natural disasters)

- The *National Health Security Strategy 2015-2018* (NHSS) – first issued in 2010 – provides strategic direction to ensure that efforts to improve health security nationwide are guided by a common vision, based on sound evidence, and carried out in an efficient, collaborative manner.
    - ASPR led the development of the NHSS in collaboration with a broad range of stakeholders, including representatives from local, state, territorial, tribal, and federal governments; community-based organizations; private-sector firms; and academia. The strategy is an important document for the public health, health care, and emergency management communities, providing a framework to build community resilience, strengthen and sustain health emergency response systems, improve capabilities, and prioritize resources based on current and future budgets.

- The NHSS Implementation Plan lists activities that stakeholders in national health security may perform over the next four years in support of the priorities.

- Prior to and since President George W. Bush's *Executive Agreement* accepting the 2005 amendments, implementation of the IHR through a number of other Presidential Directives, national strategies and plans, and agencies' policies ensures that the United States sustains its domestic commitment to global health security. Additional details related to functional aspects of the U.S. IHR NFP and the initial implementation steps in the United States are in the *IHR Coordination, Communication, and Advocacy* section of this report.

Examples of financing for national health security

- In addition to providing direct medical assistance and resources during an emergency, there are also many federal programs and efforts that strengthen state and local capabilities and capacity. ASPR's HPP and CDC's PHEP cooperative agreements serve as prime examples of federal support mechanisms for strengthening the day-to-day preparedness of public health and medical systems and health-related infrastructure, including medical surge capacity and capabilities.
  - Currently the HPP and the PHEP support 62 grantees, which includes all 50 states, eight U.S. territories in the Caribbean and Pacific, and four metropolitan areas. Since 2002, together they have provided approximately more than $13 billion to grantees, with $84 million awarded in 2014.
  - The HPP, managed by ASPR, provides federal funding and technical assistance to states, territories, and eligible municipalities to improve surge capacity and enhance community and health care system preparedness for public health emergencies. HPP promotes a sustained national focus on outcomes and enables the local level to respond during emergencies that exceed the day-to-day capacity of health and emergency response systems, minimizing the need for supplemental state and federal resources during emergencies and recovery. State, city, and territorial Departments of Public Health, working in partnership with the hospitals and health care systems within their jurisdictions, have made progress since 2001, as demonstrated in the ASPR report *From Hospitals to Healthcare Coalitions: Transforming Health Preparedness and Response in Our Communities*.
  - The PHEP, managed by CDC, provides federal funds and technical assistance to state and local public health systems to help public health departments to strengthen their ability to respond to all types of public health incidents. Preparedness activities funded by the PHEP specifically target the development of emergency-ready public health departments that are flexible and adaptable in a response. For an example of a state summary report, see Washington State Department of Health Public Health Emergency Preparedness and Response Program Annual Summary Report 2011-2012.

Table 6. Alignment between the Hospital Preparedness Program (HPP)/Public Health Emergency Preparedness (PHEP) healthcare and public health capabilities and the original (2010) IHR core capacities from the WHO monitoring and evaluation framework. In the 2017 program year, these indicators will be updated.

Healthcare and Public Health Capabilities used by HPP/PHEP	NFP Coordination	Risk Communication	Legislation Policy	Surveillance	Response	Preparedness	Laboratory	HR Capacity	Zoonotic Events	Chemical Events	Food Safety	Radiation	Points of Entry
Community (Healthcare System Preparedness)	X	X	X	X	X	X		X					X
Community (Health System) Recovery	X	X	X	X		X		X					X
Emergency Operations Coordination	X	X	X		X	X		X					X
Fatality Management	X	X	X		X	X		X					X
Information Sharing	X	X	X	X	X	X		X					X
Mass Care	X		X	X	X	X		X	X	X	X	X	X
Medical Countermeasure Dispensing			X		X	X		X					X
Medical Countermeasure Distribution			X		X	X		X					X
Medical Surge			X		X	X		X	X	X	X	X	X
Non-pharmaceutical Interventions			X		X	X		X					X
Public Health Laboratory Testing			X	X	X	X	X	X	X	X	X	X	X
Public Health Surveillance and Epidemiological Investigation			X	X	X	X	X	X	X	X	X	X	X
Responder Safety and Health			X	X	X	X		X					X
Volunteer Management			X		X	X		X					X

Examples of cross-border agreements supporting health security

- HHS is an active member of the Global Health Security Initiative (GHSI), an informal network of countries formed in 2001 to ensure health-sector exchange and coordination of practices for confronting risks to global health posed by chemical, biological, and radiological and nuclear threats, including pandemic influenza. The members of GHSI are Canada, France, Germany, Italy, Japan, Mexico, the United Kingdom, the United States, and the European Commission with WHO as a technical advisor. An annual meeting of health ministers is held to foster dialogue on topical

policy issues and promote collaboration. Throughout the year, senior health officials, policy, technical, and scientific personnel focus on risk management, communications, information sharing, and global laboratory cooperation.

- ASPR, in close collaboration with DoS, USDA, and DHS, leads the implementation of the North American Plan for Animal and Pandemic Influenza (NAPAPI), which is a comprehensive, regional, and cross-sectoral health security framework. NAPAPI outlines how the health, security, agricultural, and foreign affairs sectors of Canada, Mexico, and the United States intend to strengthen their respective emergency response capacities and trilateral collaborations and capabilities; and to foster policy solutions for assisting each other to ensure a quick and coordinated response to outbreaks.
- The IHR NFPs of the United States, Canada, and Mexico, in coordination with the Pan American Health Organization (PAHO), have agreements in place to include one another in all official notifications under IHR.
- In 2006, the United States, Canada, and Mexico developed a joint concept of operations for Pandemic Influenza Operational Response among the three states' civil aviation authorities with common objectives, principles, communication mechanisms and protocols, and coordination requirements. The joint concept of operations was developed utilizing guidance from the WHO, the International Civil Aviation Organization (ICAO), and International Air Transport Association (IATA).
- The United States plays a central role in the GHSA, building partnerships with nearly 50 countries to coordinate and conduct capacity -building activities. GHSA action packages focus on infectious disease risks, while GHSA roadmaps are designed to create systems and infrastructure that help to fulfill the IHR more broadly.
- In 2012, Secretary of HHS Kathleen Sebelius and Mexico's Secretary of Health Salomón Chertorivski signed a declaration adopting a shared set of technical guidelines that both countries will follow to respond to public health events affecting both countries. *The Technical Guidelines for United States-Mexico Coordination on Public Health Events of Mutual Interest* complement the IHR, which call for the countries to develop accords and work together on shared epidemiologic events and public health issues. Secretaries Sebelius and Chertorivksi also signed a renewed agreement between the United States and Mexico that strengthens existing bilateral food safety cooperative activities.

- ***The state can demonstrate that it has adjusted and aligned its domestic legislation, policies, and administrative arrangements to enable compliance with the IHR (2005) P1.2***

Evidence that U.S. IHR implementation has been effective

- Since July 4, 2007 when the United States submitted its first report to WHO in response to a contaminated food export, there have been 102 official NFP communications between the United States and the WHO in accordance with IHR *Articles 6, 7, 30,* or *44*. There have been innumerable unofficial communications. Seventy-seven of those notifications have been under Article 6 (PHEIC).

- The United States typically meets the timelines for notification of potential PHEIC and handles all other official communications with the WHO and other countries' NFPs within approximately 24-48 hours.
- Additional evidence regarding the effectiveness of the U.S. IHR implementation is provided in the sections on *IHR Coordination, Communication, and Advocacy* and *Reporting*.

Best Practices, Challenges, Gaps, and Recommendations

Through a comprehensive, all-hazards approach, the United States maintains strong capacities to prepare for, respond to, and recover from public health emergencies. Many of the capacities and capabilities required to fulfill the IHR existed in the United States prior to the 2007 entry into force. The federal government is capable of intervening domestically in support of state and local government and U.S. private institutions, and coordinates with regional and international partners to prevent multiple types of threats from having significant public health impacts. Because individual states and jurisdictions are primarily responsible for public health and initial emergency response, the federal government has established numerous programs and agreements that enhance their capabilities. During an emergency, the states and federal governments have the authority to declare an emergency and gain access to additional resources and authorities to protect the public.

Although all of the IHR core capacities are present in the United States, including a multisectoral approach to IHR implementation, the U.S. multilevel approach to governance and public health protection poses some challenges. In a country that is as large and diverse as the United States, when there are epidemiologically complex, emerging, large-scale or international public health threats, organizing all of the stakeholders, assets, and information is commensurately difficult. For instance, the initial authorities for responding to public health events that fall short of being disasters is sometimes uncertain, and the extent to which the federal government can provide direct, adaptive, preparatory assistance to the states and other jurisdictions is limited.

Other challenges to U.S. public health emergency response coordination are highlighted through this report. For instance, sharing situational awareness among the federal departments and agencies, and ensuring that the public is accurately informed of the situation and the U.S. Government's related response, can be inconsistent. In some disciplines and areas of professional specialization, there are limited and dwindling numbers of experienced people at the federal level, and significant human resources shortages in many professions in subnational areas. For most of the IHR-required capacities, there are still some areas of improvement that perhaps go beyond the minimum requirements for the IHR. The U.S. system has evolved considerably in the face of recent public health events, but there are still opportunities for improvement described in subsequent sections of this report. With respect to *National Legislation, Policy, and Financing* for IHR implementation, one area that deserves further

evaluation is the appropriate mechanism for facilitating interagency coordination and response in situations that fall below the threshold for an emergency declaration.

While the current U.S. government's authority to declare a public health emergency is well established, there are limitations to the flexibility of those authorities. A Presidential declaration under the Stafford Act requires that state and local response assets are (or will certainly be) overwhelmed by a response to a specific event. The Secretary of HHS may declare a public health emergency, but does not have the authority under the U.S. Public Health Service Act to declare a "potential public health emergency" and nor do those authorities extend beyond the department to (necessarily) involve the rest of the U.S. Government in the response. As has been seen recently, many emerging public health threats, including those that begin at an international source, do not have an immediate, serious impacts on the health of Americans, but require significant, federal interagency collaboration for extended periods of time in order to prevent global impacts or significant global spread. Both Ebola and Zika virus outbreaks are good examples of that phenomenon, and few types of health threats have the same potential to expand and evolve in the way that communicable pathogens do. The options for the federal government to activate and coordinate at the earliest stages of a recognized "emerging event", but prior to the need for a public health emergency declaration, is an area that could be explored.

IHR Coordination, Communication, and Advocacy

Prevent 2 (P2)

JEE Target

The effective implementation of the International Health Regulations 2005 (IHR) requires multisectoral/ multidisciplinary approaches through national partnerships for effective alert and response systems. Coordination of nationwide resources, including the sustainable functioning of a National IHR Focal Point (NFP), which is a national center for IHR communications, is a key requisite for IHR implementation. The NFP should be accessible at all times to communicate with the WHO IHR Regional Contact Points and with all relevant sectors and other stakeholders in the country. States Parties should provide WHO with contact details of NFPs, continuously update and annually confirm them.

Level of Capabilities in the United States

➢ **Summary**

Mechanisms to implement the new requirements in the updated IHR – the functions of the NFP, multisectoral coordination for health event assessment and notifications, and assessment of national core capacities – leveraged existing authorities and interagency relationships. The responsibility for management of the core and expanded functions of the NFP (as defined by the IHR) were assigned to ASPR. The Assistant Secretary serves as the national authority for the approval of official communications with WHO; the IHR Program in the ASPR Office of Policy and Planning (described in greater detail below) performs managerial and advocacy functions; and the HHS SOC provides full-time situational awareness and communication channels.

Coordination among the U.S. departments and agencies is critical to maintaining IHR implementation. Existing directives (PPD 2, PPD 8), laws (PAHPRA), and systems require multisectoral dialogue with a robust planning, implementation, and response capacity to protect the health of the country. Fulfillment of the IHR is a unique obligation, and the U.S. IHR NFP is an integral component of the national public health system. Along with the agencies with direct responsibility to preserve and protect public health, the U.S. IHR NFP continues to evolve and adapt to new circumstances and challenges.

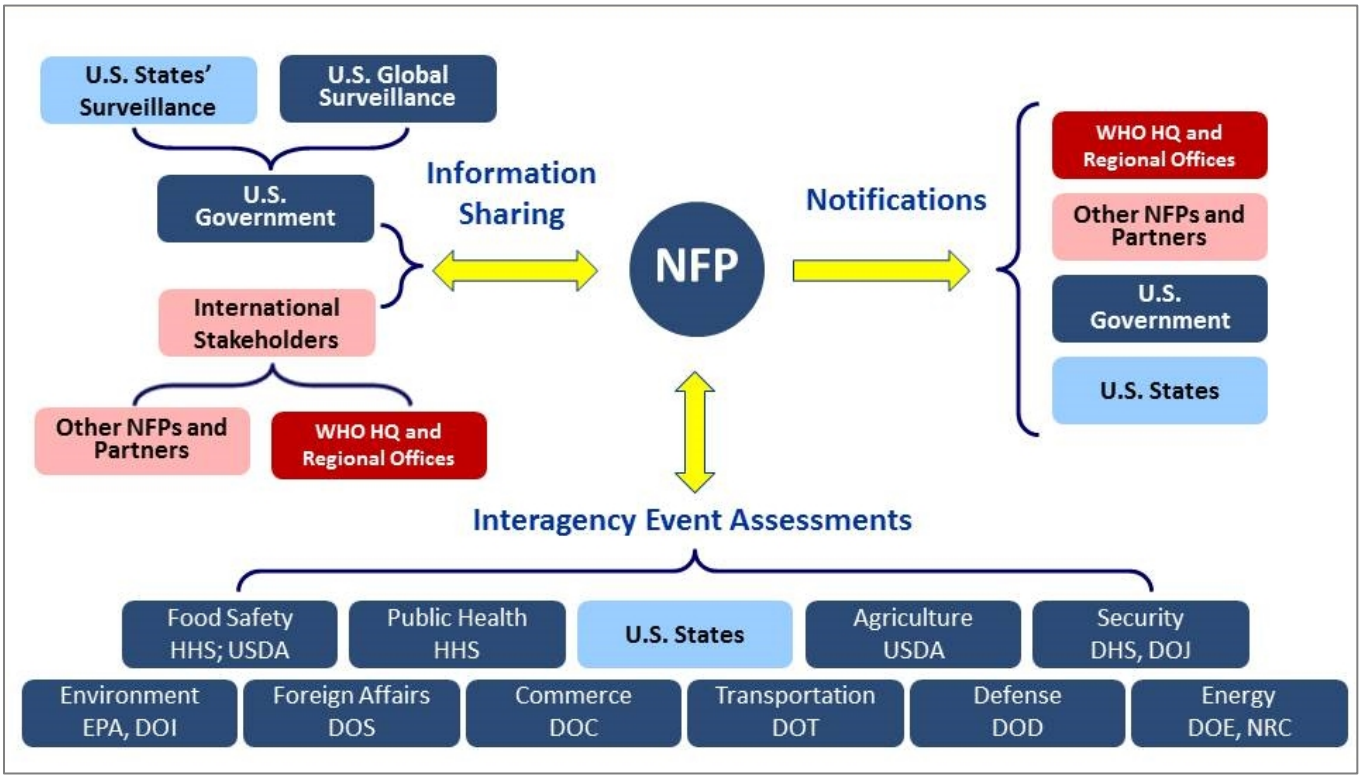
➢ Indicators

■ ***A functional mechanism is established for the coordination and integration of relevant sectors in the implementation of IHR*** ***P2.1***

Structure of the U.S. IHR NFP

- The *ASPR IHR Program* in the Office of Policy and Planning provides policy and procedural oversight for all IHR obligations (both core and expanded functions).
- The *Assistant Secretary for Preparedness and Response* provides overall leadership and acts as the approval authority for all IHR official communications.
- The HHS SOC, managed by the ASPR Office of Emergency Management, provides 24/7/365 situational awareness and communications nationally and internationally in close coordination with operation centers of other federal departments and agencies.

Figure 1. Information flow through the United States IHR Focal Point



Interagency coordination for events that may constitute a public health emergency

- The U.S. IHR NFP provides day-to-day coordination of IHR-related assessment and notification activities in consultation with IHR Stakeholders based on interagency policy agreements. Individual

departments and agencies maintain their own internal structures and policies for interagency coordination related to public health surveillance, detection, and assessment of potential events, and communication of those events to the NFP.

- Figure 1 depicts the functional relationships among components of the United States federal and state public health systems and the international stakeholders, with information and coordination through the U.S. IHR National Focal Point
  - Routine information sharing on emergency and non-emergency situations from the U.S. states and the global surveillance systems operated by the U.S. Government, and information from the World Health Organization and other governments' National Focal Points, all reach the U.S. IHR NFP through established channels.
  - When needed, the U.S. IHR NFP coordinates public health event assessments with the U.S. interagency via points of contact with the many agencies that maintain some component of the U.S. domestic health security system. U.S. states are typically involved only as needed.
  - Finally, when event assessments have been completed, the U.S. IHR NFP helps to compose the final notification messages that are sent to the WHO and the regional offices (such as the Pan American Health Organization or the Western Pacific Regional Office in which reside the U.S. Territories), other countries' National Focal Points (directly), other parts of the U.S. Government not already involved in the event assessment or the U.S. states (as needed).

- The U.S. IHR NFP maintains and regularly tests and updates, as needed, the contact list for the U.S. IHR Stakeholders. Many contact points include the agencies' respective EOCs.
- A detailed description of the U.S. IHR NFP procedures for coordinating potential PHEIC notifications with other agencies can be found in the section on *Reporting* in this report.

Procedures and guidelines are available for coordination between NFP and other relevant sectors

- A comprehensive set of NFP standard operating procedures (SOP) describes the roles and responsibilities of the U.S. IHR NFP functional components and outlines specific protocols and processes. The most recent revision of the U.S. IHR NFP SOP in 2015-2016 is in the process of official review and approval.
- NFP communication protocols, operating procedures, and supplemental instructions are reviewed and updated as needed. Standard instructions for messaging between the U.S. IHR NFP and the WHO have been developed to standardize those activities and provide a basis for process improvement when new circumstances arise.
- Given the wide variety of complex and unpredictable circumstances that are typical in public health situations, the IHR Program frequently collaborates with the PAHO and relevant U.S. departments or agencies to clarify event notification procedures. An example of updated instructions is shown in the "NFP Procedural Supplement" in Appendix 1 of this report.

Timely and systematic information exchange between all sectors

- Many collaborations and mechanisms are identified throughout this Report that ensure and facilitate coordination.
- U.S. IHR NFP, OIE, and FAO contact points (described in detail in the section on *Reporting*) leverage cross-cutting coordination mechanisms, when necessary, for sharing information about public health event detection, assessment, and notification occurring in the animal or human sectors.
- As an output of multisectoral coordination and national IHR implementation, the United States has sent 77 *Article 6* (potential PHEIC) notifications since 2007 as of May 2016.
    - Three *Article 6* notifications have been related to PHEICs declared by WHO:
        - 11 March 2009 – Transmission of pandemic influenza A H1N1 in the U.S
        - 1 October 2014 – Imported Ebola virus disease
        - 18 December 2015 – Local transmission of Zika virus in Puerto Rico

Using lessons learned to improve IHR implementation

- U.S. departments and agencies review and revise their policies and procedures for coordination and communication, in collaboration with relevant stakeholders, at regular intervals or as needed based on new departmental processes, agreements, and lessons learned from responses.
- The ASPR IHR Program is collaborating with the NFP of Mexico and Canada and the PAHO Contact Point for IHR to develop a series of training modules for IHR NFP capacity building. The benefit to the United States has been an increased efficiency of communication within North America as well as a deeper understanding of the challenges experienced by other countries in the region. The lessons learned from this collaboration are applicable within the United States, especially along the U.S. border states.

IHR implementation assessments and updates

- ASPR led the U.S. IHR implementation process in close collaboration with an interagency IHR implementation working group. The White House NSC Staff and Homeland Security Staff monitored the progress of IHR implementation. The U.S. Government IHR implementation plan, developed and initiated prior to the IHR entry into force in 2007, identified and completed 97 individual actions that the U.S. addressed in 2007 and 2008 to meet its obligations.
- To fulfill the annual IHR obligation to report on the status of domestic compliance and maintenance of the IHR capacities, the IHR Program established an annual IHR assessment process. ASPR's IHR Program convenes federal policy and technical subject matter experts – representing more than 20 U.S. Government departments and agencies – for consultations and domestic data review using the

IHR questionnaire as the guide. This serves as the annual U.S. Government forum that assesses domestic compliance and maintenance of IHR capacities in the United States.

- In 2012, to further support the annual review and continuous monitoring of U.S. domestic IHR capacities, ASPR's IHR Program began aligning performance and program measures from the combined CDC PHEP cooperative agreement and the ASPR HPP with the IHR core capacities (Table 6). As a result, the U.S. Government is better able to visualize and understand the growth and expansion of state and local elements of the U.S. public health system in the context of the IHR core capacities. (NOTE: the PHEP and HPP capabilities are undergoing revision for the 2017 budget year.)

Monitoring and evaluation of U.S. IHR NFP functions

- Management of the U.S. IHR NFP is complex at times. The IHR Program Manager, the IHR Branch Chief and the Director of the Division of International Health Security (all in the ASPR Office of Policy and Planning) monitor and assess the NFP functions continually. Feedback from the SOC and the leadership in ASPR, as well as the U.S. IHR Stakeholders, are also critical and incorporated into SOP and procedural updates as needed.
- ASPR IHR Program has developed a number of internal quality control mechanisms.
    - The IHR Program's shared email account allows IHR Action Officers and the IHR Branch Chief to maintain consistent situational awareness and assist one another when needed.
    - A rotational duty roster, which includes night and weekend coverage, ensures that a qualified person is serving as the IHR Action Officer. The IHR Program Manager provides routine updates of the IHR duty roster to the SOC, the ASPR leadership, and others in the Office of Emergency Management, to ensure that a point of contact for IHR issues can be reached 24/7 as needed.
    - The IHR Action Officer *Functionality Checklist* tracks all of the IHR Program's weekly, monthly, quarterly, bi-annual, and annual tasks pertaining to the management of the U.S. IHR NFP.
    - The SOC maintains its own SOPs for daily and emergency operations. The IHR Program regularly meets with staff from the SOC in order to review and revise IHR-specific procedures and implement revisions as needed.

Best Practices, Challenges, Gaps, and Recommendations

The United States meets the existing IHR implementation standards, consistently reports compliance through the annual questionnaire, and notifies the WHO of public health events when needed. The U.S. IHR NFP, through its defined relationships with the U.S. IHR Stakeholders group, engages departments and agencies in ongoing IHR-relevant issues. The U.S. Government currently operates a NFP and interagency IHR coordination model that are recognized as a best practice for reporting potential PHEIC.

Since 2007, the refinement of U.S. policies and procedures for compliance with the IHR has been an ongoing effort, taking advantage of the multiple channels for public health communication within and outside the United States. Because of the size and diversity of the United States, and the variety of authorities and capacities for public health, there are sometimes challenges in developing concurrence at the federal level that an event requires IHR-specific risk assessment. It is also challenging at times, because of the U.S. national structure, to obtain information from state and local health departments that is needed for an IHR-specific (international) risk assessment. While modest in scale, those challenges can result in delays in reporting IHR-relevant events that have subtle or uncertain international implications.

There is an opportunity for the U.S. IHR NFP to engage more frequently and strongly with U.S. IHR Stakeholders in all of the departments and agencies to help refine complementary IHR policies and structures that facilitate reporting in all sectors. Specific IHR implementation policies, as described in the *National Legislation, Policy, and Financing* section, could include opportunities for the NFP to develop sustainable training and planning methods for agency-specific consideration. In collaboration with the departments and agencies, the U.S. IHR NFP and ASPR could also consider opportunities to reach out to individual state and jurisdictional health departments, especially those that experience significant international travel or trade, to enhance their analytical methods and communications to promote national awareness of potentially international events.

Antimicrobial Resistance

Prevent 3 (P3)

JEE Target

Support work being coordinated by WHO, FAO, and OIE to develop an integrated and global package of activities to combat antimicrobial resistance, spanning human, animal, agricultural, food and environmental aspects (i.e. a one-health approach), including: a) Each country has its own national comprehensive plan to combat antimicrobial resistance; b) Strengthen surveillance and laboratory capacity at the national and international level following agreed international standards developed in the framework of the Global Action plan, considering existing standards, and; c) Improved conservation of existing treatments and collaboration to support the sustainable development of new antibiotics, alternative treatments, preventive measures and rapid, point-of-care diagnostics, including systems to preserve new antibiotics.

Level of Capabilities in the United States

➢ Summary

In September 2014, the President of the United States issued an Executive Order resulting in the creation of the National Strategy and National Action Plan for Combating Antimicrobial Resistant Bacteria (CARB). The CARB Strategy calls for broad multisectoral coordination to control the development and spread of antimicrobial resistance (AMR), and reduce the overall impact of AMR on the population. For more than five years (the benchmark set by the JEE Tool), the United States has had a number of coordinated surveillance systems in place to detect the WHO priority AMR pathogens. Those systems are a combination of passive and active surveillance activities that utilize reliable and reproducible procedures among the United States' PHL.

Primarily CDC and DoD function as national coordinators for clinical AMR detection, surveillance, and response, as well as molecular characterization, international coordination, and repositories for isolates. Active, case-based hospital surveillance programs are also widespread throughout the country and can identify infections caused by AMR bacteria, including health care-associated infections (HCAI), bloodstream infections, and resistant *Neisseria gonorrhoeae*. The National Antimicrobial Resistance

Monitoring System (the multiagency NARMS[6]) was established in 1996 as a collaboration between FDA, CDC and USDA to aggregate and report on national surveillance data.

The 2009 Omnibus Appropriations Law (Public Law 111-8) required that states receiving Preventive Health and Health Services Block Grant funds submit a plan to prevent HCAI to the Secretary of HHS. HHS received plans from all 50 states, the District of Columbia, and Puerto Rico. The HHS Office of Disease Prevention and Health Promotion, on behalf of the Federal Steering Committee for the Prevention of Health Care-Associated Infections, released the *National Action Plan to Prevent Health Care-Associated Infections* in April 2013.

CDC, USDA, and FDA provide key components of the national AMR surveillance strategy, organizing and reporting the results of surveillance for AMR in humans, animals, and food. Their roles are also critical in working with U.S. states and various segments of private industry to promote and monitor the judicious use of medically important antibiotics in humans and animal agriculture. ASPR's Biomedical Advanced Research and Development Authority (BARDA), CDC, FDA, USDA, DoD, NIH, DHS, the Department of Veterans Affairs, and EPA, are all federal partners in the ASPR-led Public Health Emergency Medical Countermeasures Enterprise (PHEMCE), which works across the medical research, development and regulatory agencies to bring new antimicrobial drugs to market quickly.

➢ Indicators

■ *Antimicrobial Resistance Detection* *P3.1*

National AMR plans

- On March 27, 2015, the U.S. released its CARB Action Plan, which advances a One Health approach to combating the emergence and spread of antibiotic resistant bacteria. Actions taken by departments and agencies under CARB have already achieved several of the first-year goals. The assessment of CARB implementation has been posted online.
- All affected pharmaceutical companies that produce medically important antimicrobials for use in animals have pledged to implement FDA guidance (document #213 described below) by December 2016. They will voluntarily withdraw approvals related to any production uses of medically important antimicrobials and change the labeling of their products to provide for veterinarian

[6] The NARMS acronym has two meanings in the United States, one referring to the multiagency data collection and reporting system (the multiagency NARMS); and another referring to a unique CDC program area (the CDC NARMS).

oversight of their use. As of February 2016, implementation of FDA guidance had resulted in 26 pharmaceutical companies withdrawing 30 antimicrobial drugs previously used in food-producing animals from the market.

Laboratory capacity for AMR detection

- The CDC laboratory in Atlanta functions as the national civilian AMR reference lab. For many years, it has been capable of detecting the WHO priority AMR pathogens. Under the CARB Action Plan, CDC plans to fund up to eight regional laboratories to provide advanced molecular characterization of AMR clinical isolates.
- The DoD Multidrug-resistant Organism Repository and Surveillance Network (MRSN) functions as the military's AMR reference lab.
- The FDA's Veterinary Laboratory Investigation and Response Network includes diagnostic laboratories in 37 U.S. states and 1 laboratory in Canada. In addition to assisting with food safety investigations, the network is capable of detecting and evaluating AMR in zoonotic and veterinary pathogens in food and companion animals.
- Detection of AMR follows national standards, such as those established by the Clinical & Laboratory Standards Institute (CLSI), or (in some laboratories) international standards, such as European Committee on Antimicrobial Susceptibility Testing standards. The section on *National Laboratory System* in this Report contains more details on laboratory quality assurance and accreditation in the United States.
- CDC has defined categories of drug-resistant bacteria as "urgent" or "serious" based on their current or potential public health risk (Table 7). All U.S. hospital laboratories are capable of diagnosing infections with both urgent (except for drug-resistant *Neisseria gonorrhoeae*) and serious AMR pathogens (a more detailed explanation can be found below).

Testing and reporting AMR in animal products and the environment

- The USDA's Food Safety and Inspection Service (FSIS) Eastern Laboratory routinely conducts antimicrobial susceptibility testing of isolates from animal origin using CLSI standards. FSIS is a major collaborator in the multiagency NARMS reports and contributes over 7,000 antimicrobial susceptibility testing results on an annual basis, described in detail in the section on *Food Safety* in this report.
- The FDA retail meat program is expanding surveillance from 14 to 20 states in 2016 by funding additional state laboratories. FDA collaborates with FSIS through the multiagency NARMS to improve detection of pathogens and AMR bacteria by coordinating routine collection of meat samples at slaughterhouses with cecal samples.

- Through the FDA Veterinary Laboratory Investigation and Response Network, the FDA Center for Veterinary Medicine is initiating antimicrobial susceptibility testing of clinical isolates as a part of the CARB initiative.
- In DOI, the United States Geological Survey (USGS) Michigan Bacteriological Research Laboratory conducts research on the occurrence, transport, and fate of AMR in the environment, specifically *Escherichia (E.) coli* and *Salmonella* species. Findings from those studies are typically published in peer-reviewed literature.

Surveillance programs for AMR bacteria in the United States

- The CDC National Healthcare Safety Network (NHSN) receives required or voluntary reporting of AMR cases (depending on the pathogen) diagnosed at hospitals in all 50 states.
- In CDC's Emerging Infections Program (EIP), a selected number of civilian hospital laboratories in California, Colorado, Connecticut, Georgia, Maryland, Minnesota, New Mexico, New York, Oregon, and Tennessee conduct population-based surveillance and send isolates to the CDC for confirmatory testing and further characterization.
- The CDC's National Antimicrobial Resistance Monitoring System for Enteric Bacteria (CDC NARMS) receives isolates for *Shigella*, *Salmonella*, and *Campylobacter* species from all 50 states for resistance/susceptibility testing and further characterization.
- MRSN supports all military hospital and clinical facilities around the world with confirmatory testing.

Table 7. Surveillance programs for "urgent" and "serious" antimicrobial resistant pathogens in the United States.

Pathogen	Program	Infections Surveyed	Surveillance Area, Reporting and Referral
Carbapenem-resistant *Enterobacteriaceae*	Emerging Infections Program (EIP)	Infections by 5 non-susceptible species	8 states; isolates from cases collected and sent to CDC or designate laboratories for testing.
	National Healthcare Safety Network (NHSN)	Infections associated with a medical procedure or device	50 states – voluntary reporting
	Multidrug-resistant Organism Repository and Surveillance Network (MRSN)	Infections by non-susceptible Gram negative bacteria or surveillance isolates	54 military hospitals and at least 5 overseas laboratories; confirmed at DoD reference lab

Pathogen	Program	Infections Surveyed	Surveillance Area, Reporting and Referral
***Neisseria gonorrhoeae**	CDC Gonococcal Isolate Surveillance Project	Urethral isolates from the first 25 men with urethral gonococcal infection each month	27 sentinel sites in 21 states; isolates tested in 5 CDC-funded reference laboratories
	DoD Gonococcal Resistance Study	Urethral isolates of *N. gonorrhoeae* from STI clinic visits	4 U.S. military training sites; 4 overseas laboratories; isolates tested in DoD-funded reference laboratory after identified in partner laboratories in the U.S. and abroad
***Clostridium difficile**	EIP	All infections	10 states; culture in CDC or designated laboratory
	NHSN	All infections	50 states – required reporting
	MRSN	All infections	2 military hospitals (to expand to 5); confirmed at DoD reference lab
***Acinetobacter* species**	EIP	Infections caused by carbapenem-non-susceptible *Acinetobacter* or any *Acinetobacter baumannii*	8 states; isolates from cases are collected and sent to CDC for testing
	NHSN	Infections associated with a medical procedure or device	50 states – voluntary reporting
	MRSN	Infections caused by carbapenem non-susceptible *Acinetobacter* or surveillance isolates	54 military hospitals and at least 5 overseas laboratories; confirmed at DoD reference lab
***Pseudomonas aeruginosa**	EIP	All infections	8 states; isolates from cases are collected and sent to CDC for testing
	NHSN	Infections associated with a medical procedure or device	50 states – voluntary reporting
	MRSN	Infections caused by carbapenem non-susceptible or >3 class non-susceptible *Pseudomonas* or surveillance isolates	54 military hospitals and at least 5 overseas laboratories; confirmed at DoD reference lab
***Extended spectrum *beta*-lactamase-producing**	EIP	Planned to be introduced in 2016	
	NHSN	Infections associated with a medical procedure or device	50 states – voluntary reporting

Pathogen	Program	Infections Surveyed	Surveillance Area, Reporting and Referral
Enterobacteriaceae	MRSN	Gram negative infections characterized as harboring ESBL and/or resistant to 3/more classes of antibiotics	54 military hospitals and at least 5 overseas laboratories; confirmed at DoD reference lab
****Staphylococcus aureus***	EIP	Invasive disease: isolation of methicillin-resistant *S. aureus* from a normally sterile site in a resident of the surveillance area. In FY16 surveillance expanded to include invasive methicillin-sensitive *S. aureus* infections	10 states; isolates from cases collected and sent to CDC or designate laboratories for testing.
	NHSN	Bloodstream infections	50 states – required reporting
	MRSN	All isolates from any clinical culture and surveillance isolates	54 military hospitals, 2 overseas facilities; confirmed at DoD reference lab
****Shigella* species**	NARMS (CDC)	Any isolate from a clinical specimen	50 states; isolates are sent to CDC for testing
	GTD	Any isolate from a clinical specimen from overseas travelers	21 military hospitals and clinics within and outside the U.S.; confirmed or diagnosed at DoD reference labs
****Salmonella* species**	CDC NARMS	Any isolate from a clinical specimen	50 states; isolates are sent to CDC for testing
	GTD	Any isolate from a clinical specimen from overseas travelers	21 military hospitals or clinics within and outside the U.S.; confirmed or diagnosed at DoD reference labs
***Campylobacter* species**	NARMS (CDC)	Any isolate from a clinical specimen	10 states; isolates are sent to CDC for testing
	GTD	Any isolate from a clinical specimen from overseas travelers	21 military hospitals or clinics within and outside the U.S.; confirmed or diagnosed at DoD reference labs
****Streptococcus pneumoniae***	EIP	Invasive pneumococcal disease: isolation of *Streptococcus pneumoniae* from normally sterile site in resident of a surveillance area	10 states; isolates from cases collected and sent to CDC or designate laboratories for testing.
***Candida* species**	EIP	Bloodstream infections	4 states; isolates are sent to CDC for testing
	NHSN	Infections associated with a medical procedure or device	50 states – voluntary reporting

*WHO priority pathogens: Global Antimicrobial Resistance Surveillance System Manual for Early Implementation).

Public reporting related to AMR

- The DoD Global Emerging Infections Surveillance and Response System's *Global Traveler's Diarrhea & Acute Gastroenteritis Study* (GTD) receives isolates from selected military hospitals and clinics (including military recruit training sites) for *Shigella*, *Salmonella*, and *Campylobacter* species for susceptibility testing and further characterization.
- Both CDC and DoD have unique programs for the surveillance of *Neisseria gonorrhoeae*, including the Gonococcal Isolate Surveillance Project and Uniformed Services University of the Health Sciences Infectious Disease Clinical Research Program.
- CDC and MRSN both provide reports for their surveillance activities on public websites. Additionally, other unusual findings or the results of outbreak investigations are often reported in CDC's *Morbidity and Mortality Weekly Report* (MMWR), within other agency-specific reports sent through the clinical or laboratory networks, published in peer-reviewed literature, and/or posted on the CDC's Food Safety Outbreak website.
- The FDA posts a multiagency Integrated NARMS Report and makes NARMS data available to the public on the web.
- Hospital and hospital systems throughout the country typically circulate local antibiograms among their medical providers, or post them on public websites, to guide selection of antimicrobial therapies.

■ *Surveillance of infections caused by AMR pathogens* *P3.2*

Clinical surveillance programs

- There are approximately 5,000 acute care hospitals in the country (including 54 military facilities). Nearly all are enrolled and report data through NHSN (or a military-specific program). NHSN also serves as a surveillance platform for non-acute care health care settings, with >17,000 medical facilities enrolled.
- CDC's EIP conducts a Healthcare Associated Infections Point Prevalence Survey in acute care hospitals; this survey will be expanded to long-term care facilities in 2017.

Animal surveillance programs

- Data from the USDA's Economic Research Service, National Animal Health Monitoring System, and National Agricultural Statistics Service have been used (and will be updated annually beginning in 2017) to select farms with cattle-on-feed, hogs and pigs, broilers (chickens). Based on the 2012 Census of Agriculture – a census which is conducted every five years – there were 26,586 cattle-on-feed operations in the United States; 63,246 hog and pig operations; 32,935 broiler chicken operations; and 9,677 turkey operations.

- The FSIS NARMS Cecal Sampling Program was launched for food animals monitoring. Isolates of *Salmonella*, *Campylobacter*, *E. coli*, and *Enterococcus* are recovered from the cecal contents of swine (market swine, sow), cattle (dairy cow, beef cow, steer, and heifer), young chicken, and young turkey in FSIS-regulated livestock and poultry slaughter establishments. This program generates at least 4800 isolates (1200 for each microbial target) and their AMR profiles that may be reflective of animal exposure from the farm to pre-slaughter environment.
- At the Federal level, the NVSL serves as the national veterinary diagnostic reference and confirmatory laboratory. NVSL coordinates activities, participates in methods validation, and provides training, proficiency testing, technical assistance, materials, and prototypes for diagnostic tests. These are all important functions for AMR surveillance, and some resources are currently devoted to AMR testing in surveillance. In addition, NVSL provides a *Salmonella* serotyping service for clinical isolates submitted by veterinary diagnostic laboratories across the United States. Currently, antimicrobial susceptibility testing is not performed on these *Salmonella* isolates. A proposed initiative in the USDA Action Plan was to begin performing susceptibility testing on these isolates.

■ *Healthcare associated infection prevention and control programs* *P3.3*

National HCAI plans and programs

- The HHS National Action Plan to Prevent Health Care-Associated Infections (2009) is currently being revised.
- The 2009 Omnibus Law required states receiving Preventive Health and Health Services Block Grant funds to submit a plan to prevent HCAI to the Secretary of HHS. All 50 states, the District of Columbia, and Puerto Rico submitted plans.
    - U.S. health care facilities are actively involved or developing capacities for surveillance, policy development, research, and prevention. Recent progress summaries are at the Office of Disease Prevention and Health Promotion's National Targets and Metrics, Monitoring Progress Toward Action Plan Goals webpage.
    - The *National and State Healthcare-Associated Infections Progress Report* is released annually by the CDC. Data includes central-line associated bloodstream infections, catheter-associated urinary tract infections, selected surgical site infections, hospital-onset *Clostridium difficile* infections, and hospital-associated MRSA infections.

- The Veterans Health Administration implemented a nationwide plan to reduce the overall incidence of MRSA among its acute care hospitals. The bundle of activities included "universal nasal surveillance for MRSA, contact precautions for patients colonized or infected with MRSA, hand hygiene, and a change in the institutional culture whereby infection control would become the responsibility of everyone who had contact with patients."[7]

Trained health care infection prevention professionals

- CDC recommends that a qualified person with infection control training manage the infection control program at all health care facilities. The Association for Professionals in Infection Control and Epidemiology (APIC) supports national training and professional development.
- Based on APIC guidelines, DoD hospitals meet, and in some locations exceed, the recommended staff-to-bed ratio for infection prevention and control professionals in all tertiary hospitals.
- The Veterans Health Administration reports availability of trained infection prevention and control professionals in its tertiary facilities.
- CMS develops Condition of Participation and Coverage that include safety and quality of care standards, including activities related to prevention of HCAI, that participating health care organizations must meet in order to participate in Medicare and Medicaid.

Hospital safety and infection prevention guidelines

- Extensive guidelines exist at the national, local and facility level to protect health care workers and patients. The CDC and the Healthcare Infection Control Practices Advisory Committee (HICPAC) produce infection control guidelines. CDC also produces guidance for protection during public health emergencies in health care settings. HICPAC is made up of 14 external infection control experts who offer guidance regarding the practice of health care infection control and strategies for the surveillance, prevention, and control of health care-associated infections in U.S. health care facilities. Members are recommended by the CDC and appointed by the Secretary of HHS. Members consist of experts in the fields of infectious diseases, health care epidemiology, health care-associated infections and health care-related events, epidemiology, health policy, health services research, public health, and related fields.
- HICPAC has produced guidelines for establishing and controlling isolation rooms in U.S. hospitals. Currently, isolation rooms (or rooms that can be adapted for isolation) are commonly available in

[7] Jain R, Kralovic SM, Evans ME, et al. Veterans Affairs Initiative to Prevent Methicillin-resistant Staphylococcus aureus Infections. New England Journal of Medicine 2011;364:1419-30.

tertiary and acute care hospitals throughout the country. As needed, CDC issues supplemental guidelines for unique infectious disease threats.

- Federal requirements set forth by OSHA apply to health care employers , as noted on OSHA Healthcare and OSHA Bloodborne Pathogens and Needlestick Prevention websites. In particular, the OSHA Bloodborne Pathogens Standard and guidelines for use of personal protective equipment (PPE) and the respiratory protection programs help to protect health workers as well as patients from nosocomial infections.

HCAI surveillance and monitoring

- NHSN is the nation's most widely used health care-associated infection tracking system. Beginning decades ago with 300 hospitals, NHSN now serves over 17,000 medical facilities tracking HCAI. Current participants include acute care hospitals, long-term acute care hospitals, psychiatric hospitals, rehabilitation hospitals, outpatient dialysis centers, ambulatory surgery centers, and nursing homes, with hospitals and dialysis facilities representing the majority of facilities reporting data.
- The CDC EIP also conducts population-based surveillance. The EIP population is roughly representative of the U.S. population based on demographic characteristics such as age, gender, race, and urban residence, as well as health indicators such as population density and percent at or below the poverty level. The network has generated more than 510 publications since 1995**Error! Hyperlink reference not valid.**with data obtained from core EIP activities, Active Bacterial Core surveillance, FoodNet, influenza projects, and HCAI-Community Interface projects, as well as other special studies.
- In addition, facilities often conduct surveillance for other HCAI or specific pathogens and report to public health authorities according to state and local regulations.
- Examples of agency-specific programs:
  - DoD follows the National Action Plan to Prevent Health-Care-Associated Infections written in April 2013.
  - The Targeted Assessment for Prevention Strategy, developed by the CDC, uses HCAI data from the federal, state, local, and facility level in order to identify gaps in infection prevention programs and activities.
  - CMS and the Joint Commission **Error! Hyperlink reference not valid.**require that facilities be evaluated regularly to ensure they meet infection control requirements. The Joint Commission is an independent, non-profit organization that accredits and certifies both private and public health organizations and health care programs in the United States.
  - The Veterans Health Administration facilities evaluate their infection prevention and control plans at least annually.

- The DOI National Park Service operates three national parks with year-round clinics that include infection prevention and control policies that include components for AMR identification and reporting.

■ ***Antimicrobial stewardship activities*** ***P3.4***

National plans and programs

- The multiagency NARMS and the USDA National Action Plan describe the approach for identifying gaps and mitigation strategies to help prolong the effectiveness of antibiotics for treating both humans and animals.
- Antimicrobial stewardship goals were included in the White House's 2015 CARB Action Plan.
  - Objectives address prescribing practices in community and hospital settings, elimination of medically-important antibiotics for growth promotion in animals, strengthening and monitoring stewardship programs, improving educational programs about antibiotic stewardship, implementing annual reporting for antibiotic use, and developing interventions to address outlier populations.
  - All acute care hospitals are to establish antibiotic stewardship programs by 2020 with reduction of inappropriate antibiotic use.
- The DoD developed its Antibiotic Stewardship Policy (2016, DoD-I 6025), which is currently under review.
- CDC developed the Core Elements of Hospital Antibiotic Stewardship and guidelines for nursing homes. CDC is also developing guidance for outpatient settings.
- The Department of Veterans Affairs published Direction 1031 in 2014 to address antimicrobial stewardship in that nationwide hospital system.
- The DOI U.S. Fish and Wildlife Service (FWS) has a program working on FDA approval of pharmaceuticals for use as therapeutics in aquaculture and fisheries management in order to minimize the impact on the development of AMR.

Antimicrobial use monitoring in human medicine

- All but a handful of commercial products that contain antibiotics require a licensed health care provider's prescription. CDC assesses the appropriateness of antibiotic use for the most common conditions through its National Ambulatory Medical Care Survey and Hospital Ambulatory Medical Care Survey.
- CDC and DoD conduct point prevalence surveys to assess antibiotic use in hospitals and are characterizing antibiotic prescribing practices on outpatients as well.

- CDC recommends that all facilities in the United States conduct antibiotic use surveillance and implement stewardship programs. CDC is collaborating with several large health systems that are routinely tracking and reporting antibiotic use through the NHSN. A recent survey of U.S. acute care facilities indicated that 39 percent of all hospitals are adhering to all of CDC's Core Elements for Hospital Stewardship.
- DoD has developed a network of epidemiologists, informatics specialists, policy makers, and health care providers called the Antimicrobial Resistant Monitoring and Research Program.[8]

Antimicrobial use monitoring in food production, veterinary medicine and the environment

- As part of its new animal drug approval process (described below), FDA makes a determination as to whether the marketing of a given animal drug should be limited to a use that is "by or on the order of a licensed veterinarian". If such a limitation is necessary, such drugs would be designated as veterinary feed directive drugs (for feed-use animal drugs) or prescription drugs (for all other dosage forms).
    - In 2012, FDA issued the Guidance for Industry (GHI) #209 on *The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals*. The non-binding recommendations were aimed at veterinary and animal producer organizations to limit use of medically important drugs and encourage veterinary oversight and coordination.
    - In 2013, FDA issued GFI #213 – New Animal Drugs and New Animal Drug Combination Products Administered in or on Medicated Feed or Drinking Water of Food-Producing Animals: Recommendations for Drug Sponsors for Voluntarily Aligning Product Use Conditions with GFI #209. GFI #213 outlined a process by which all medically important antimicrobial drugs used in animal feed or drinking water (and that are currently available as over-the-counter drugs) will be transitioned to veterinary feed directive or prescription status, respectively. Although the GFI #213 process is voluntary, all affected drug companies have committed to transition their products by the January 1, 2017 target date. Once these changes are completed, it will be illegal to use these medically important antimicrobial drugs without the authorization of a licensed veterinarian.

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[8] Lesho EP, Waterman PE, Chukwuma U, et al. The antimicrobial resistance monitoring and research (ARMoR) program: the U.S. Department of Defense response to escalating antimicrobial resistance. Clinical Infectious Diseases 2014 Aug 1;59(3):390-7.

Best Practices, Challenges, Gaps, and Recommendations

The U.S. Government has established comprehensive strategies and plans to prevent, detect, and control the emergence and spread of antimicrobial resistant pathogens in humans and animals. Strengthening detection and control of resistance requires the adoption of a One Health approach that promotes the integration of public health and animal disease, food, and environmental surveillance. As a complex, multifactorial and multisectoral issue, various levels and sectors of the U.S. Government, along with other public and private stakeholders, are working to address the many opportunities for improvement. For example, the CARB National Action Plan, the multiagency NARMS, and the HHS National Action Plan to Prevent Health Care-Associated Infections, along with expertise from other departments and agencies, continue to inform the overall national approach for monitoring effectiveness.

While significant work and effort is underway, there are challenges in the implementation and maintenance of the many activities and proposed regulatory changes. Not all hospitals or laboratories have the same ability to identify AMR organisms and not all facilities (hospitals or farms) are actively documenting and publishing the results of their stewardship activities. Effective regulation and behavior change will require the federal government and individual states to establish mechanisms to monitor effects that the restricted use of medically-important antimicrobials and changes in animal management have on the evolution and distribution of AMR species.

Zoonotic Disease

Prevent 4 (P4)

JEE Target

Adopted measured behaviours, policies and/or practices that minimize the transmission of zoonotic diseases from animals into human populations.

Level of Capabilities in the United States

➢ Summary

In the United States, the CDC and the USDA routinely coordinate and partner with other federal and state animal and human health partners and stakeholders to prevent zoonotic diseases of public health importance. The United States has an extensive animal and human epidemiology, surveillance, response, and laboratory capacity with a strong focus on zoonotic diseases in both human and animal populations. A One Health approach, focusing on the interface of human, animal, and environmental health, is critical to the prevention and control of zoonoses.

At the federal level, the CDC and USDA collaborate on a number of well-established and important zoonotic disease surveillance programs including rabies, bovine spongiform encephalopathy, trichinellosis, enteric zoonoses, brucellosis, bovine tuberculosis, and animal (primarily swine and avian) influenza. Additionally, CDC is responsible for investigating illnesses and outbreaks of zoonotic diseases in humans, and works in tandem with other U.S. Government partners for a coordinated One Health approach. CDC's nationally notifiable disease list covers reportable zoonotic diseases in humans, and USDA has proposed an extensive reportable disease list for animal populations that complements the CDC list.

In the United States, 30 colleges of veterinary medicine provide many students with opportunities to receive advanced public health training. A number of sponsored internship and fellowship programs exist for pending or recent graduates, and there is coursework available for established professionals to gain new skills related to epidemiology and laboratory capacity for zoonoses in animals and people.

➢ Indicators

- ***Surveillance systems in place for priority zoonotic diseases/pathogens*** ***P4.1***

Priorities for national zoonotic disease surveillance and control

- The CDC Surveillance Strategy is available online with descriptions of four major initiatives related to reportable zoonoses (and other diseases) in humans, including (1) standardizing health data and exchange systems; (2) enhancing electronic health record systems; (3) accelerating electronic laboratory reporting; and (4) modernizing mortality surveillance systems.
    - The National Notifiable Diseases Surveillance System (NNDSS) (described in detail in the section on *Real-Time Surveillance* in this Report) is a nationwide collaboration that enables all levels of public health to share notifiable disease-related health information, which includes zoonoses.
    - Public health departments use that information to monitor, control, and prevent the occurrence and spread of state-reportable and nationally notifiable zoonoses as well as other diseases and conditions.
- The USDA Animal and Plant Health Inspection Service (APHIS) published the *National List of Reportable Animal Diseases (NLRAD) Concept Paper* in July 2014 that proposes a single, standardized list of reportable animal diseases based on species affected. The paper outlines which organizations will be responsible for reporting and describes how to report diseases. USDA is beginning rulemaking to establish a new part in Title 9 of the Code of Federal Regulations (CFR) for the NLRAD. Appendix 2 of this Report shows the proposed list of nationally reportable disease for animals.
- In order to advance One Health models, both domestically and internationally, several One Health tools have recently become available and are in various stages of implementation.
    - The University of Minnesota and USDA's APHIS and Veterinary Services jointly developed the One Health Systems Mapping and Analysis Resource Toolkit, which is a step-wise, structured approach by which a network of agencies can review and visualize their procedures and processes for inter-disciplinary coordination on complex issues at the human-animal-environment interface.
    - The CDC One Health Zoonotic Disease Prioritization Tool has the goal of identifying zoonotic diseases or pathogens of greatest concern so financial and personnel resources can be effectively focused. This tool requires that human and animal health agency representatives jointly identify criteria, such as pandemic potential, human morbidity or mortality, or economic impact, that are appropriate for defining a disease of concern.

Laboratory capacity for zoonoses and animal health

- The NAHLN is a cooperative effort by APHIS, the USDA National Institute of Food and Agriculture, and the American Association of Veterinary Laboratory Diagnosticians NAHLN consists of 62 state and university-associated veterinary diagnostic laboratories located in 40 states. Other federal

members of NAHLN include the USDA's NVSLs in Iowa and New York, and the USGS National Wildlife Health Center Laboratory in Wisconsin.

  - The network of laboratories focuses on diseases of animals, using common testing methods and data standards to process diagnostic requests, providing diagnostic services, and sharing information.
  - State, university, and other affiliated laboratories in the NAHLN perform routine diagnostic tests for endemic animal diseases as well as targeted surveillance and response testing for foreign animal diseases. Institutions also participate in cooperative research and the development of new methodologies.
  - NAHLN contributes important data to the National Animal Health Surveillance System (NAHSS), which is described below.
  - The USGS National Wildlife Health Center maintains diagnostic laboratories that are included in the NAHLN with the ability to identify zoonotic diseases in non-domestic animals.

- The NVSLs are accredited to International Standards Organization (ISO) 17025 standards. All state- and university-associated veterinary diagnostic and other laboratories affiliated with the NAHLN are accredited by either AAVLD or ISO 17025 standards, or by an independent party. The NAHLN Program Office audits some of the affiliates. Accreditation organizations may require that laboratories enroll in additional relevant and available proficiency testing schemes.
- Additional laboratory capacity for zoonoses and human health are described in the *National Laboratory System* section of this report.

Animal population surveillance systems

- The USGS Wildlife Health Information Sharing Partnership (WHISPers) is a partner-driven, web-based event reporting system for sharing basic information about historic and ongoing mortality and morbidity events in wild animals in North America. The system provides timely, accurate information on those events to facilitate disease management and planning.
- Since 2000, the USGS-CDC Vector-Borne Disease Maps website has integrated vector (mosquito, tick), animal, and human vector-borne disease surveillance data from across the U.S. on dynamic maps. Currently, these nearly real-time maps contain data on West Nile virus, St. Louis encephalitis, Eastern equine encephalitis virus, La Crosse encephalitis virus, Powassan virus, dengue virus, and Chikungunya virus.
- The USDA APHIS NAHSS is a network of federal, state, industry, university, and laboratory partners that collaborate through surveillance to protect animal health. NAHSS systematically collects, collates, and analyzes animal health data to disseminate vital information, especially to those partners responsible for maintaining animal health. The NAHSS is responsible for integrating

existing animal health monitoring programs and surveillance activities into a comprehensive and coordinated system to support the development of new surveillance methods and approaches.

- National Animal Health Reporting System (NAHRS) integrates animal health monitoring and surveillance activities conducted by many federal, state, and local government agencies into a comprehensive and coordinated system. Similar to the proposed NLRAD, data are collected and analyzed at USDA and reports are published annually.
- The National Animal Health Monitoring System conducts national studies on animal health and health management practices among U.S. livestock and poultry operations. The primary source of data for the System is the USDA Census of Agriculture.

Linkages between human and animal disease surveillance and outbreak response

- Human and animal health agencies are independent government departments at the state and federal level within the United States. However, these departments typically work collaboratively on animal-human interface issues of public health importance, including zoonoses. While, traditional systems of zoonotic and infectious disease surveillance in humans operate separately from those in animals, partners routinely share data during cluster or outbreak investigations and on an *ad hoc* basis as requested.
- A number of focused cross-government and cross-departmental groups have been established to address specific areas such as enteric/foodborne bacteria, zoonotic influenza viruses, and others. Human and animal health agencies maintain EOCs for sharing information, exchanging liaison personnel, and contacting relevant experts to deal with emergencies 24/7. In addition, animal health and human health programs within CDC, FDA, APHIS, FSIS, DOI, and DHS maintain liaisons embedded in each other's organizations to ensure ongoing and daily collaboration in surveillance, detection, and response.
- The APHIS Veterinary Services National Preparedness and Incident Coordination Center develops strategies and policies for effective incident management and helps to coordinate incident response. As a liaison to outside emergency management groups, the Center ensures that emergency management policies, strategies, and responses are consistent with national and international standards. The Center also maintains a comprehensive Veterinary Service National Training and Exercise Program in partnership with external stakeholders to enhance national emergency response capabilities to address foreign animal and emerging disease incidents.
- The APHIS Veterinary Services Logistics Center manages the National Veterinary Stockpile (NVS) that provides veterinary countermeasures, animal vaccines, antivirals, or therapeutic products, supplies, equipment, and response support services that states, tribes, and territories need to respond to damaging animal disease outbreaks. The NVS program also leverages, where appropriate, the mechanisms and infrastructure that have been developed for the management, storage, and distribution of the CDC SNS as directed by Homeland Security Presidential Directive 9.

The NVS and the CDC Division of SNS maintain a memorandum of understanding (MOU) to formalize the collaborative relationship, share expertise, and explore other collaborative opportunities.

- Linkages between public health and animal health laboratories have been increasing. To varying degrees, there are:
  - Increased communication and collaboration, physical collocation (either in the same building or vicinity) and common management or directorship;
  - Joint staffing, memoranda of understanding (MOU) or agreements, and shared committees and working groups; and,
  - Frequent collaboration during public health events.
- Interoperability among the many information systems used in the animal and human health sectors for zoonotic diseases is at a minimum. However, the CDC and USDA collaborate directly on a number of well-established and clinical serious zoonotic disease surveillance programs including rabies, bovine spongiform encephalopathy, trichinellosis, swine influenza, avian influenzas, and foodborne diseases. A significant number of the notifiable diseases listed by the CDC are zoonoses (see Appendix 3).
- CDC's laboratories work collaboratively with the NVSL on routine surveillance for zoonoses and during priority zoonotic disease and animal-human interface (One Health events). USDA liaisons embedded at CDC have an important role in connecting laboratories with emerging public health issues.
  - A few zoonoses have a routine specimen-sharing process in place, but for the most part the current process is informal and *ad hoc* for zoonotic pathogens, typically driven by an outbreak response. Examples of zoonotic pathogens with specimen-sharing protocols in place are swine and avian influenza, *Mycobacterium bovis*, and *Brucella* species.
  - The investigation of a cluster of illnesses or an outbreak of a zoonotic pathogen in humans is the most common trigger for determining that a specimen should be shared between public health and animal health laboratories. The protocol varies depending on the zoonotic pathogen and level of active collaboration on surveillance and response.
- Tracking sentinel animal populations, pet populations, and foreign animal diseases requires multiagency coordination. U.S. veterinarians are at the forefront of reporting suspicious and potentially dangerous animal diseases to authorities. USDA APHIS Veterinary Services maintains an extensive set of manuals and process descriptions for detection and response to foreign animal diseases.

Public reporting and information sharing

- A variety of informal and formal reports of surveillance data and disease outbreaks are shared among federal agencies on routine standing conference calls, facilitated by liaison officers, as well as via email on an *ad hoc* basis. Many of these reports are also shared publicly via agency websites.
  - The NNDSS includes zoonoses and other diseases in humans
  - Zoonotic and foodborne outbreaks caused by enteric bacteria
  - Foodborne Outbreak Online Database (FOOD Tool)
  - Tick-borne Diseases Surveillance (TickNET)
  - Mosquito-borne Diseases Surveillance (ArboNET)
  - USGS NWHC Wildlife Health Bulletins
  - Reported infections with variant influenza viruses in the U.S. since 2005
  - "Is rabies in your state?"
  - Animal Disease Information

■ ***Veterinarians*** ***P4.2***

Graduate-level training

- There are currently 30 colleges of veterinary medicine in the United States, with many offering doctor of veterinary medicine and Master of Public Health dual-degrees. For accreditation by the American Academy of Veterinary Medical Colleges, veterinary medical degrees require four years of graduate education with multiple public health and One Health related topics included.
- In the USDA's Smith-Kilborne Program, one student selected from each veterinary school receives training on public health, foreign animal diseases, international veterinary medicine, and communications. Students also participate in laboratory exercises at the Foreign Animal Disease Diagnostic Laboratory at Plum Island, New York. Students practice taking diagnostic samples and performing necropsies, as well as observe live animals with certain foreign animal diseases.
- Veterinarians may become certified in a numbers of specialties, such as toxicology, veterinary microbiology, veterinary pathology, and veterinary preventive medicine (with subspecialties in epidemiology, food safety, and veterinary public health).
- The USGS National Wildlife Health Center veterinary externship program trains approximately six veterinary medicine students per year in wildlife disease investigation techniques, including wildlife pathology and epidemiology.
- CDC offers the Epidemiology Elective Program, an internship program in epidemiology and public health for veterinary and medical students during their last two years of their training.

Supplemental veterinary public health training opportunities

- Veterinarians and doctoral-level scientists are eligible to apply for CDC's competitive fellowship program, the Epidemic Intelligence Service (EIS). EIS is CDC's two-year training program in the practice of applied epidemiology that provides rigorous on-the-job training, supervision, and mentoring as participants provide public health service. The USDA has a dedicated space for an EIS officer.
- The mission of the USDA National Veterinary Accreditation Program is to establish a workforce of accredited veterinarians and to provide them with the information needed to ensure the health of the nations' livestock and animal population and to protect public health and well-being. Zoonoses included in this program are anthrax, tuberculosis, brucellosis, and others.
- USDA Veterinary Services offers a number of professional development training opportunities. USDA has partnered with state veterinary labs in Virginia, Maryland, and Mississippi to coordinate veterinary laboratory outreach and education efforts. Through this collaboration, USDA has trained between 1,200 and 1,500 students per year in wet labs and case studies, and hosted between 50 and 60 externs per year.
- Post-doctoral training is available through academic institutions, conferences, professional associations (such as the American Veterinary Medical Association and the National Association of State and Public Health Veterinarians) and national veterinarian accreditation programs.
- Continuing education on zoonoses for animal and human health care providers is offered routinely through conferences, meetings, and webinars. Specialty training and board qualification are also available to enhance a veterinarian's training and expertise in public health.
- Military veterinarians receive institutional and continuing professional training throughout their careers that includes veterinary public health and One Health emphasis. Specialty training and board qualification are requirements for career progression. Additional training is provided as needed via outside continuing education, academia, and government as required for job positions and situational requirements.

■ ***Mechanisms for responding to zoonoses and potential zoonoses are established and functional.***

P4.1

National strategies for zoonotic outbreaks

- Agencies maintain their own internal strategies and plans based on the surveillance systems that they routinely use. There are also interagency agreements to collaborate when there is potential (or evidence) of human-animal crossover.

  - The CDC One Health Office and the USDA One Health Coordination Center have a strong relationship that addresses all aspects of surveillance and response. A MOU between CDC and USDA ensures coordination.
  - There is a MOU between the CDC and the DOI National Park Service to coordinate on disease outbreak investigations.
- FDA and USDA liaisons at the CDC help to promote coordination prior to and during events. In lieu of a specific national policy, the existing functional relationships among the agencies fulfill the need for multisectoral exchanges.
- DOI National Park Service also operates an internal, interdisciplinary Disease Outbreak Investigation Team composed of subject matter experts in public health, wildlife health, environmental health, and other disciplines.

Examples of coordination between the sectors

- CDC collaborates with other agencies to investigate zoonotic diseases in humans, regardless of the source or method of transmission. Some diseases are caused by "high consequence pathogens" that warrant individual case investigation, while other zoonoses evolve into multistate or nationwide outbreaks of human illness. CDC is responsible for tracking human illnesses and investigating outbreaks. U.S. Government agencies also collaborate on trace-back investigations to identify the origin of animals linked with outbreaks of human illness.
- CDC collaborates with USDA and FDA (and others) to respond to many multistate outbreaks of gastroenteritis linked to animals and animal products.
  - One example of collaboration on a domestic public health issue includes outbreaks of human *Salmonella* infections linked to poultry in backyard flocks. In those outbreaks, CDC and APHIS, along with multiple other partners including state public and animal health officials, industry, and health professionals, continue to identify and develop prevention and control recommendations and guidance at multiple levels from the hatchery to the consumer to reduce the risk of *Salmonella* infections in people associated with live poultry.
  - An example of collaboration in an international setting was in response to the avian influenza A (H7N9) outbreak event in China in 2013. CDC, USAID, and USDA worked collaboratively to understand the epidemiology of H7N9 infections among humans and animals in China. Liaison officers at USDA, USAID, and CDC worked closely to facilitate information sharing.

Best Practices, Challenges, Gaps, and Recommendations

The United States has a robust system in place that meets the IHR requirements for the zoonotic disease prevention, surveillance, and response. There is increasing emphasis on the One Health approach to better understand and respond to the rapidly changing disease dynamics at the human-

animal-environment interface. Programs are in place at both the national and state levels to monitor specific animal populations for emerging and reemerging zoonotic diseases and the potential to affect human populations.

There are many animal and human surveillance systems, pathogen-specific response plans, algorithms, and partnerships to help guide response to outbreaks of zoonotic diseases in both human and animal health sectors. However, there are still opportunities for improvement. Steps the U.S. can take involve (1) establishment of a national One Health approach to public health that accounts for steady state and emergency response; (2) further strengthening, integrating and linking relevant surveillance and reporting systems between animal and human sectors; and (3) delineating common goals and clear roles and responsibilities for the multidisciplinary sectors during the investigation and response to zoonotic events.

Food Safety

Prevent 5 (P5)

JEE Target

State parties should have surveillance and response capacity for food and water borne diseases' risk or events. It requires effective communication and collaboration among the sectors responsible for food safety and safe water and sanitation.

Level of Capabilities in the United States

➢ **Summary**

The United States has a strong regulatory system for the safety of the U.S. food supply, a system shared by many federal, state, and local agencies. The U.S. Government has the authority to establish regulatory standards, inspect facilities, and take action if there are violations, but industry has the primary responsibility to ensure that food products are safe and meet applicable regulatory requirements. State and local government agencies also have similar authorities regarding food safety. In 2011, the FDA Food Safety Modernization Act was signed into law, augmenting numerous other existing laws and regulations to better protect human and animal health by helping to ensure the safety and security of the food and feed supply, including through implementation of specific prevention activities. That Act was the largest expansion of FDA's food safety authorities since 1938.

Federal partners work closely with each other as well as with state and local agencies, private companies, and consumers to address food safety from farm to table. CDC and state public health agencies are responsible for monitoring, identifying, and investigating foodborne illness and outbreaks. CDC coordinates closely with FDA and USDA as the U.S. regulatory authorities for food products. The U.S. capacity to detect and respond to foodborne outbreaks, including those that result in a public health emergency, has improved dramatically in the past two decades. Since 1996, CDC has used DNA "fingerprinting" of bacteria to enhance outbreak detection and define the scope and scale of outbreaks beyond traditional methods. That system, *PulseNet*, consists of over 80 federal, state, and local laboratories in the United States.

CDC works closely with State and local health departments, which have the primary statutory authority and responsibility for disease surveillance. Most foodborne outbreaks are local events in just one city or county; local public health officials investigate those outbreaks. State health departments investigate outbreaks that spread across several cities or counties. Those health departments often work with their departments of agriculture and with federal food safety agencies as needed. In partnership with FDA

and FSIS, CDC typically leads investigations of multistate outbreaks – those that affect many states at once. However, the FBI is the lead federal agency for law enforcement investigations of any potentially intentional biological or chemical threat or incident, such as, but not limited to, food adulteration.

➢ Indicators

■ ***Mechanisms for multi-sectoral collaboration are established to ensure rapid response to food safety emergencies and outbreaks of foodborne diseases*** ***P5.1***

Roles and responsibilities for national food safety and outbreak response

- USDA FSIS regulates the safety, wholesomeness, and proper labeling of most domestic and imported meat, poultry, egg products, and fish in the order Siluriformes (catfish) sold for human consumption. FSIS utilizes physical inspection, and laboratory data, and risk assessment methodologies to address new and evolving risks. FSIS also has programs to develop and implement innovative methodologies, processes, and tools to protect public health.
- FDA regulates all other foods, products, and food ingredients not regulated by USDA, including dietary supplements, bottled water, food additives, and infant formulas. The Center for Food Safety and Applied Nutrition is the lead within FDA for food safety and works to assure that the food supply is safe, sanitary, wholesome, and honestly labeled. General roles include:
    - The Recalls, Outbreaks, and Emergencies section provides information regarding the measures that FDA takes when food products are misbranded or adulterated, present a health risk because of contamination, or have caused an outbreak of illness. This section also provides information regarding the safe storage, use, and disposal of food during public health emergencies.
    - The Foodborne Illness and Contaminant section conducts surveillance and inspection of domestic and imported foods, in part, through monitoring programs for pathogens, natural toxins, pesticides, and other contaminants and assessment of potential exposure and risk.
    - Through the Food Defense program, FDA also works with other government agencies and private organizations to help reduce the risk of tampering or other malicious, criminal, or terrorist actions on the food and cosmetic supply.
- At CDC, several programs across four different centers work on food safety.
    - The Division of Foodborne, Waterborne and Environmental Diseases (DFWED) in the National Center for Emerging and Zoonotic Infectious Disease is the lead at CDC for food safety. DFWED collaborates and coordinates with state epidemiologists and other public health officials who investigate clusters of foodborne, waterborne, zoonotic, and other enteric (gastrointestinal) illnesses in the U.S.

    - DFWED oversees the Foodborne Diseases Active Surveillance Network (FoodNet), which conducts surveillance for *Campylobacter, Cryptosporidium, Cyclospora, Listeria, Salmonella,* Shiga toxin-producing *E. coli* O157 and non-O157, *Shigella, Vibrio*, and *Yersinia* infections diagnosed by laboratory testing of samples from patients.
    - FoodNet was established in July 1995 and is a collaborative program among CDC, 10 state health departments, FSIS, and the FDA. Personnel located at state health departments regularly contact the clinical laboratories in Connecticut, Georgia, Maryland, Minnesota, New Mexico, Oregon, Tennessee and selected counties in California, Colorado, and New York to get reports of infections diagnosed in residents of these areas. The surveillance area includes 15 percent of the United States population (48 million persons). FoodNet is the principal foodborne disease component of CDC's EIP.
    - FoodNet accomplishes its work through active surveillance; surveys of laboratories, physicians, and the general population; and population-based epidemiologic studies.
  - The Division of Viral Diseases in the CDC National Center for Infectious Respiratory Diseases leads agency efforts on enteric viruses, including noroviruses, the leading cause of foodborne disease outbreaks in the United States.
  - Other programs within CDC that contribute to food safety include the Division of Emergency and Environmental Health Services in the National Center for Environmental Health, the Division of Parasitic Diseases and Malaria in the Center for Global Health, and the Division of Viral Hepatitis in the National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention.

- CDC collaborates with FDA, FSIS, and the EPA (when significant amounts of decontamination and waste disposal are required) throughout all phases of an outbreak investigation and subsequent regulatory response, such as food recalls. More information is available on the CDC food safety website.

Specialized training and resources for foodborne outbreak investigation

- CDC, FDA, FSIS, and APHIS staffs are composed of epidemiologists, microbiologists, medical doctors, veterinarians, and other public health professionals with training and experience in foodborne outbreak investigation. Several CDC epidemiologic staff have also received training from regulatory partners in food facility and farm investigations and product tracing.
- The U.S. Government works closely with state and local public health, food, and regulatory officials to ensure rapid and coordinated surveillance, detection, and response to multistate outbreaks. The Foodborne Diseases Centers for Outbreak Response Enhancement, located in 10 U.S. states as a partnership among the CDC, FSIS, and Association of Public Health Laboratories (APHL), work together to develop new and better methods to detect, investigate, respond to, and control multistate outbreaks of foodborne diseases.

- The Integrated Food Safety Centers of Excellence in Colorado, Florida, Minnesota, New York, Oregon, and Tennessee provide assistance and training to **other** state and local health departments to build their capacities to track and investigate foodborne disease.
- The Norovirus Sentinel Testing and Tracking Network (*NoroSTAT*) is a collaboration among seven state health departments and CDC to perform near-real time assessment and reporting of norovirus outbreak activity, including the enhanced integration of laboratory and epidemiologic surveillance to monitor for the emergence and impact of new norovirus strains.
- FDA's Rapid Response Team Program strengthens state food program rapid response and coordination around emergencies to human food or animal feed. Efforts include training, investigations, data sharing, data analysis and communications, and developing best practices that can be widely used and adopted.
- Foodborne disease outbreak investigations follow standard epidemiological principles. However, because circumstances can vary substantially, CDC often creates investigation-specific questionnaires for multistate outbreaks, which CDC shares with affected states to allow for standard data collection and analysis.
    - CDC, along with public health staff in the affected states, determines what the outbreak case definition will be for the investigation.
    - Investigators compile and manage line lists of cases using the information sent to them from state public health partners. Subject matter experts are available at CDC to provide information about the pathogen-causing illness.
    - The local health departments oversee collection of clinical specimens; however, in some cases, states will send specimens to CDC for advanced laboratory testing and characterization.

Coordination, communication, and collaboration among stakeholders

- FDA has embedded a full time liaison at CDC; similarly, CDC has a food safety liaison at FDA, in Washington, D.C. APHIS and FSIS each have a liaison at the CDC in Atlanta. Two other FSIS scientists on the CDC campus also coordinate interagency activities. Information from foodborne outbreaks and food contamination is used to strengthen food management systems, safety standards, and regulations. Additionally, a CDC/FDA/FSIS/APHIS conference call occurs weekly as part of the coordination related to ongoing outbreaks.
- FERN is an integrated, secure laboratory system for federal, state, and local government agencies engaged in food safety and food defense activities. Consisting of 170 laboratories, a key objective of the network is to strengthen the capacity of state laboratories and, where possible, harmonize and standardize laboratory methods. FDA and the FSIS jointly sponsor FERN to detect, identify, and respond to emergencies involving the biological, chemical, or radiological contamination of food.

- CDC maintains the System for Enteric Disease Response, Investigation, and Coordination, which is a data-sharing platform that allows local, state, and federal investigation partners to access epidemiologic, laboratory, and trace-back data under a single, secure platform during multistate outbreaks.
- Data on foodborne disease outbreaks, along with enteric disease outbreaks spread through all other means, are collected by CDC through the National Outbreak Reporting System. The Foodborne Outbreak Online Database (FOOD Tool), a publically available database of outbreak data, is updated annually.
- In 2014, FSIS and the CDC Agency for Toxic Substances and Disease Registry (ATSDR) completed a MOU to provide a more comprehensive and multidisciplinary approach to address foodborne health hazards associated with meat, poultry, and processed egg products.
- FSIS and APHIS completed a separate MOU for assessing the root cause in outbreaks of foodborne illness. APHIS seeks voluntary participation and collaboration in its epidemiological investigations from individual producers or companies associated with an outbreak. The objective is to identify on-farm risk factors for disease occurrence or spread that could be controlled or mitigated.
- FoodSHIELD, sponsored by the DHS Food Protection and Defense Institute, is a secure web-based system for communication, coordination, education, and training for the nation's food and agriculture sectors. FoodSHIELD allows public health and food regulatory officials at the local, state, and federal levels across the nation to work together. It also helps communicate food safety information among other government agencies.

Multi-sectoral risk profiling and risk management

- The Interagency Risk Assessment Consortium, established in 1998, provides a forum for enhanced communication and coordination among federal agencies that develop and utilize food safety risk assessments.
- The Interagency Residue Control Group/Surveillance Advisory Teams help to (1) identify and select chemical compounds that could present health-based concerns to consumers of meat and poultry; (2) sample and test meat and poultry for residues of these compounds; and (3) take enforcement action against those who market products that contain potentially hazardous levels of these compounds.
- Since 2011, the Interagency Food Safety Analytics Collaboration has brought CDC, FDA and FSIS scientists together to systematically share and analyze epidemiological data related to food contamination. Analyses strive to integrate foodborne illness and outbreak information with data from across the food chain.
- The FDA Coordinated Outbreak Response and Evaluation Network also employs a team to pursue long-term analysis on outbreaks. This team looks at all aspects and factors of the outbreak, from

ingredient sourcing to production and distribution, including ingredients from foreign countries. Team members work to identify the source of an outbreak and to prevent contamination in the future. Their work may lead to new research on how contamination can occur, or it may lead to outreach to industry and other food safety agency partners on new ways to prevent future outbreaks. Improving FDA internal processes is also a key interest of the team, which evaluates, along with other federal and state partners, the FDA response in order to incorporate lessons learned and improve future responses.

- The U.S. Government plays a major role in research and setting the direction of the risk-analysis field in the national and international risk-analysis communities.
  - The quantitative predictive risk assessment model can be used as a "virtual laboratory" that will predict and characterize risks from the consumption of fresh produce. These risks result from specific behaviors and practices on farms and during the processing and consumption of crops.
  - *FDA-iRISK* is an interactive tool that compares and ranks public health risks from multiple hazard/food combinations to inform FDA's risk prioritization and resource allocation. This comprehensive risk assessment tool generates results relatively quickly and makes them available to the public. *FDA-iRISK* is a highly accessible tool that allows risk assessors to construct, evaluate, and compare hazard/food scenarios that may involve multiple hazards (both microbial and chemical), foods, process pathways, and populations.
  - The *Virtual Deli* is a model that simulates, thousands of times per second, all the actions involved in the preparation and serving of sliced deli meats to customers, based on observational studies of real-world practices. It is part of an interagency risk assessment on *Listeria monocytogenes* in the retail setting and is designed to estimate at what points deli contamination is most likely to occur and what interventions will be most effective in reducing contamination and illness.

Communication with the public about food safety and food hazards

- The Interagency Foodborne Outbreak Response Collaboration was established in 2012 to develop processes by which agencies assess hypotheses of suspect food sources early in outbreak investigation and to improve public communications during outbreaks.
- FoodSafety.gov is the gateway to food safety information provided by government agencies. Some websites have subscription services available that allow subscribers to receive notifications when information is posted about current topics of interest, food recalls, outbreaks, and emergencies:
  - FDA food recalls.
  - CDC listing of current multistate outbreaks.
  - FSIS current food alerts and recalls.
  - FDA updates on food-related safety evaluations and guidelines.

- FDA, FSIS, and CDC use letters to industry to inform affected sectors about safety concerns related to a particular commodity.
- The Council to Improve Foodborne Outbreak Response is a multidisciplinary working group convened to increase collaboration across the country and across relevant areas of expertise in order to reduce the burden of foodborne illness in the United States. CSTE and the National Association of County and City Health Officials (NACCHO) co-chair that Council with support from the CDC and FDA.

Authorities that establish the FDA food management systems

- Key components of the Food Safety Modernization Act include preventive controls, inspection and compliance, imported food safety, response (mandatory recall authority for all food products), and enhanced partnerships.
- FDA performs its public health duties pursuant to some of the following statutory authorities. This isnot an exhaustive list, but illustrates the broad authority of FDA:
  - Federal Import Milk Act (1927)
  - Federal Food, Drug, and Cosmetic Act of 1938, as amended
  - Public Health Service Act (1944)
  - Fair Packaging and Labeling Act (1966)
  - Infant Formula Act of 1980, as amended
  - Nutrition Labeling and Education Act of 1990
  - Dietary Supplement Health and Education Act of 1994
  - Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act)
  - FDA Food Safety Modernization Act (2011)
- FSIS Authorities are established in the Acts listed below:
  - Federal Meat Inspection Act (1906)
  - Agricultural Marketing Act (1946) (selected sections)
  - Poultry Products Inspection Act (1957)
  - Egg Products Inspection Act (1970)
  - Humane Methods of Slaughter Act of 1958 (requires that livestock are handled and slaughtered humanely).

Examples of recent food safety actions

- Food safety recalls and investigations:
  - The FSIS Office of Field Operations announced 150 food recalls in 2015.
  - The FDA Office of Regulatory Authority announced over 400 recalls in 2015 .
- Food-related outbreaks:
  - Multistate outbreak of *Salmonella* Virchow infections linked to *Garden of Life RAW Meal* organic shake and meal products
  - *Listeria* and packaged salad
  - *Salmonella* and raw nut butters
- Reviews and evaluations are essential components of the U.S. food safety system. FSIS performs a final assessment after the closure of each foodborne illness investigation. The FDA Coordinated Outbreak Response and Evaluation Network does a formal "after-action review" with CDC and any appropriate participating state partners.
  - Coordinated Outbreak Response and Evaluation Network
  - Guidelines for FSIS foodborne disease investigations, including after-action review

Best Practices, Challenges, Gaps, and Recommendations

The United States has a strong primary prevention system for foodborne illnesses through regulatory, public health, and risk analysis efforts across the farm-to-table continuum. To accomplish secondary prevention of foodborne illness requires information sharing with consumers and food industry, and the development of enhanced policies and education efforts based on newly identified hazards and risks. There are strong public-private partnerships for science-based food safety best practices to reduce the risk of illness from entities that produce, process, and distribute food.

Multiagency and multidisciplinary participation through every stage of detecting, investigating, and responding to foodborne outbreaks and illness has become routine during multistate outbreak investigations, yet challenges still remain. Multistate outbreaks are difficult to detect and investigate due to the wide distribution and multiple sources of many food ingredients and products. There are challenges related to coordination of specialized laboratory testing to trace and track cases and unexpectedly contaminated foods sources. Although coordination among federal agencies and experts from health, food, and agricultural sciences is consistent, there is a need to continuously evaluate, modernize, and strengthen the coordination of detection and investigation activities.

Developing new epidemiological tools that enhance foodborne illness outbreak investigations and reduce foodborne illnesses and deaths could help advance food safety capacity. The U.S. Government should continue developing next-generation laboratory methods (such as whole genome sequencing)

for pathogen identification. There is also an opportunity to reinforce coordination and support for state and local governments by conducting more clinical, food, and environmental testing, and isolate characterization.

Biosafety and Biosecurity

Prevent 6 (P6)

JEE Target

A whole-of-government national biosafety and biosecurity system is in place, ensuring that especially dangerous pathogens are identified, held, secured and monitored in a minimal number of facilities according to best practices; biological risk management training and educational outreach are conducted to promote a shared culture of responsibility, reduce dual use risks, mitigate biological proliferation and deliberate use threats, and ensure safe transfer of biological agents; and country-specific biosafety and biosecurity legislation, laboratory licensing, and pathogen control measures are in place as appropriate.

Level of Capabilities in the United States

➢ Summary

The United States has a national biosafety and biosecurity system in place across its laboratories designed to protect laboratory workers, public health, agriculture, the environment, and national security. Multiple and complementary biosafety and biocontainment oversight requirements exist within and among governments at the federal, state, and municipal levels, as well as individual research institutions. Correspondingly, multiple government entities – at all levels – participate in the current system of biosafety and biocontainment oversight and, in many cases, coordinate their oversight activities with those of individual institutions. The approach to biosafety and biocontainment oversight rests on a foundation of federal regulations, guidelines, and policies at multiple levels. However, this approach is implemented locally.

Certain federal entities are responsible for ensuring compliance with biosafety, biocontainment, and biosecurity regulations, standards, and other requirements. The federal regulations that pertain most directly to biosafety and biosecurity oversight at laboratories are the applicable OSHA regulations (General Duty Clause, Personal Protective Equipment Standards, and Bloodborne Pathogens Standard); Select Agent Regulations (SAR), promulgated by HHS and USDA (see 42 CFR Part 73, 7 CFR Part 331 and 9 CFR Part 12); APHIS permitting regulations; and CDC regulations that require a permit for the importation of infectious biological agents, infectious substances, and vectors of human disease into the United States, excluding those items listed under 42 CFR §71.54(f) (i.e., select agents listed in 42 CFR Part 73 whose importation has been authorized in accordance with 42 CFR §73.16 or 9 CFR §121.16).

The SAR cover both human and agricultural pathogens and toxins, and provide for federal oversight of laboratories that possess, use, or transfer any biological agent or toxin on a designated list of select

agents and toxins that have the potential to pose significant risks to public health or agriculture. The DOT, Department of Commerce, APHIS, and CDC regulations restrict the transfer (import, export, transportation within the United States) of hazardous biological agents and toxins unless certain conditions are met. Through its permitting system, APHIS regulates the interstate transport and use of agents that are hazardous to agriculture (certain livestock, poultry, and crop pathogens). APHIS also inspects facilities to ensure they provide adequate containment of regulated agricultural agents.

Relevant federal guidelines include the Biosafety in Microbiological and Biomedical Laboratories (BMBL), fifth edition, and the *National Institutes of Health Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (*NIH Guidelines*). The BMBL provides guidance on protecting laboratory workers from exposure to infectious organisms and biological toxins that pose various levels of risk to human health. The *NIH Guidelines* require compliance by any entity funded by NIH for recombinant or synthetic nucleic acid molecule research. Some other federal agencies also require compliance with the NIH Guidelines as a term and condition of their own funding. In addition to regulations and guidelines, the U.S. Government has published policies relevant to biosafety and biosecurity.

➢ Indicators

■ *Whole-of-Government biosafety and biosecurity system is in place for human, animal, and agriculture facilities* *P6.1*

Accountability for dangerous pathogens and toxins

- The biological select agents and toxins (BSAT) list and the National Select Agent Registry (NSAR) are maintained jointly by the Federal Select Agent Program (FSAP). The CDC's Division of Select Agents and Toxins and APHIS' Agriculture Select Agent Services together administer the FSAP. The biennial review of the BSAT list includes an opportunity for public comment. The current list is in Appendix 4.
- The Federal Bureau of Investigation (FBI) security risk assessment is an electronic records check to determine whether an entity or an individual meets one of the statutory criteria which would either prohibit registration; or prohibit or restrict access, respectively. This pertains to those who wish to register to possess, use, or transfer a BSAT or an individual who has been identified by a registered entity as having a legitimate need to access a BSAT.
- Information about individuals or entities who use, possess, or transfer BSAT within the United States is maintained in NSAR, and their registration must be amended any time a change in BSAT holdings, personnel with access to BSAT, or procedures utilizing BSAT occur within their facility..

National biosafety and biosecurity legislation, regulations, and guidelines

- The Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism Act Of 2001 (USA PATRIOT Act) establishes the definition of a "restricted person" and makes possession of BSAT by a "restricted person" a violation of criminal law.
- The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 requires that individuals or entities that possess, use, or transfer BSAT register with either HHS or USDA. This legislation is implemented through the HHS and USDA SAR (42 CFR part 73, 7 CFR part 331, and 9 CFR 121). Pursuant to the SAR, registered entities must develop and implement biosafety, security, and incidence response plans commensurate with the risk of the agent possessed and the work performed, and must take measures sufficient to prevent unauthorized access to BSAT.
- The federal regulations that pertain most directly to biosafety and biosecurity oversight at laboratories are:
    - Applicable OSHA regulations (the General Duty Clause, Personal Protective Equipment Standards, and Bloodborne Pathogens Standard);
    - SAR, promulgated by HHS and USDA;
    - USDA APHIS permitting regulations; and,
    - HHS CDC permitting regulations.
- Other federal regulations and regulatory oversight can have an impact on containment facilities. DOT, Department of Commerce, APHIS, and CDC regulations restrict the transfer (import, export, transportation within the United States) of hazardous biological agents unless certain conditions are met.
    - Through its permitting system, APHIS regulates the interstate transport and use of agents that are hazardous to agriculture (certain livestock, poultry, and crop pathogens); APHIS also inspects facilities to ensure they provide adequate containment of regulated agricultural agents.
    - The HHS and USDA SAR cover both human and agricultural pathogens and toxins, and provide for federal oversight of laboratories that possess, use, or transfer any agent or toxin on a designated list of select agents that have the potential to pose significant risks to public health or agriculture.
    - The DOT Hazardous Material Regulations provide requirements regarding classifying, marking, labeling, packaging, and describing shipments of hazardous materials, creating and adhering to transportation security plans, and incident reporting. See the DOT *Guidance on Transporting Infectious Substances Safely*.
- The Resource Conservation and Recovery Act Regulations cover the handling of biological waste . These regulations require that all solid and hazardous wastes are handled in a manner which minimizes harm to humans or the environment.

- The U.S. report to the United Nations Security Council 1540 Committee on *Effective U.S. National Practices for the Implementation of UN Security Council Resolution 1540* (29 February 2014) highlights U.S. policies and programs aimed at preventing bioterrorism and the misuse of biological materials, technology and expertise.
    - Biosecurity legislation and enforcement measures are also listed in the U.S. national report to the 1540 Committee on September 29, 2014 and the 1540 Committee Matrix of the United States of America.
- General worker safety in the United States, including in biomedical laboratories, is regulated in part by OSHA under the Occupational Safety and Health (OSH) Act of 1970.
    - OSHA's Personal Protective Equipment standards (29 CFR 1910 Subpart I), among others, clarify the requirements for eye and face, respiratory, head, foot, hand, and other bodily protection from laboratory hazards (including certain biomedical reagents and materials).
    - The Bloodborne Pathogens standard (29 CFR 1910.1030) establishes specific protections for workers with occupational exposure to blood, body fluids, and other potentially infectious materials, including those resulting from work in laboratories .
    - OSHA's Laboratory Standard (29 CFR 1910.1450) requires protections for workers in laboratories that use hazardous chemicals .
    - OSHA's Hazard Communication standard (29 CFR 1910.1200) establishes specific protections for workers exposed to hazardous materials used in the workplace .
    - Other OSHA requirements, including the General Duty Clause, Section 5(a)(1), of the OSH Act and the agency's recordkeeping and injury/illness reporting mandates, may also apply to laboratory employers and workers.
- CDC Import Permit Regulations require importers to implement biosafety measures commensurate with the hazard posed by the infectious biological agent, infectious substance, and/or vectors of human disease and the level of risk given its intended use (42 CFR §71.54) for materials to be imported to the United States. Materials covered include microorganisms capable of causing disease in humans, bats, arthropods, snails, and non-human primates and primate trophies. The regulations also permit CDC to inspect facilities for the biosafety prior to approval of the permit.
- Through its permitting system, APHIS regulates the transport and use of agents that are hazardous to agriculture (certain livestock, poultry, and crop pathogens). APHIS inspects facilities to ensure they provide adequate containment of regulated agricultural agents (9 CFR Part 122, 7 CFR Part 330 and 340).
- As a condition for NIH funding of recombinant or synthetic nucleic acid molecule research, institutions must ensure that such research conducted at or sponsored by the institution, irrespective of the source of funding, complies with the *NIH Guidelines*. This includes following a set of biocontainment practices specific to that work, and includes the creation and maintenance of an

"Institutional Biosafety Committee," which has specific requirements for membership and reviews, approves, and oversees projects to "identify any potential risk to public health or the environment." Many institutions have broadened the suggested scope of such committees to include all work with biological agents or toxins, and not just that work involving recombinant or synthetic nucleic acid.

- The U.S. Government has published several policies relevant to dual use research of concern (DURC), with the intention of raising awareness and limiting the potential for misuse of scientific information derived from life sciences research.
  - *United States Government Policy for Institutional Oversight of Life Sciences DURC*.
  - *United States Government Policy for Oversight of Life Sciences DURC* .
  - Deliberative Process and Funding Pause on Certain Types of Gain-of-Function Research .
  - HHS Framework on H5N1 DURC Research.

Federal outreach

- Federal outreach and education activities are conducted that pertain to biosafety and biosecurity. Examples follow:
  - The *S3: Science, Safety, and Security* campaign was established to promote increased awareness of hazardous biological agents, and the safe and secure use of these agents. The S3 website provides a single, coordinated portal for scientists, laboratory staff, policy makers, and the public to locate and link to existing resources about biorisk management, including information about legislation, regulations, and policies.
  - FSAP provides technical assistance and guidance to registered entities to promote laboratory safety and security through FSAP staff members who serve as liaisons with the registered entities. In addition, FSAP has multiple formal means of communicating with regulated entities and the public, including a comprehensive website . The select agent website includes applicable regulations, guidance documents, frequently asked questions, links to guidelines, and other helpful information. Workshops for registered entities and partners help inform individuals of their legal responsibilities for implementing the SAR.
  - The NIH Office of Science Policy has a robust outreach program relating to the requirements and responsibilities under the *NIH Guidelines*, as well as the *United States Government Policy for Institutional Oversight of Life Sciences DURC*. The NIH Office of Science Policy staff conduct workshops for entities subject to the *NIH Guidelines* and the DURC policy, give presentations and trainings at professional society meetings and key scientific conferences, and have developed a series of educational tools and materials including frequently asked questions and guidance documents. In addition, The NIH Office of Science Policy has an educational site visit program focused on enhancing awareness of biosafety policies and procedures related to the oversight of research subject to the *NIH Guidelines*. The program also serves to foster a

dialogue between the NIH and the research community regarding the establishment of best biosafety oversight practices.

- Other biosafety and biosecurity resources (e.g., see *BMBL*and *Morbidity and Mortality Weekly Report*) and meetings (USDA Agricultural Research Service International Biosafety and Biocontainment Symposium Series) and the CDC International Biosafety Symposium are available to stakeholders.
- FBI biosecurity outreach efforts to provide security awareness and facilitate partnerships with our WMD Coordinators. For more information, see:
  - FBI Weapons of Mass Destruction Directoratehttps://www.fbi.gov/news/stories/2012/february/wmd_022112
  - AAAS-FBI Partnership
  - International Biosecurity and Prevention Forum

Inspection and enforcement

- Under section 175 of Title 18 of the U.S. Code, development, possession, or use of a biological weapon is a felony punishable by a fine or life imprisonment, or both. Section 175 also makes it a felony to knowingly possess any biological agent or toxin that is not reasonably justified by a prophylactic, protective, bona fide research, or other peaceful purpose. Under section 175b of Title 18 of the U.S. Code, possession of a select agent or toxin by either a "restricted person" or an entity not registered with HHS or USDA is also a felony punishable by a fine or imprisonment for not more than five years, or both. These provisions are consistent with and support U.S. obligations under the Biological and Toxin Weapons Convention.
- All entities registered with the FSAP are required to comply with the SAR, which establish biosafety and biosecurity requirements to be followed within laboratories handling BSAT. The FSAP monitors compliance with these federal biosafety and biosecurity regulations through an inspection program that involves site visits . At a minimum, the FSAP performs an initial inspection prior to registration, followed by a renewal inspection every three years. The FSAP conducts site visits on an average 18-month cycle. Laboratories that work at the highest levels of risk (e.g., Tier 1) are inspected on an annual basis. Inspections may be announced or unannounced.
- The FSAP has systems in place for the reporting of incidents of theft, loss, and release of BSAT. These reports may generate follow-on investigations to identify lapses in compliance with the regulations and ensure all findings are corrected. There are anonymous and non-anonymous mechanisms available for reporting concerns to the FSAP.
- In cases of serious noncompliance with SAR, the FSAP has the authority to suspend or revoke an entity's registration to possess, use, or transfer BSAT. There are also civil and criminal penalties for noncompliance.

- OSHA regulations (General Duty Clause; Personal Protective Equipment Standards, including the Respiratory Protection Standard; Bloodborne Pathogens Standard; and Hazard Communication or Laboratory Standard) apply to nearly all private sector workplaces, with some limited exceptions. In states that operate their own OSHA-approved occupational safety and health programs (OSHA State Plans), public sector workers are also covered. The heads of federal agencies are responsible for the safety and health of their workers.
- USDA requires permits for the importation or transfer of animals, animal products, plants and soil, or biological organisms if such actions are necessary to prevent the introduction into or the dissemination within the United States of pathogens or pests. APHIS has the authority to inspect facilities that possess or use plants, animals, or other biological agents and products governed by the USDA regulations.
- The Export Administration Regulations (15 CFR 730-774) are enforced by the Department of Commerce Bureau of Industry and Security. The regulations set the rules for the control of export and re-export of commodities, software, and technology, including biological materials.
- The BMBL, which has become the recognized code of biosafety practice, is an authoritative reference and de facto standard of operation for U.S. laboratory biosafety and biocontainment principles, practices, and procedures. Adhering to the BMBL is a requirement for entities in receipt of funding from HHS for certain classes of research grants and contracts. The guidelines in the BMBL are designed to ensure the safety and security of working with biological agents, the protection of laboratory workers, and the public, and the containment of biological hazards within the laboratory.
- The NIH Guidelines specify scientifically-based practices for constructing and handling recombinant or synthetic nucleic acid molecules, and cells, organisms and viruses containing such molecules. The NIH Guidelines also articulate the responsibilities of institutions, investigators, and Institutional Biosafety Committees at institutions that receive any support for recombinant or synthetic nucleic acid research from the NIH. The *NIH Guidelines* direct reviews of proposed recombinant or synthetic nucleic acid research, including post-approval monitoring that may include laboratory inspections or follow-up reporting of events or incidents. Compliance with the *NIH Guidelines* is a term and condition of NIH funding.

Monitoring activities

- Federal regulations mentioned above require compliance and include mechanisms for oversight and monitoring. FSAP assessments allow inspectors to confirm that the appropriate safety and security measures are in place at registered entities as well as ensure that lab workers are adequately trained. Information regarding inspections is provided on the FSAP website.
- The Responsible Official (an entity-designated individual approved by FSAP) must have the authority and responsibility to act on behalf of an entity to ensure that the entity's select agent program complies with the SAR.
- Facilities handling BSAT are inspected periodically by the FSAP for both biosecurity and biosafety. Inspection programs and other mechanisms provide a means to monitor compliance and identify

deviations from acceptable laboratory safety or security practices. Other third parties may also assess facilities handling BSAT or non-BSAT.

Laboratory accreditation for biosafety and biosecurity

- The American Biological Safety Association International (ABSA) has developed a voluntary Laboratory Accreditation Program for containment laboratories (biosafety level [BSL]-2, BSL-3, ABSL-2, and ABSL-3) that are not under the jurisdiction of the SAR. ABSA accreditation will provide entities recognition of excellence and compliance with rigorous standards, while providing facilities guidance in generating processes and policies to create a safer environment for their organization, employees, research animals, and the community. The ABSA accreditation program accredits the biosafety management programs of U.S.-based entities with research laboratories relative to technical and operational competence compatible with applicable regulations, guidelines, and standards.
- Laboratories that have clinical components must comply with Clinical Laboratory Improvement Amendments (CLIA) for accreditation purposes (described in detail in the section on *National Laboratory System*). The accreditation process contains biosafety components.
- Laboratories with animal facilities housing species governed by the Animal Welfare Act are inspected by APHIS, unless exempted. Federal agencies that conduct research are not inspected by APHIS, but are responsible for complying with all USDA standards of animal care. Laboratories with animal facilities may choose to be certified by the American Association for the Accreditation of Laboratory Animal Care International, which also contains both biosafety and biosecurity components. Although voluntary, accreditation has become a significant manner in which labs that do not have BSAT allow for a third party review.
- The United States is one of two nations authorized by the World Health Assembly to maintain a repository of variola virus. The SAR have specific additional biosecurity requirements for this agent (42 CFR § 73.11), and the variola virus repository and research program is reviewed biennially during an on-site biosecurity assessment by the WHO.

Recent Federal recommendations to enhance biosafety and biosecurity

- Federal departments and agencies have the ability to seek external review of their programs. As an example, in July 2014, CDC's External Laboratory Safety Workgroup (ELSW) was established to review laboratory safety practices at the CDC, FDA, and NIH at the request of the HHS Secretary. The ELSW made recommendations in 2015.
- On October 29, 2015, the U.S. Government released two sets of recommendations and implementation plans addressing biosafety and biosecurity. The Federal Experts Security Advisory Panel (FESAP)conducted an internal U.S. Government review of biosafety and biosecurity practices.

The Fast Track Action Committee on Select Agent Regulations (FTAC-SAR) conducted an external review that focused on the effects of the SAR on science, technology, and national security.

- Recommendations made by both the FESAP and FTAC-SAR address the culture of responsibility, oversight, outreach and education; applied biosafety research; incident reporting; material accountability; inspection processes; and regulatory changes and guidance to improve biosafety and biosecurity. In addition, an approach was identified to determine the appropriate number of federally funded high-containment U.S. laboratories required to possess, use, or transfer BSAT.
- The U.S. Government has developed a plan to implement the FESAP and FTAC-SAR recommended actions . The U.S. Government expects that implementing the FESAP and FTAC-SAR recommended actions will strengthen biosafety and biosecurity practices and oversight activities.

Laboratory licensing in the United States

- Licensing, per se, is the responsibility of individual U.S. states and territories. Laboratories in the United States that possess, use, or transfer BSAT are required to register with the FSAP. Entities that are registered with FSAP include the following types: federal, non-federal (e.g., state PHL), academic, government, commercial, and private.
- The FSAP registers and monitors entities that possess, use or transfer BSAT. Entity information is maintained in NSAR. In accordance with the SAR, entities under these regulations must amend their registrations any time that there is a change in the agents they possess (agent transfer or destruction), their activities with these agents, and the personnel with access to these agents.
- ABSA administers a laboratory biosafety accreditation program based on the European Committee for Standardization's standard 15793 Laboratory Biorisk Management. Through its Vienna agreement with the Committee, the ISO is now adopting this as standard 35001. Third party accreditation is not a federal requirement for biological laboratories.
- Additional details on accreditation of PHL and clinical laboratories in the United States are provided in the section on the *National Laboratory System*.

Oversight of dual use research

- The U.S. Government has played a leading role in responding to the challenges associated with dual use research. In the aftermath of the 2001 anthrax attacks, the U.S. Government established the National Science Advisory Board for Biosecurity (NSABB) to provide advice on federal biosecurity oversight of dangerous biological pathogens. In 2007, the NSABB published the *Proposed Framework for the Oversight of Dual Use Life Sciences Research: Strategies for Minimizing the Potential Misuse of Research Information*. In the years following the publication of this report, the

NSABB published a series of guidance documents relating to various dual use issues including synthetic biology, the growing field of amateur biology, synthesis of select agents, scientific codes of conduct, and personnel reliability .

- Policies relevant to DURC and gain-of function studies intend to raise awareness and limit the potential for misuse of scientific information derived from life sciences research.
- DURC is 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. .
  - The *United States Government Policy for Oversight of Life Sciences DURC*, published in March 2012, sets forth a process of regular federal review of U.S. government-funded or -conducted research . This policy requires federal agencies that fund or conduct life sciences research to identify DURC and evaluate this research for possible risks, as well as benefits, and to ensure that risks are appropriately managed and benefits realized.
  - On September 24, 2014, the U.S. Government published the *United States Government Policy for Institutional Oversight of Life Sciences DURC*. This policy applies to institutions receiving federal funds to conduct or sponsor life sciences research that also conducts or sponsors research with the agents or toxins listed in the policy. The policy requires institutions to review the research for experiments that may involve dual use research (as defined in the policy), to perform a risk/benefit analysis, and to implement appropriate risk mitigation measures. This activity is to be reported to the appropriate federal funding agency.
  - In February 2013, HHS developed a Framework for Guiding Funding Decisions about Research Proposals with the Potential for Generating Highly Pathogenic Avian Influenza H5N1 Viruses that are Transmissible among Mammals by Respiratory Droplets to guide funding decisions on proposals for research anticipated to generate highly pathogenic avian influenza H5N1 viruses. The framework outlines a robust review process that takes into account the scientific and public health benefits, the biosafety and biosecurity risks, and the appropriate risk mitigation measures pertinent to the proposed research. In August 2013, the framework was expanded to cover certain types of gain-of-function experiments involving the H7N9 influenza virus.
  - On October 16, 2014, the White House announced the *Deliberative Process and Funding Pause on Certain Types of Gain-of-Function Research* . During this deliberative process, U.S. Government departments and agencies, in accordance with the provisions in the policy, paused the release of federal funds for gain-of-function studies that are reasonably anticipated to confer attributes to influenza, Middle East respiratory syndrome (MERS), or severe acute respiratory syndrome (SARS) viruses such that the virus would have enhanced pathogenicity and/or transmissibility in mammals via the respiratory route. The pause will allow the U.S. government, in partnership with the life sciences community and stakeholders, to conduct a

comprehensive assessment of gain-of-function research with the explicit goal of developing a new federal policy to guide future investments in this area of research.

Physical security

- Physical security measures are in place commensurate with the risk. Entities that possess, use, or transfer BSAT must adhere to requirements detailed within the SAR.
- Additional requirements exist for a subset of BSAT known as Tier 1 BSAT. In 2012, the SAR designated "Tier 1" BSAT as those BSAT considered to have the greatest risk for deliberate misuse and the most significant potential for mass casualties, or devastating effects on the economy or critical infrastructure. The requirements for registered entities working with Tier 1 BSAT include enhanced physical security standards, suitability assessments of lab workers before they can work with Tier 1 agents (e.g., verification of prior education and employment, periodic performance reviews), and ongoing monitoring of personnel with access to agents or toxins on the Tier 1 list.
    - Additional information on the suitability assessment requirements is available on the FSAP's website. A FBI security risk assessment is completed on any person requesting access to a select agent or toxin.
- The SAR require FSAP registered entities to develop and implement security and incident response plans to minimize the potential for unauthorized access, theft, loss, or release. These measures must address both natural or intentional events that could lead to a release. These measures are exercised and updated at least annually or upon a change in circumstances. In addition, the SAR require the immediate reporting of incidents that may involve a theft, loss, or release to the FSAP. The FBI may be notified of any suspicious activity that may be criminal in nature concerning an entity, its personnel, or its BSAT.
- In addition, FSAP proactively works to provide assistance to registered entities in advance of natural disasters or national events to ensure that BSAT are properly secured to protect them from theft, loss, or release.
- The BMBL describes laboratory biosecurity planning for microbiological laboratories. Although the information is advisory, the application of the principles and risk assessment process may enhance overall laboratory management. Section four of *BMBL* is available on the CDC's BMBL website.

Information Security

- The SAR contain a set of security provisions in section 11 that must be met by all entities registered with the FSAP including information security. Entities with Tier 1 BSAT are subject to additional security measures set forth in the SAR.

Transportation Security

- Procedures for the safe and secure transport of culture, specimens, samples, and other contaminated materials are established. The U.S. DOT has promulgated regulations in 49 CFR Parts 171-180 that describe packaging and shipping standards for these materials.
- These standards are consistent with the requirements contained in the 13th and 14th editions of the *United Nations Recommendations for the Transport of Dangerous Goods* (United Nations Recommendations), the 2005-2006 edition of the ICAO *Technical Instructions for the Safe Transport of Dangerous Goods by Air*, and the International Maritime Organization *Dangerous Goods Code*.
- There are specific measures to ensure that infectious substances are shipped safely, including DOT Hazardous Materials Regulations (49 CFR Parts 171-180). Answers to "General questions about transport of select agents and toxins" are available on the FSAP's website.

Personnel security and professional qualifications

- Using the security risk assessment process, the FSAP works closely with the FBI to identify those individuals who are prohibited from having access to BSAT ("restricted persons") based on the criteria established by the USA PATRIOT Act. Any individual, as defined in the SAR, who is approved to have access to Tier 1 BSAT is required to be enrolled in the entity's suitability assessment program (pre-access and ongoing).
- CDC and the Association of Public Health Laboratories have developed *Guidelines for Biosafety Laboratory Competency* and *Competency Guidelines for Public Health Laboratory Professionals* .

Facility emergency planning

- The United States has in place a graded system of protection for pathogens and biological toxins according to the risk these agents pose to human and animal health, the environment, and the economic well-being of the nation. These graded protections include a range of biorisk management procedures for biosafety, biocontainment, and biosecurity practices, and equipment at individual laboratories. There is a range of oversight mechanisms provided by the laboratory supervisor or principal investigator (in research facilities), as well as the biosafety officer, Responsible Official (for select agents and toxins), or other institutional official(s); to local and state regulations and oversight of certain facilities; to federal regulations and oversight, where applicable.
- The SAR contain a set of incident response provisions outlined in section 14 that must be met by all entities registered with FSAP based upon a site specific risk assessment (biosafety and biosecurity). The incident response plan must be coordinated with any entity-wide plans, kept in the workplace, and available to employees for review.
- The SAR contain a set of biosafety and security provisions outlined in sections 11 and 12 that must be met by all entities registered with FSAP, and that were developed by the entity based on the risk

of the select agent or toxin, given its intended use. The written biosafety plan must be commensurate with the risk of the select agent or toxin, given its intended use; and the written biosecurity plan must be sufficient to protect the select agents or toxins from unauthorized access, theft, loss, or release.

- Sections 11 and 12 of the SAR also include provisions that plans must be reviewed annually and revised as necessary. Drills or exercises must be conducted at least annually to test and evaluate the effectiveness of the plans. The plan must be reviewed and revised, as necessary, after any drill or exercise and after any incident.

Laboratory audits

- In accordance with section 18 of the SAR, the FSAP inspects registered entities to ensure compliance with SAR. These assessments allow inspectors to confirm that the appropriate safety and security measures are in place as well as ensure that laboratorians are adequately trained. In addition, there is a requirement in the SAR for the registered entities to conduct internal annual inspections.
- The FSAP performs an initial inspection prior to registration, followed by a renewal inspection every three years. Unannounced verification/compliance inspections are performed every 12 to 18 months. Finally, inspections are performed, as needed, when an entity requests significant changes to its registration or in response to an incident. In addition, these entities are required by regulation to perform self-inspections on an annual basis.
- Entities that are involved in voluntary accreditation programs must undergo audits in conjunction with the terms of their accreditation.
- In addition, other assessments are conducted for work with agents of less risk than BSAT and for other aspects of laboratory compliance (e.g., NIH Office of Laboratory Animal Welfare Assurance for facilities conducting animal research.
- Some examples of organizations that evaluate laboratory safety in the context of a broad laboratory quality management system include the College of American Pathologists and the American Association for Clinical Laboratory Accreditation.
- ISO accreditation is not a federal requirement for biological laboratories. Laboratories may pursue ISO accreditation through voluntary accrediting entities in the United States, such as the American Association for Laboratory Accreditation.

National laboratories and relevant classifications

- CDC alone houses 24 active WHO Collaborating Centers that support work in a wide range of areas including occupational health, injury control, tobacco risk control, and control of infectious diseases. Details regarding the CDC WHO Collaborating Centers can be found on the WHO's website.

- There are at least 10 U.S. Government and academic institutions that sponsor FAO/OIE reference laboratories or Collaborating Centers. Examples of collaboration with OIE follow:
- The USGS, which conducts environmental and wildlife disease surveillance and research, works closely with USDA and the OIE. For example, the USGS National Wildlife Health Center is part of USDA's National Animal Health Laboratory Network, and the USGS Western Fisheries Research Center is an OIE Reference Laboratory for fish diseases (such as bacterial kidney disease, infectious hematopoietic necrosis virus).
    - The USGS National Wildlife Health Center is an OIE Collaborating Center for Research, Diagnosis and Surveillance of Wildlife Pathogens.
    - The DOE Sandia National Laboratory is an OIE Collaborating Center for Laboratory Biorisk Management in Albuquerque, New Mexico.

Reducing access to dangerous pathogens and toxins

- The U.S. Government is currently determining the appropriate number of federally funded high containment U.S. laboratories required to possess, use, or transfer BSAT.
    - A federal review was conducted by the FESAP to identify an approach to determine the "appropriate number of high-containment U.S. laboratories that are required to possess, use, or transfer BSAT."
    - The FESAP recommended a three-phase process characterized by federal assessment (Phase I), external review (Phase II), and consideration of the recommendations of the external non-federal review by the U.S. Government (Phase III). The proposed three-phase process will include the development of a 'best practices checklist' for departments and agencies to follow when they are considering the need to modify or augment existing high and maximum containment laboratory space capacity. The approach identified by the FESAP is currently being implemented and could potentially inform consideration of consolidation of dangerous pathogens and toxins.
- Although all facilities that possess collections of BSAT must register with FSAP, there is not currently in place a program to consolidate these collections. The approach identified by the FESAP to determine the appropriate number of federally-funded high containment U.S. laboratories required to possess, use, or transfer BSAT is currently being assessed. The assessment could inform efforts to consolidate collections.
- Many first-line detection/identification tests employ targeted molecular testing or polymerase chain reaction test methodologies, which do not require the culturing of dangerous pathogens.
- PHL have the capability to identify diseases caused by various select agents utilizing a molecular diagnostic method known as polymerase chain reaction (PCR). In addition to PCR, there are other non-culture based methods, such as immunohistochemistry, that have been in use for many decades as a means to identify infectious agents, especially those rendered non-viable in fixed-

tissues. Food testing and animal diagnostic laboratories also employ molecular diagnostic and other non-culture based methods to screen specimens for dangerous pathogens or toxins.

- Examples of molecular tests that preclude culturing dangerous pathogens include:
  - CDC Human Influenza Virus Real-Time PCR Diagnostic Panel, includes influenza A/H5 (Asian Lineage) with subtyping
  - CDC *Bacillus anthracis* Real-Time PCR Assay
  - JBAIDS Anthrax Detection System

■ *Federal funding for federal biosafety and biosecurity oversight* *P6.1*

- The availability of federal funding to support biosecurity programs/initiatives and their oversight and enforcement is subject to the federal budget process and congressional appropriations.

■ *Biosafety and biosecurity training and practices* *P6.2*

Training at laboratory facilities

- The SAR contain training requirements in section 15 that must be met by all entities registered with FSAP including training on biosafety, security (including security awareness), and incident response.
  - Entities with Tier 1 BSAT must also provide insider threat awareness training to personnel enrolled in the suitability assessment program.
- Part of the Institutional Biosafety Committee review of recombinant and synthetic nucleic acid research involves the assessment of the training and expertise of personnel performing the work.
- Federal departments and agencies provide agent-specific training, biosafety training, incident response training, and security training. Under the conditions of certain grants and funding, research institutions may be required to complete additional training specific to the risks associated with the research.
- Multiple U.S. organizations provide professional training for staff in biosafety and biosecurity, including the major U.S. biological safety organization (i.e., ABSA) as well as other institutions, such as the NIH National Biosafety and Biocontainment Program, Sandia Laboratories, the Frontline Foundation, and Johns Hopkins University. The training is generally focused on those responsible for biosafety and biosecurity at their home institution.
- Biosafety and biosecurity training programs for personnel are offered by the federal government, professional societies, individual research and educational institutions, and other entities. Training of laboratory personnel is planned and managed at the local level, and takes into account the needs of the individual institutions. Local institutions teach site-specific information to better address the needs of their staff.

- Multiple resources for training in biosafety, biocontainment and laboratory biosecurity are provided at the local level as well as from courses offered by institutions, professional societies, others, and the U.S. government. U.S. Government resources include those developed or supported by HHS and USDA (Biosafety for BSL-2 Laboratories training modules); the DOS and DoD (such as the Global Biorisk Management Curriculum); the NIH Division of Occupational Health and Safety National Biosafety and Biocontainment Training Program; and CDC Office of Safety, Health and the Environment Laboratory Biosecurity Training.
- CDC and the Association of Public Health Laboratories have developed *Guidelines for Biosafety Laboratory Competency* and *Competency Guidelines for Public Health Laboratory Professionals*.
- ABSA offers two types of credentialing for biosafety professionals – a Registered Biosafety Professional and a Certified Biological Safety Professional.

Oversight of the training and exercise requirement

- The SAR contain training requirements in section 15 that must be met by all entities registered with FSAP. These requirements specify that training must be conducted prior to the granting of access to BSAT and must be refreshed on an annual basis thereafter. Training must also be conducted when substantive changes to policies or procedures occur. There are other additional annual training requirements.
- There has been a proposal to revise the SAR to require that registered entities document any problems identified during drills/exercises and the corrective action(s) taken.
- All academic institutions that work with BSAT are required to provide training to each individual with access approval from the FSAP.
- The U.S. Government has increased its emphasis on promoting and improving biosafety and biosecurity within laboratories that maintain or work with dangerous pathogens and toxins, including training. The availability of federal funding is subject to the federal budget process and congressional appropriations. U.S. entities have dedicated funding for these activities and it is sustainable.
- There is no single mechanism to ensure and monitor staff competence and proper training at all laboratories. For laboratories that possess, use, or transfer BSAT, the SAR require that laboratory staff is trained prior to access to BSAT, that refresher training is done on an annual basis and when substantive changes to policies or procedures occur, and that staff demonstrate that they understand the material.

■ ***Facilities and biosafety equipment maintenance***

Maintenance planning for new facilities

- New facilities are designed, constructed and resourced using a life-cycle planning model that incorporates an asset business planning (ABP) protocol to ensure resources (personnel, architects, engineers, technicians, and funding) are commensurate to the level of facility sustainment required. This ABP also forecasts/estimates facility costs relative to preventive maintenance, operations, and out-year recapitalization to ensure sustained facility performance.
- The commissioning process starts at the beginning of project planning and occurs throughout construction, and officially ends prior to beneficial occupancy. However, continuous verification is performed throughout the life of the facility through monitoring of facility performance in order to perform regular and preventive maintenance. The process also applies when facilities are renovated.

Availability of medical maintenance and waste management

- In general, all laboratory safety systems and equipment can be maintained through local contracts or on-staff medical maintenance professionals. Ensuring a budget for medical maintenance is a key component of the ABP.
- The U.S. Government has increased its emphasis on promoting/improving biosafety and biosecurity within laboratories that maintain or work with dangerous pathogens and toxins. Resources are dedicated to ongoing operations and maintenance of facilities and equipment.
- U.S. regulations under the Resource Conservation and Recovery Act require that all hazardous wastes are handled in a manner which minimizes harm to humans and the environment. Many states are authorized or approved to administer the RCRA programs and to ensure compliance, and states may regulate solid and hazardous wastes under their own authorities as well. Most if not all states require that hazardous biological agents are either destroyed on site before disposal as solid waste, or packaged as regulated medical waste, or handled as a special Category A infectious substance and transferred to a licensed third party for decontamination via autoclaving or incineration

Transportation of biological material

- There are national regulations in place and up-to-date for the transport of infectious substances (Categories A and B).
- The transportation of infectious substances is regulated by DOT's Hazardous Materials Regulations which specifically address requirements for Category A and B infectious substances. These regulations are maintained by the U.S. DOT and are found in 49 CFR Parts 171-180. These requirements cover packaging, marking, labelling, shipping paper documentation, training, security, and incident reporting.

- DOT engages in regulatory enforcement to ensure that local carriers transport infectious substances according to the national regulations. When violations are identified, DOT levies penalties and may terminate related special permits and approvals. DOT has harmonized its regulations with international standards.
- Training is available for people responsible for shipments of infectious substances. DOT has also published guidance on transporting infectious substances safely (see above).

Occupational health and safety

- The SAR contain biosafety provisions outlined in section 12 requiring the development of a biosafety plan based on the risk of the select agent or toxin, given its intended use. Requirements for employers to provide personal protective equipment in laboratories that contain BSAT follow the general, national guidelines described in the section on the *National Laboratory System*. Because of the additional hazards related to BSAT, CDC and FDA have established additional, special guidelines and requirements for personal protective equipment.
- For entities that possess the agents and toxins of highest risk to public health, agriculture, and agricultural products (Tier 1 BSAT), the SAR require that all individuals with access to these agents/toxins be enrolled in an occupational health program.
- The SAR and *NIH Guidelines* include requirements to report certain categories of laboratory incidents. Certain types of laboratory incidents trigger the OSHA recordkeeping and reporting requirements.
- As noted in the BMBL, occupational medical services should be designed to comply with the OSHA requirements, patient confidentiality laws, and the American Disabilities Act of 1990. Medical support services should be based upon detailed risk assessments and tailored to meet an organization's needs.
- Under U.S. regulations (OSHA Bloodborne Pathogens Standard), employers must make a Hepatitis B vaccination available to any worker who is reasonably anticipated to be in contact with blood or other potentially infectious materials, such as unfixed human tissues and certain body fluids. OSHA encourages employers to make other vaccinations available to their employees when there is an anticipated occupational exposure to the disease agent against which the vaccine protects.
- FSAP developed a guidance document to assist entities in developing and implementing an occupational health program, including a post-exposure response that protects workers with access to Tier 1 BSAT. In a public health emergency with a biological threat agent, the investigation and response resources of the federal government would be engaged and may provide emergency medical countermeasures (e.g., vaccines and therapeutics) as appropriate.

Best Practices, Challenges, Gaps, and Recommendations

The current biosafety and biocontainment oversight system in the United States is very comprehensive. However, the federal government recognizes that the oversight framework could be enhanced. To that end, a number of federally supported working groups have analyzed the framework for biosafety and biosecurity, identified opportunities for improvement and are implementing actions to address these opportunities. For example, the White House National Security Council and Office of Science and Technology Policy established parallel federal and broad stakeholder reviews resulting in specific recommendations to strengthen biosafety and biosecurity practices and the government's system of oversight. The U.S. Government is currently implementing those recommendations to enhance biosafety and biosecurity. The U.S. Government expects that implementing the FESAP and FTAC-SAR recommended actions will strengthen biosafety and biosecurity practices and oversight activities.

Related to the broader ongoing focus on laboratory safety and security is the challenge of gain-of-function studies involving pathogens with pandemic potential. The U.S. Government, in partnership with the life sciences community and stakeholders, is conducting a comprehensive assessment of gain-of-function research with the explicit goal of developing a new federal policy to guide future investments in this area of research.

Immunization

Prevent 7 (P7)

JEE Target

A functioning national vaccine delivery system—with nationwide reach, effective distributions, access for marginalized populations, adequate cold chain, and ongoing quality control—that is able to respond to new disease threats.

Level of Capabilities in the United States

➢ Summary

The United States sustains a comprehensive and accessible system to administer and document immunizations, providing specific recommendation for children and adults in various age categories, with special guidance for those with health conditions as well as other occupational hazards, international travel, or chronically ill family members. The National Vaccine Program Office in HHS oversees national vaccination policy related to research, administration, logistics, and clinical responsibilities of many Federal agencies to strengthen the control of infectious diseases through immunization . CDC's National Center for Immunization and Respiratory Diseases oversees the National Vaccination Program. Immunization programs, often with federal support, are implemented by state, territorial and municipal health departments, schools, colleges, public and private health care practitioners, private employers, and elements of the commercial health sector, including many pharmacies.

Immunization policies across the country are guided by the CDC Advisory Committee on Immunization Practices (ACIP), which ensures that the U.S. programs are consistent with the WHO's Global Vaccine Action Plan (GVAP) and extends recommendations for immunizations that optimize the health of Americans. ACIP considers recommending new vaccines as safety and efficacy data become available.

Public perception toward immunization is monitored utilizing quantitative and qualitative methods including national periodic and longitudinal surveys of different populations (children, adolescents, adults, pregnant women, health care providers) and in-depth interviews and focus groups. These tools enable program administrators to identify parental concerns about vaccinating children, possible barriers to accessing vaccines for adults, vaccine-related concerns among different populations, and identify specific communications strategies to address those challenges. The U.S. Government has developed numerous campaigns to address common questions and concerns about vaccination, with specific focus on infant and childhood vaccination (including measles), vaccination during pregnancy,

human papillomavirus vaccination of adolescents, pneumococcal vaccination for older persons, and influenza vaccination across the lifespan.

The capacity to rapidly develop, acquire, and stockpile public health emergency vaccines and other medical countermeasures (therapeutics, PPE, diagnostics, etc.) for health security threats is described in the section on *Medical Countermeasures and Personnel Deployment*.

➢ Indicators

■ *Vaccine coverage (measles) as part of national program* *P7.1*

Current U.S. programs supporting vaccination (in general)

- The U.S. National Vaccine Plan, established in 2010 prior to the GVAP, has five broad goals, including:
  - Develop new and improved vaccines;
  - Enhance the vaccine safety system;
  - Support communications to enhance informed vaccine decision-making;
  - Ensure a stable supply of, access to, and better use of recommended vaccines in the United States; and,
  - Increase global prevention of death and disease through safe and effective vaccination.
- The Vaccines for Children Program, operational since 1994, is an entitlement program to provide free vaccinations for eligible children age 18 years and younger. In that program, CDC purchases vaccines at a discount and distributes them to participating providers in private practices and public health clinics. Vaccines must be administered free-of-charge to the patient as well.
- The Affordable Care Act, enacted in 2010, mandates that most insurance plans in the United States cover ACIP-recommended vaccines without cost sharing. The U.S. Public Health Service Act, at section 317 (42 U.S.C. 247b), provides additional funding for purchase of vaccines for public health departments and to fund the infrastructure of state health department immunization programs.

Specific coverage for measles in the United States

- With respect to measles vaccination, children in the United States typically receive a standard two-dose series in combination with mumps and rubella (MMR), which may also include varicella (MMRV).
- Coverage estimates for data collected in 2014 for children 19-35 months indicate 91.5 percent coverage for ≥1 dose of MMR (confidence interval (CI) ±0.9). Coverage was 84.2 percent (CI: ±1.2) for ≥4 doses of diphtheria, tetanus, and acellular pertussis vaccine, below the *Healthy People 2020*

target of 90 percent. The methods for determining coverage rates are described below in this section.

Vaccination requirements in the United States (in general)

- Immunization with particular vaccines is mandated by each State, with some exemptions, for school attendance in the United States. The United States' *Healthy People 2020* campaign sets vaccination targets for children 19-35 months of age (90 percent coverage for most recommended vaccines), adolescents 13-15 years of age (80 percent coverage for select vaccines), and adults (varying by population and vaccine).
- The DoD maintains a unique and robust immunization program for service members and beneficiaries, with the addition of FDA-approved vaccines for select agents that are required in certain circumstances. Otherwise, the DoD follows the standard ACIP recommendations for both children and adult health care beneficiaries.
- State governments have the authority to require vaccination for select populations, which is manifested through school attendance laws. The states determine their own specific requirements, closely based on ACIP recommendations, including policies for exemptions. Some federal and state agencies and many private institutions require vaccination of health workers and the federal government has set vaccination requirements for those applying for residency status in the United States.
- Human vaccination for zoonotic diseases in the United States is typically limited to those who have occupational risk factors (such as veterinarians or health researchers) or who are planning to travel overseas (including certain military personnel).
- The USDA makes specific recommendations for federal, state, and local veterinary services to conduct vaccinations among domestic animals and wildlife to reduce human exposure to zoonotic diseases and to support the agricultural industry. Many localities throughout the United States have mandatory pet registration and vaccination requirements.

Monitoring national vaccination rates (in general)

- National vaccination rates are monitored by CDC with data reported annually. Each state and territory, and many individual institutions and government entities, monitor vaccination rates for their respective populations through both direct and indirect methods.
- Most vaccination coverage in the United States (at the national level) is estimated using complex sample surveys. For children 19-35 months and adolescents 13-17 years, vaccination data are obtained in the National Immunization Survey (NIS), NIS-Teen, and NIS-Flu. The results of those surveys are available on the CDC's National Immunization Surveys' website.

- CDC estimates vaccination rates for school-aged children using school vaccination records. State immunization programs collect and report school vaccination coverage and exemption results to CDC annually. States use a variety of methods for estimating vaccination coverage estimates.
- Adult vaccination rates are determined by CDC through a combination of the National Health Information Survey and the Behavioral Risk Factor Surveillance System. Additional information about the methods for those surveys, including data quality monitoring, are on the CDC's website.

Systems for identifying and addressing disparities

- Disparities in the coverage of some vaccines occur in relationship to socioeconomic status because accessing immunization services may be difficult in some areas and for some populations. Evidence-based strategies assist providers and public health systems in maintaining overall immunization coverage and addressing disparities to improve coverage in vulnerable subpopulations.
- The Guide to Community Preventive Services recommends strategies to enhance access to vaccination services and increase community demand for vaccination through identified effective provider and system-based strategies.
- The infrastructure for routine immunizations for adults is not as robust as for children. Addressing barriers such as reimbursement (payment), provider and patient education, and increasing opportunities for adult vaccination in places such as pharmacies and workplaces are efforts to improve adult immunization coverage.

■ *National vaccine access and delivery* *P7.2*

Appropriate management of vaccine stock

- In the United States, public sector vaccine is distributed through CDC's centralized system, which is designed to support cold chain integrity through standardized processes and to minimize the number of steps in the distribution process. Vaccines are shipped directly to provider offices and clinics at the direction of state and local public health departments.
- With technical and financial support from CDC, state and local health departments work directly with providers, conducting training and site visits, to ensure that vaccines are appropriately stored, monitored, and administered.

Distribution of vaccine

- Vaccine availability in the United States is safeguarded through a number of mechanisms. CDC maintains stockpiles of all routinely recommended pediatric vaccines that can be used to mitigate vaccine supply shortages. Manufacturers who contract with CDC to provide vaccines for the public

sector are required to notify the CDC about anticipated supply issues, allowing CDC to determine how and when stockpiled vaccines should be deployed as well as to communicate with vendors of alternative products who might be able to fill a gap.

- In the event that vaccine supply is not sufficient to support vaccination according to the routine schedule, the CDC may recommend an interim reduced vaccination schedule until vaccine supplies return to normal.
- The DoD maintains its own cold-chain supply system, operational stockpiles of many vaccines, and independent mechanisms for the routine and emergency purchase of vaccines to ensure the availability of vaccines for Service members and their families in many locations around the world.

Ensuring the capability for rapid distribution in an emergency

- The annual influenza vaccine is distributed throughout the country every year , with 146.3 million doses distributed between September 2015 and February 2016.
- During the 2009-2010 influenza pandemic, the U.S. was able to mobilize the public health community and distribute approximately 126 million doses of influenza A (H1N1) 2009 monovalent vaccine between October 2009 and January 2010, which was **in addition** to the seasonal influenza vaccine already planned for the year.
- The U.S. SNS has large quantities of medicine and medical supplies to protect the American public if there is a public health emergency (e.g., terrorist attack, influenza outbreak, earthquake) that is severe enough to cause local supplies to run out. The SNS includes a number of vaccines, which are distributed through the federal system and released to states for further distribution to affected communities. States are required to establish and maintain their own distribution plans. More details regarding the SNS are in the *Preparedness* and *Medical Countermeasures and Personnel Deployment* sections of this report.

■ ***Other relevant references for this section***

- Examples of communication campaigns
  - Infant and childhood vaccines
  - Tdap vaccine during pregnancy
  - Human papillomavirus vaccination of preteens
  - Influenza vaccination across the lifespan
- Recommended immunization schedule for children 0-18 years
- Recommended immunization schedule for adults

Best Practices, Challenges, Gaps, and Recommendations

The United States has a comprehensive and functional national vaccine delivery system that is able to respond to new disease threats based on the current best available science and technology platforms. Strong public-private partnerships exist with nationwide reach, effective distribution chains, access for marginalized populations, adequate cold chain, and ongoing quality control. Sustained, supplemental Federal funding is available through the Vaccines for Children Program, the U.S. Public Health Service Act, and the Affordable Care Act to improve access to vaccines. Vaccine safety monitoring and assessment tools enable rapid identification and investigation of concerns about vaccines, with rapid actions when needed to prevent harm. U.S. vaccination programs have eliminated many vaccine-preventable diseases and reduced the incidence of several others; however, opportunities exist for additional reductions in the incidence of vaccine-preventable diseases and the associated decrease in morbidity and mortality.

The U.S. Government has identified programmatic challenges, evolving issues, and some effective interventions related to adult and adolescent vaccination programs. Among current programmatic challenges, there are still persistently low vaccination rates in small sub-populations and at-risk (socioeconomic) groups. There are also problems with societal awareness and understanding of vaccine recommendations beyond those for children. Financing for adult vaccines varies by state and local levels creating different challenges and solutions from one state to another.

The U.S. Government could consider increased emphasis on enhancing and expanding interoperable, state-based immunization information systems and promoting participation in such systems by all vaccination providers. Such systems have additional benefits, such as vaccine management, maintenance of lifetime vaccination histories, and interoperability with other health information systems, which could support many other aspects of the U.S. immunization system. The United States could continue to strengthen programs and initiatives to provide sub-populations and at-risk groups and communities with information about the safety and benefits of vaccination, and to improve access to vaccine and vaccination services. The federal government should also continue to support ongoing efforts by the state and local health departments to promote immunization as a public health priority and protection against preventable infections.

DETECT

National Laboratory System

Detect 1 (D1)

JEE Target

Real-time biosurveillance with a national laboratory system and effective modern point-of-care and laboratory-based diagnostics.

Level of Capabilities in the United States

➢ **Summary**

The United States has a federated, decentralized public health system of 50 semi-autonomous states, some territories, and large municipalities. The national laboratory system in the United States included designated PHLs in all 50 states, the four territories, and selected, large metropolitan areas (such as Los Angeles and New York City). Additionally, the NAHLN consists of 62 state- and university-associated veterinary diagnostic laboratories located in 40 states, plus USDA's federal reference and confirmatory laboratory, the NVSLs in Iowa and New York. Both the human and animal laboratories provide essential services including disease and outbreak detection, emergency response, environmental monitoring, and disease surveillance. The labs integrate data management, reference and specialized testing, clinical laboratory oversight, emergency response, public health research, training and education, maintaining partnerships, and public communication.

The U.S. health care system is primarily private and financed through private and government health insurance of individuals. Over 4,000 (non-PHL) hospital and commercial laboratories perform the majority of clinical microbiology testing and are designated as "sentinel laboratories." There are numerous smaller laboratories throughout the country that are not included in the sentinel network but that are required to abide by national quality standards and state-based rules. PHLs actively communicate and interact with many hospital and commercial clinical laboratories in each jurisdiction. Federal funding requires each PHL to keep a database of sentinel clinical laboratories that also receive specific training, SOP, and access to referral mechanisms.

States and other jurisdictions also have food and animal/veterinary microbiology laboratories that are often collocated with other public health facilities or aligned with the PHL. States and designated PHL

receive overall direction, guidance, requirements, and support from CDC and other federal agencies as part of the three tiers (clinical, state, and national) of the LRN. The LRN is the primary network for identifying human pathogens that have epidemic potential in addition to chemical threats. Additionally, the LRN coordinates with other disease-specific programs and networks to share capacity and coordinate the response for different emerging threats.

Both the human and animal health laboratory networks participate in the ICLN. The ICLN provides a venue for coordination of federally sponsored analytical laboratory services for chemical, biological, radiological, and nuclear incidents through planning, identification of responsibilities, and information sharing. An overarching goal of ICLN is to establish enduring governance policies that facilitate a coordinated and operational system of laboratory response networks

➢ Indicators

■ *Laboratory testing for detection of priority diseases* *D1.1*

Determination of priority pathogens in the United States

- Notifiable and reportable diseases and conditions (described in detail below) represent the wide range of public health situational awareness and capabilities in the United States. Local jurisdictions establish priorities according to those risks. Most locations are capable of a very wide range of screening and diagnostic testing and all locations have access to a regional reference laboratory for both human and animal health.
- Consistent with the requirements for the JEE, reference laboratories are capable of conducting the following core tests.

Table 8. Turnaround time for different types of laboratory diagnostic tests in the United States.

Core test	Indicator pathogen	Turnaround time from receipt in the laboratory
Polymerase chain reaction	Influenza virus	Within 24 hours
Virus culture	Poliovirus	Within 14 days
Serology	Human immunodeficiency virus (HIV)	Within 5 days
Microscopy	Mycobacterium tuberculosis	Within 3 days
Rapid diagnostic test	Plasmodium species	Within 2 hours
Bacterial culture	Salmonella enteritidis serotype Typhi	Within 3 days

- Other testing capabilities at selected sites in the U.S. laboratory system include:
  - MERS-CoV (an example of an emerging infection): 1–2 day turnaround time for lab results.

  - Measles (an example of a vaccine preventable disease): 1–2 day turnaround time for lab results.
  - Carbapenem-resistant *Enterobacteriaceae* (CRE) confirmation and characterization (an example of a hospital-based infection): 2 day turnaround time for lab results.
  - Ebola virus PCR (an example of a pandemic infection): 24-hour turnaround time for lab results.
    - NOTE: These additional four disease tests do not represent an official prioritization of diseases by the U.S. Government but are listed here as examples of disease testing that, for the purposes of the JEE, can help with assessing the variety of approaches and capabilities of the U.S. national laboratory system.

- Selection of pathogen tests in animal health laboratories is congruent with OIE standards. Within the NAHLN, all approved laboratories receive SOP for specific emerging and foreign animal diseases to ensure uniformity of testing.
- The NVSL and each state veterinary diagnostic laboratory uses an electronic laboratory information management system for collating diagnostic results from submitted specimens, and reporting these results back to the submitting veterinarian. Results are usually available within 24-48 hours, but may be dependent on the diagnosis and tests performed. For the zoonotic diseases listed above (influenza, *Mycobacterium tuberculosis*, and *Salmonella* Typhi), 100 percent of the veterinary community has access to testing services.
- Current list of NAHLN laboratories and the diseases they are approved to test.

System of federal and state public health laboratories

- The national system of laboratories includes state and federal laboratories, and multiple programmatic laboratory networks such as the LRN and the ICLN, with state statutes for referral, reporting, and case notification, among other features. Partners include but are not limited to individual states, CDC, FDA, APHL, DoD, VA, EPA, and USDA.
- Founded in 1999, the CDC LRN is an integrated network of state and local public health, federal, military, and international laboratories that can respond to bioterrorism, chemical terrorism, and other public health emergencies. The LRN is a unique asset in the nation's growing preparedness for biological and chemical terrorism and serves to collaborate with other disease-specific programs and networks during response.
- The ICLN provides interagency coordination for all of the national networks including food, environmental, and veterinary laboratories managed by the FDA, EPA, DoD and USDA.
  - The ICLN was established in June 2005 and includes the USDA, DOE, HHS, DHS, DOI, DOJ, DoS, DoD, and EPA. The goal of the effort is to create the basis for a system of laboratory networks capable of integrated and coordinated response.

  - The Joint Leadership Council (chaired by DHS) includes senior leadership from the partner agencies and ensures strategies to support an all-hazard laboratory response capability.

- Each state has statutes for referral, reporting, and case notification that are modeled on national standards for notifiable diseases. State-based reporting and federal notification requirements are coordinated by the CSTE. State surveillance systems transmit case report data to CDC for national surveillance. The LRN along with other CDC programs represent an inter-jurisdictional structure and private/public interface that provides national coverage for existing diseases, potential threats, and emerging pathogens. The LRN includes laboratories in all 50 U.S. states as well as laboratories in Australia, Canada, the United Kingdom, Mexico, and the Republic of Korea.
  - For biological testing, there are currently 150 laboratory members.
  - For testing human exposure to toxic chemicals, there are 62 laboratories.
- APHL is a unique non-governmental organization that is supported by CDC (and to a lesser degree by funding from other federal agencies) to represent the interests of the member PHL and assist CDC with management of the LRN.
- For human health, all 50 state and selected city and territorial PHLs have the capacity to identify all the significant pathogens. Many large commercial and academic centers also have clinical laboratories with significant microbiology capabilities and expertise. In the rare instance of not having a specific capacity, such as for Ebola confirmation, there are specific referral agreements with neighboring states.
- Both the DoD and the Veterans Health Administration have large health systems for military personnel, family members, and veterans. The DoD and Veterans laboratories refer and report reportable/notifiable disease pathogens to the state and/or PHL where their facilities are located. Additionally, numerous DoD laboratories are a part of both LRN and ICLN, including the U.S. Army Medical Research Institute for Infectious Diseases (USAMRIID) and Navy Medical Research Center (NMRC), which serve as national and global reference laboratories for the DoD.
- The EPA established the Environmental Response Laboratory Network (ERLN) to assist in addressing chemical, biological, and radiological threats by providing consistent analytical capabilities, capacities, and quality data in a systematic, coordinated response. The ERLN integrates capabilities of existing public sector laboratories with accredited private sector labs to support environmental responses.
- The Food Emergency Response Network (FERN) is an integrated, secure laboratory system for federal, state, and local government agencies engaged in food safety and defense activities. Consisting of 170 federal, state, and local laboratories, FERN is organized to ensure federal and state inter-agency participation and cooperation in the development and operation of the network, allowing participating government agencies to compare, share, and coordinate laboratory analysis

findings and in strengthening the capacity of state laboratories. More detail about the system is provided in the *Food Safety* section of this report.

Laboratory support for clinical services

- Clinical practice and clinical practice guidelines rely on clinical microbiology testing that is readily available either onsite or through 24-hour shipping. CDC and major medical and laboratory organizations work collaboratively to develop, promote, and communicate national guidelines for laboratory testing of suspected dangerous pathogens. The USDA and DOI support similar guidelines for veterinary testing.
- Although there is significant variation from location to location within the United States, there is extensive use of rapid electronic reporting of laboratory results through clinical information systems, web portals, email, facsimile, and health level (HL) 7-based electronic messaging. When paper-based reporting is still the primary mechanism, there are national and local guidelines for laboratories or epidemiologists to contact providers by phone with urgent results.
- 100 percent of the U.S. population has access to some portion of the national laboratory system. There may be some delays due to transportation of specimens from geographically isolated parts of the United States or its territories (such as the Pacific Islands).

Accreditation

- All U.S. laboratories performing clinical testing (i.e. testing human specimens for the purposes of health assessment and disease diagnosis, prevention, or treatment) – including laboratories that are a part of the federal government – are governed by the CLIA. Enrollment in CLIA, and certification by CMS or an accredited equivalent, is mandatory.
- Overseen by HHS CMS, CLIA covers 252,384 laboratories (as of February 1, 2016). The majority of clinical microbiology laboratories in the United States are accredited by organizations deemed to have requirements that meet or exceed CLIA regulations.
- The DoD uses a CLIA-compliant system called the Clinical Laboratory Improvement Program that currently accredits 826 laboratories.
- The CLIA regulations, while overlapping with international laboratory standards such as ISO 15189 and certain CLSI guidelines, are distinct from those standards in many aspects including the requirements for personnel qualifications and responsibilities, quality control mechanisms, quality management, testing specialties (and subspecialties), and annual proficiency testing (PT). PT is the term used in the United States for external quality assessment.
- CMS reviews and approves private and state-based PT programs on an annual basis to ensure they meet the CLIA requirements for number and type of samples. The availability of PT for priority diseases varies because the development and implementation of PT programs with consistent and

challenging samples may be somewhat delayed for emerging pathogens, such as Ebola virus. Almost all priority pathogens have available PT programs with mandatory enrollment for labs performing those tests.

- CDC supports a specific program with the College of American Pathologists that involves samples as an educational exercise to measure capabilities for detection of biological threat agents that might not normally be included in routine PT schemes. Both the CLIA regulations and the certified accrediting organizations have broad and prescriptive requirements for PT program quality controls and performance.
- Organizations authorized to provide laboratory accreditation include:
  - American Association of Blood Banks
  - American Association for Laboratory Accreditation
  - American Osteopathic Association
  - American Society for Histocompatibility and Immunogenetics
  - Commission on Office Laboratory Accreditation
  - College of American Pathologists
  - Joint Commission
- Organizations in the United States that provide PT samples to satisfy accreditation requirements include:
  - Accutest, Inc. (800) 665-2575. PT for microbiology, diagnostic immunology, chemistry, hematology, and immunohematology
  - American Academy of Family Physicians – (800) 274-7911. PT for microbiology, diagnostic immunology, chemistry, hematology, and immunohematology
  - American Association of Bioanalysts (AAB) - (800) 234-5315. PT for microbiology, diagnostic immunology, chemistry, hematology, and immunohematology
  - American Proficiency Institute (API) - (800) 333- 0958. PT for microbiology, diagnostic immunology, chemistry, hematology, and immunohematology
  - California Thoracic Society (CTS) (415) 536-0287. Limited PT for chemistry and hematology)
  - The College of American Pathologists (CAP) – SURVEYS - (847) 832-7000. PT for microbiology, diagnostic immunology, chemistry, hematology, immunohematology, and cytology
  - American College of Physicians (ACP) (800) 338-2746, (202) 261-4500. PT for microbiology, diagnostic immunology, chemistry, hematology, and immunohematology
  - Commonwealth of Pennsylvania (610) 280-3464. PT for blood alcohol and blood lead
  - Puerto Rico Proficiency Testing Service (787) 274-6827. PT for microbiology, diagnostic immunology, chemistry, hematology, and immunohematology

- Wisconsin State Laboratory of Hygiene (800) 462-5261. PT provided for microbiology, general immunology, chemistry, hematology, and immunohematology
- New York State Department of Health (518) 474-8739. PT provided for microbiology, diagnostic immunology, chemistry, and hematology

Sharing data between human and animal laboratories

- Most zoonotic diseases of concern are nationally notifiable diseases with corresponding state-level statutes for case reporting and referral of specimens or isolates. Most of the animal diseases that are on the proposed list of reportable conditions are also potential zoonotic diseases.
- Generally, data are shared via direct exchange between subject matter experts on an ad hoc basis. This is also variable and depends on the disease. For *Salmonella*, the USDA NVSL and CDC routinely share data via CDC's *PulseNet* network. *GenBank* is a curated sequencing database overseen by the NIH and used extensively for sharing sequencing data publicly. Other exchanges of human and animal laboratory data occurs through One Health arrangements (detailed in the section on *Zoonotic Diseases*) as well as during outbreaks or research projects.

Use of personal protective equipment

- Under U.S. regulations, PPE usage is determined on a site-by-site basis, using a risk assessment for each laboratory. Based on their local risk assessment, the employer is required to provide all necessary PPE and provide training on the safe usage and disinfection or disposal of PPE. In general, PPE is readily available and multiple commercial manufacturers, wholesalers, and retailers ensure that an adequate quantity can be procured as needed.
- Both accreditation organizations (under CLIA) and safety regulators such as OSHA verify usage of PPE within U.S. laboratories. Per OSHA Bloodborne Pathogen Standards, PPE are required in the context of a comprehensive infection control program. The standard incorporates recommendation from the CDC. PPE used for activities not covered in the Bloodborne Pathogens Standard must be used in accordance with the applicable OSHA PPE standards, such as 1910.132 (general requirements) and 1910.134 (respiratory protection), among others.
- Training for laboratory workers on the proper use of PPE is the responsibility of each laboratory. However, CDC's manual on safety practices, the BMBL, is widely used as general guidance within the NAHLN. The range of training for laboratory personnel is described in greater detail in the section on *Biosafety and Biosecurity*.
- CDC provides guidance for the use of PPE in general circumstances to prevent exposures among health workers as well as (when needed) guidelines that are specific to a public health hazard, such as Ebola virus.

Biosafety and biosecurity training

- Laboratory workers who could be exposed to human biological materials (e.g., blood, tissue, or body fluids) or other potentially infectious materials must be trained in the safe handling of bloodborne pathogens. Training must include exposure control plans, universal precautions, engineering and work practice controls, personal protective equipment, housekeeping, laboratories, hepatitis B vaccination, post-exposure follow-up, hazard communication and training, and recordkeeping, though such training must also be appropriate for the unique systems and risks present in each facility.
- See additional information in the section on *Biosafety and Biosecurity*.

Standardization of diagnostic testing

- All 4,000 clinical sentinel laboratories receive training and standard procedures to rule out or refer potential biological threats and emerging pathogens. All state and designated PHL in the LRN use standardized testing methods for selected pathogens using protocols, training, and reagents provided by CDC.
- Private laboratories generally perform clinical microbiology. There is a large commercial sector for diagnostic test kits that the FDA reviews and clears ("approves") for commercial distribution. Beyond meeting the minimum federal regulatory standards, many laboratories also follow guidelines and algorithms provided by the CLSI, the American Society for Microbiology, and other organizations.
- When there are duplicative (competing) test kits available on the commercial market, variations in testing methods and algorithms may result in variations among private practices or commercial and state laboratories. PHL receive guidance from CDC and work with their clinical sentinel laboratories to promote and monitor pathogen-specific algorithms, referrals, and reporting.
- All the LRN laboratories have the required equipment to perform testing and have funding for maintenance contracts. High quality laboratory equipment and instruments are also broadly available in clinical laboratories.
- CDC and other agencies have specialized services for validation of laboratory testing. CDC works collaboratively as part of many WHO networks and serves as a WHO collaborating center for a number of specific topics.
- USDA APHIS Veterinary Services has prepared a series of Case Definition documents for specific diseases that are distributed to state and federal regulatory animal health officials and their field staff. These documents describe information about the disease including public health implications, clinical signs, reporting criteria, and specific samples to collect for laboratory diagnosis.

■ ***Laboratory Quality System*** ***CC8.2***

- Quality assurance is an integral component of the laboratory accreditation system described above. Laboratory "licensing" is a function of individual state health departments controlled by their respective legislatures.
- For quality assurance purposes, in accordance with CLIA, laboratories are inspected every two years. The inspection procedures followed by CMS are delineated in the CLIA Interpretive Guidelines and in Subpart Q of the CLIA law. Subpart R contains a list of sanctions.
- In addition to providing SOP to participating laboratories, the NAHLN ensures standardization of testing for these diseases through training, annual PT, and onsite laboratory audits. The NVSL in particular are accredited to ISO 17025 standards.
- All state- or university-associated veterinary diagnostic laboratories in the NAHLN are accredited by either the AAVLD, to ISO 17025 standards by an independent third party, or are audited and approved for testing by the NAHLN Program Office.
- A number of U.S. laboratories are accredited to conduct testing as a part of the WHO global network or reference laboratories.
    - CDC serves as a Collaborating Center, or global or regional reference laboratory, for poliovirus, influenza, measles, rubella, HIV genotyping, tuberculosis, and rotavirus among others .
    - CDC and FDA participate in the Global Foodborne Infections Network.
    - FDA's Center for Biologics Evaluation and Research serves as a global reference laboratory for blood products and diagnostics.

Medical device (in vitro reagent) registration and regulation

- The FDA, which is responsible for regulating and approving, or otherwise clearing for commercial distribution, *in vitro* diagnostics (IVD) under the Federal Food, Drug, and Cosmetic Act, classifies IVD products into Class I, II, or III according to the level of regulatory control that is necessary to assure safety and effectiveness. The U.S. CFR lists the classification of existing IVD in 21 CFR Part 862, 21 CFR Part 864, and 21 CFR Part 866. The classification of an IVD (or other medical device) determines the appropriate premarket process.
- A 510(k) is a premarketing submission made to FDA to demonstrate that the device to be marketed is as safe and effective (i.e., substantially equivalent) to a legally marketed device that is not subject to premarket approval. A product is cleared for marketing in the United States, if the FDA finds that the information provided by the sponsor meets the standard of equivalency.
- Each person who wants to market Class I, II and some III devices intended for human use in the U.S. must submit a 510(k) to FDA at least 90 days before marketing unless the device is exempt from 510(k) requirements. If FDA finds that the information provided by the sponsor meets the standard of equivalency, the product is "cleared" for marketing in the U.S.

- A "premarket approval" requires an application submitted to FDA to request approval to market, or continue marketing, a class III medical device. Premarket approval is based on scientific evidence providing a reasonable assurance that the device is safe and effective for its intended use or uses.
- *Registration and Listing*: Establishments involved in the production and distribution of medical devices intended for commercial distribution in the U.S. are required to register with the FDA. Most medical device establishments required to register with FDA must list the devices they have in commercial distribution including devices produced exclusively for export.

Supervision and quality assurance for surveillance programs

- Some states have state-specific requirements for supervision, oversight, and review of laboratories or laboratory personnel. For federally subsidized PHL reference services, CDC works with APHL as a partner organization to facilitate development of detailed guidance and technical requirements, such as self-assessments in the areas of evolving technologies and laboratory practice. Programs may provide proficiency-testing panels that exceed regulatory requirements, especially for rare pathogens or drug resistance. Examples include:
    - CDC Model Performance Evaluation Program for *Mycobacterium tuberculosis* Drug Susceptibility Testing
    - APHL TB Self-Assessment Tool
- CDC programs distribute federal funds to the states that are appropriated by Congress for different disease control programs (e.g. tuberculosis, HIV, Emerging Infections, Preparedness, and antibiotic resistance). These national programs have different processes, criteria, and performance measures for the PHL. Some of the programs make an effort to visit every recipient PHL on a regular basis, such as the tuberculosis control program or the LRN, and this supportive supervision is a structured version of "checklists." These program-specific laboratory networks monitor performance through annual reporting of capabilities, isolates tested, testing services, and even instrumentation.
- The Epidemiology and Laboratory Capacity for Infectious Diseases Cooperative Agreements to state, municipal, and territorial laboratories involve regular site visits to the grant recipients. The cooperative agreements provide funding for general, flexible, and cross-cutting epidemiology, laboratory, and health information systems support for state, local, and territorial public health entities. Funding also allows specific CDC infectious diseases programs to invest in capacity development in their subject matter areas of pathogen-specific laboratory detection and epidemiologic investigation.
- Some of the CLIA-approved accreditation organizations, such as the Joint Commission and the College of American Pathologists, use standardized checklists for inspection.
- CMS bases their inspections on their Appendix C: Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services.

■ *Specimen referral and transport system* *D1.2*

Transportation of clinical and public health specimens

- In the United States, specimen and culture referral is largely accomplished through local transportation services, such as the U.S. Postal Service or commercial carriers (e.g., *FedEx*). Individual laboratories are responsible for developing their own procedures for packaging and shipping, including acquiring shipping material, which must meet standards set by the DOT plus requirements set for specific surveillance programs or network affiliations (such as NAHLN or ICLN).
- Many states also support their own ground transport courier services or work with existing courier services maintained by the large commercial laboratories (e.g., LabCorp and Quest Laboratories) that represent close to 40 percent of the clinical testing market. Commercial carriers reach all locations in all 50 states and the territories.
- DOT regulations include a classification scheme and corresponding packaging, labeling, and shipping requirements for substances that are known to contain infectious/hazardous material as well as those that are for diagnostic or investigational purposes. The DOT regulations for packaging and shipping are aligned with ICAO standards, the ICAO Technical Instructions on Dangerous Goods, and WHO guidelines.
- CDC and the PHL support ongoing training to certify PHL and clinical laboratory staff for packaging, labeling, and shipping of potentially infectious agents in compliance with the regulations. All state and designated PHLs in the LRN routinely monitor and report the number of trainings and certified staff in clinical and public laboratories and report these metrics to CDC.
- Foods, drugs, cosmetics and medical device imports are subject to the requirements of the "The Public Health Security and Bio-Terrorism Preparedness and Response Act of 2002 The DOT and FDA have joint responsibility and have authorities to regulate such imports. If the imported product is an animal biological specimen, the regulating partner is the USDA. In addition to its own regulations, CBP enforces over 400 laws on behalf of over 40 other U.S. Government agencies. Additional sources of information include:
    - CBP Importing into the United States: A Guide for Commercial Importers
    - CDC Import Permit Program (IPP) and IPP: Guide for Shipping Infectious Substance
    - CBP *Importing biological materials (blood, disease organisms, etc.)*

Federal oversight of public health specimen referral

- There is a national system for all clinical laboratories to work with their state PHL for direct shipment of specimens to CDC for selected suspect (potentially dangerous) agents and circumstances. The Ebola virus outbreak in West Africa and isolated cases in the U.S. led to the reluctance of selected

commercial carriers to transport Ebola-suspected specimens, stimulating a national discussion and focus on ensuring universal access to courier services for dangerous pathogens.

- U.S. laboratories in the United States and abroad typically receive specimens for referral testing and maintain an extensive network of formal and informal relationships with other laboratories.

■ ***Effective modern point of care and laboratory based diagnostics*** ***D1.3***

Point-of-care testing

- There is an extensive commercial market in point-of-care diagnostics for clinical care and regulations are intended to incentivize manufacturers to improve accuracy and simplicity of use. The promotion of point-of-care tests varies by detection and control strategies for different pathogens. As an example, there are national initiatives to promote rapid HIV tests at the point of service.
- CLIA defines certain simple tests with a low risk for an incorrect result even when performed by an untrained user as "waived tests," which include the tests approved for waiver by the FDA using the CLIA criteria and tests cleared by the FDA for home and clinic use. Sites performing only waived testing must have a CLIA Certificate of Waiver and follow the manufacturer's instructions, but are not subject to other CLIA requirements. There are currently more than 170,000 Certificate of Waiver sites in clinical settings in the United States.

Specialized laboratory testing services

- Referral for specialized testing is recommended for suspected dangerous pathogens such as Ebola virus. The FDA reviews and approves these POC devices for accuracy, adequate instructions for use, and manufacturing standards prior to commercial distribution.
- Although there is a robust commercial market for FDA-approved laboratory tests, there are also many specialized reference tests for which CDC and other agencies may provide SOP (especially for molecular tests such as PCR), reagents and controls, and distribution to the PHL in the form of test kits.
- Laboratories that perform tests that they have developed in-house but have not been cleared or approved by FDA, termed laboratory developed tests, must meet applicable CLIA requirements. FDA is currently promulgating new guidance for additional registration, review, and approval of all laboratory developed tests.
- If there is sufficient scientific data, FDA may authorize the emergency use (i.e., through the Emergency Use Authorization (EUA) authority) of unapproved test kits in certain types of declared emergencies, such as with Ebola or Zika virus.

Best Practices, Challenges, Gaps, and Recommendations

The United States has a comprehensive, decentralized public health system operated through a combination of laws, policies and agreements among the federal government, 50 semi-autonomous states, some territories, and large (also semi-autonomous) municipalities. Health care (including the clinical laboratories) is primarily a private industry. Jurisdictional PHL, following standards set by the CDC, are required to work closely with clinical laboratories to respond to emerging diseases through a tiered reference and referral system. The laboratories operate under close supervision and regulatory requirements (such as laboratory reagent quality control, proficiency testing, and written SOP) and employ professional staff members who are appropriately qualified.

There are challenges and opportunities with ensuring that all 50 states and jurisdictions have access to consistent and comprehensive testing services, informed by concerted and coordinated national planning, to support public health and disease control. Because PHL are state government laboratories with legislatively defined budgets, they are limited in their overall flexibility and capacity to respond rapidly to every emergency with existing resources. This results in a foundational element of the national laboratory system being dually vulnerable to fluctuations in federal and local funding. There is also a challenge with CLIA in that changes to the regulations often require a lengthy process of public notification and comment and therefore create barriers to revisions that might assist with regulation of new technologies. Lastly, the expanded use of culture-independent diagnostic tests for patient care has presented a challenge to public health, which relies on culture isolates for molecular typing to identify outbreaks. In addition, the loss of the ability to characterize and track new or emerging antimicrobial resistance, pathotypes, and genotypes for bacterial pathogens, may impede the ability to recognize new pathogens or variants quickly. To mitigate this risk, CDC will pilot reflex culture in PHL of specimens that test positive for *Salmonella* using culture-independent diagnostics in hospital laboratories. This pilot will occur in the AMR regional laboratories described in the section on *Antimicrobial Resistance*.

The U.S. Government should consider options, in collaboration with the states and public and private stakeholders, to inventory vulnerabilities in capacity and capability to provide testing services, especially with regard to surge requirements, for a concerted whole-of-government plan. The U.S. Government could consider a review and revision of CLIA to account for response situations and considerations, in context with current efforts like ensuring appropriate quality standards for the next generation sequencing technologies for infectious disease and human genetic testing. Currently, efforts are underway to address recommendations for clinical laboratories to culture or refer samples that are positive using culture-independent methods. In addition, the U.S. Government should consider strengthening and assuring bioinformatics to inform future metagenomic technologies. A leading practice is the sharing of samples and data, including whole genome sequence and associated metadata, in public repositories for public health agencies and researchers to use globally. This practice needs to be pursued and reinforced.

Another important aspect of a strong laboratory system not addressed in the JEE Tool itself is the capacity to rapidly share laboratory specimens from novel diseases (e.g., threat agents, environmental and clinical specimens) among research and public health institutions in the public and private sector. These samples are critical components of bench and epidemiological research, and necessary to develop new diagnostics and medical countermeasures. Based on experience during past PHEICs or local events with the potential of global spread, there are critical barriers for U.S. laboratories (and for other countries) to obtain samples from international partners due to policy, regulatory, and logistical challenges. They range from a lack of international agreements to share non-influenza pathogens, access and benefit sharing concerns, extremely slow system to obtain import and export permits as well as laboratory certifications, lack of understanding about international shipment documentation, reduced number of couriers to transport biological material, and cold chain capacity. To address these challenges, the U.S. Government is leveraging a variety of multilateral, regional, and bilateral partnerships to discuss the barriers and put in place protocols for rapid sample sharing in anticipation or during a public health emergency. This issue needs the attention of the multiple sectors to find policy frameworks and practical solutions to create or expedite existing processes. Once these frameworks are put in place, the U.S. is committed to continue working with international partners to exercise them and observe lessons.

There are many distinct animal and human surveillance systems, pathogen-specific actions plans, algorithms, partnerships, etc., to help prevent and guide responses to outbreaks. However, there are still opportunities for improving interactions across disciplines. Some of the current challenges include institutionalizing this coordination across the federal government and increasing multidisciplinary collaborative efforts to further strengthen, integrate, and link surveillance and reporting. The U.S. Government could consider concrete, jointly led policies and programs that integrate the human and veterinary reporting chains, laboratory information systems, surveillance for outbreaks and emerging trends, and analyses of the effectiveness of prevention and control programs.

Real-Time Surveillance

Detect 2 (D2)

JEE Target

Strengthened foundational indicator- and event-based surveillance systems that are able to detect events of significance for public health, animal health and health security; improved communication and collaboration across sectors and between sub-national, national and international levels of authority regarding surveillance of events of public health significance; improved country and regional capacity to analyze and link data from and between strengthened, real-time surveillance systems, including interoperable, interconnected electronic reporting systems. This can include epidemiologic, clinical, laboratory, environmental testing, product safety and quality, and bioinformatics data; and advancement in fulfilling the core capacity requirements for surveillance in accordance with the IHR and the OIE standards.

Level of Capabilities in the United States

➢ Summary

The United States has established a strong public health surveillance system based on a combination of clinical and laboratory reporting from medical providers and facilities through each state health department, active and sentinel surveillance programs with direct inputs from network collaborators, and several systems for collecting health event warnings from both human and animal populations. CDC and USDA maintain large numbers of dedicated staff members who specialize in surveillance for specific conditions or modes of transmission, as well as those who are dedicated to supporting outbreak response and other public health emergencies. Other agencies, including FDA, DOI, and DoD, conduct surveillance with a special population or hazard focus. Syndromic surveillance systems based on the availability of multiple and diverse electronic data sources have been pioneered by the CDC and DoD and are gaining functionality as the quality of data and data systems improve. Several agencies collaborate with DHS through the National Biosurveillance Integration System to enable large-scale, all-hazard biosurveillance using disparate data sources, novel methods and advanced technological components.

➢ Indicators

■ ***Indicator-based and event-based surveillance systems*** ***D2.1***

Examples of national event-based surveillance systems

- CDC's Global Disease Detection Operations Center (GDDOC) is an innovative epidemic intelligence and response unit that provides early warning and rapid response to international disease threats. Using Internet-based reports captured by sophisticated "text-mining" with multilingual translation systems, and through a global network, GDDOC is often the first to alert CDC staff and international partners to the potential of a disease or adverse health event. GDDOC leads the operations for the GHSI Early Alerting and Reporting (EAR) project and is CDC's liaison with the Global Outbreak Alert and Response Network (GOARN).
- CDC's "Red Sky" is a secure, web-based public health dashboard and knowledge management system that provides CDC personnel and leadership with access to critical public health emergency information anywhere, anytime. Red Sky uses inputs from various structured indicator-based surveillance systems (aggregate reports) as well as contextual all-source information. All data are collected electronically for this cloud-based dashboard that will allow users to access real-time information of public health events on an interactive map. The multi-user environment allows staffs to report, upload, collaborate, and apply their collective knowledge in one virtual location.
- The FDA operates several post-market surveillance efforts from the Office of Surveillance and Epidemiology, including FDA's Adverse Event Reporting System, MedWatch and the Sentinel Initiative.
- The DoD conducts event-based surveillance through the Integrated Biosurveillance Section in the Armed Forces Health Surveillance Branch (AFHSB) to detect and communicate all-hazard events relevant to the health of service members and associated populations.
- USAID, including the Emerging Pandemic Threats program, strengthens capacities in developing countries, emphasizing early identification of and response to dangerous pathogens from animals before they can become significant threats to human health in partnership with the FAO and WHO. Information from those programs is routinely shared with the United States and other regional partners to mount a rapid and effective containment of the threat.
- The DOI FWS and the National Park Service conduct passive surveillance for disease outbreaks of free-ranging fish and wildlife at all National Wildlife Refuges, National Fish Health Centers, National Parks, and other National Park Service units. The USGS National Wildlife Health Center conducts passive surveillance for pathogens through nationwide investigations of wildlife morbidity and mortality, and posts information through the WHISPers. Active surveillance is also conducted by the National Wildlife Health Center for high-consequence diseases in wildlife, including highly pathogenic avian influenza. The USGS conducts real-time water quality assessments, including collaborations with EPA for harmful algal bloom surveillance.
- The National Biosurveillance Integration Center (NBIC), housed within DHS, collects large volumes of open source information from numerous online sources using information technology tools for

automated aggregation as well as manual retrieval. NBIC also integrates finished analytical products from various U.S. sources on a routine basis or for a specific event.

Sub-national surveillance programs

- At present, all states and local jurisdictions are engaged in case-based surveillance through the NNDSS (described below) and many are also engaged in syndromic surveillance. Some sub-national syndromic surveillance systems also contribute directly to the National Syndromic Surveillance Program (NSSP).
- Although "Red Sky" is currently CDC-centric, the plans are to make this tool available to state and local jurisdictions. This will allow state and jurisdictions to contribute their data to this system as well as ingest and utilize relevant data for their use in public health decision making.

Examples of national indicator-based surveillance

- NNDSS is a nationwide collaboration that enables all levels of public health to share notifiable disease-related information.
- In the United States, disease surveillance begins at the state, territorial, or local public health departments. Each state identifies a list of conditions (referred to as "reportable"), that law or regulation to be reported to health departments. Instructions for reportable diseases are disseminated throughout the jurisdiction and posted on the health department's website (see examples from California and Georgia).
    - The requirements apply to multiple sources including health care providers (e.g., physicians), health care settings (e.g., hospitals, urgent care centers, and ambulatory care centers), and laboratories. Cases (infectious and non-infectious) are reported to health departments by various mechanisms that differ by state and by disease.
    - The mechanisms of collecting data include phone calls, facsimile, paper case report forms, and electronic methods. See examples of case data collection forms from Arkansas and Washington.
    - Some jurisdictions also allow electronic submission of case reports by providing access to their disease surveillance systems, such as in the Wisconsin Electronic Disease Surveillance System. The health department then works with health care providers, laboratories, hospitals and other partners to obtain the information needed to monitor, control, and prevent the occurrence and spread of these conditions.
- While the list of reportable condition varies by state, the Council of State and Territorial Epidemiologists (CSTE) works with every state and CDC to promulgate standard case definitions. CSTE and CDC, along with local and state jurisdictions, developed a list of selected conditions (referred to as "notifiable") through a consensus process. CDC then officially recommends that state health departments notify CDC about the occurrence of those notifiable conditions. Not all

reportable conditions are notifiable and some notifiable conditions may not be reportable in some states.

- The United States Nationally Notifiable Diseases list for 2016 is shown in Appendix 3. For comparison, see examples of state reportable disease lists from California and Georgia.
- All NNDSS notifications are submitted electronically. Although the notification is standardized in terms of required variables, structure and vocabulary of the message, the software to be used for local surveillance and case management can be selected by each jurisdiction.
- Modernization of NNDSS is part of CDC's surveillance strategy to update the systems and processes used to receive nationally notifiable disease data to provide more comprehensive, timely, and higher quality data than ever before for public health decision making.

- The DoD, through all of its medical facilities worldwide, maintains a similar reportable disease surveillance system. These facilities typically report both to their local (county or state jurisdiction) as well as the service (Army, Navy, and Air Force) public health centers. Case reports are submitted electronically through a secure website and AFHSB receives an extract of data elements on a weekly basis.
- The Defense Medical Surveillance System documents medical experiences of service members throughout their careers. As the central repository of medical surveillance data for the U.S. Armed Forces, it contains up-to-date and historical data on diseases and medical events (e.g., hospitalizations, ambulatory visits, reportable medical events, HIV tests, and casualty data) and longitudinal data on personnel and deployments. DoD also uses a version of the Electronic Surveillance System for the Early Notification of Community-based Epidemics (ESSENCE) to enhance detection of unusual health events (described in detail below).

Data validation and quality assurance

- In addition to data validation and quality assurance systems in place at local, state, and territorial levels, CDC continues its efforts to improve data quality. With the evolution of technology and data exchange standards, CDC now has the opportunity to strengthen and modernize the infrastructure supporting the NNDSS.
- The NNDSS Modernization Initiative is underway to enhance the system's ability to provide more comprehensive, timely, and higher quality data for public health decision-making. The Modernization Initiative will eventually provide a dashboard view for health departments that will provide data quality reports.
- *Ad hoc,* in-depth special studies are conducted when needed, including surveillance system assessments as a routine part of training in the CDC Epidemic Intelligence Service (EIS), which is described in greater detail in the section *Workforce Development*. Qualitative and quantitative

assessments of surveillance data use Updated Guidelines for Evaluating Public Health Surveillance Systems.

- The DoD conducts multiple data validation and quality assurance steps, from the clinical data entry point to specific "business rules" that control when a medical encounter or reportable medical event record is registered as a case in the surveillance system databases.

■ ***Inter-operable, interconnected, electronic real-time reporting system*** ***D2.2***

Training for surveillance activities

- Public health professional training is described in detail in the section *Workforce Development*. In general, standard public health curricula include the essential elements of disease surveillance and reporting. Public health staffs receive additional "hands-on" training on the systems they will be required to use after being hired.
- A number of organizations have helped to define core competencies for various aspects of the public health profession.
  - Public Health Foundation
  - Association of Schools and Programs of Public Health
  - National Association of County and City Health Officials
  - Council of State and Territorial Epidemiologists
- National public health organizations, such as Council for State and Territorial Epidemiologists and International Society for Disease Surveillance provide online courses as well as in-person training at organized meetings and events.
- CDC provides core competency and subject matter specific training via the CDC TRAIN portal.
- CDC Center for Surveillance, Epidemiology, and Laboratory Services' Division of Scientific Education and Professional Development provides technical assistance and fellowships.
- The DoD has instructions (internal regulations) requiring a minimum number of trained personnel at each facility for public health surveillance and also conducts periodic training. DoD provides "on-the-job" vocational training for both professionals and paraprofessionals (public health technicians) to utilize existing information sources, conduct both passive and active surveillance activities, investigate cases or abnormal trends, and complete the reporting/notification requirements.

Qualifications of public health personnel

- There is a wide range of competencies among the surveillance-related personnel in each jurisdiction. Identifying, hiring, and ongoing training of health department staff is the primary responsibility of the state and territorial health departments.

- The federal government supports jurisdictional priorities of many types through the CDC-managed PHEP Cooperative Agreements. States have the flexibility to apply funding to their highest priorities, which may include training purposefully designed to close operational gaps and sustain jurisdictionally required preparedness competencies.

Examples of electronic surveillance systems

- While individual jurisdictions collect information in various ways, including traditional paper or facsimile, states and territories transmit notifiable cases to the CDC electronically through NNDSS. Similarly, all case reports are sent to public health officials in the DoD electronically.
- The NHSN (see page 23 for more information) AUR module is capable of capturing electronic antimicrobial use (AU) data and antimicrobial resistance (AR) data from electronic medical records. AU data collection has been implemented in select healthcare systems and AR data collection pilots are in process.
- State participants in the USDA NAHRS have the option to submit their monthly reports online.
- Numerous systems and sub-systems have proliferated largely due to categorical funding over several decades. CDC has documented over 100 unique systems ranging from birth defects and chronic diseases to environmental health and vaccination coverage. Generally, the various systems are not linked electronically, though combined analysis occurs when needed.

Interoperability and interconnectedness

- Inter-relatedness and common use of data (and data definitions) among systems varies by condition but is improving under CDC's surveillance strategy, as explained on its website and *Public Health Reports* article. Information is shared on a limited basis between the human and animal health sectors primarily for zoonotic diseases.
- Both the DoD and the Veterans Health Administration health care systems have universal electronic medical records that are used for disease surveillance. The systems are increasingly communicative with one another, though the unique needs of those beneficiary populations and federal privacy rules result in inherent limitations.
- Efforts are under way to enhance electronic case (indicator-based) reporting and electronic laboratory reporting in surveillance systems. Progress in increasing electronic laboratory reporting was reported in MMWR in 2013 and work continues in this area in collaboration with public health partners.
- While DoD's version of ESSENCE is not accessible outside of the DoD, the system administrators provide an outpatient encounter dataset to the CDC for inclusion in NSSP and the non-DoD NSSP partners have web-based access to data from that extract.

Reporting to the national and regional stakeholders

- Data from both NNDSS and NDSS are routinely used to develop reports for dissemination primarily in official publications such as the MMWR. Ad-hoc and situational reports are routinely developed during responses to outbreaks (e.g., MERS, Ebola, Zika, tuberculosis, HIV, and food-borne), usually in the public domain.
- Prior to publication, depending on the nature of the threat or emergency, reports may be distributed through HHS or other agency points of contact, including the EOCs, or the 10 Regional Emergency Coordinators.
- In certain situations, technical liaisons may share reports with their counterparts in the PAHO directly; or the U.S. IHR NFP may transmit reports (officially or as a courtesy) with approval from the originating agency.

Public reporting of surveillance data

- Many different types of surveillance reports from various sources are available to the public in MMWR.
- More detailed data are available in the Notifiable Diseases and Mortality Tables and the Interactive Database Systems webpage.
- The DoD regularly publishes surveillance reports for the public on the AFHSB website.

■ ***Analysis of surveillance data*** ***D2.3***

Availability of electronic laboratory data

- NNDSS collects laboratory data at the state and local level, which is part of a case investigation that also involves obtaining clinical data (e.g., from medical records, patient interviews, family interviews, etc.). There is currently a digital information project that will assist states to receive messages from laboratories in their jurisdiction through the use of a common platform. This effort is part of CDC's strategy for improving national surveillance overall.
- For case reporting where non-electronic forms are used, the forms are usually finalized by state and local jurisdictions in collaboration with relevant programs at the CDC. For example, the Manual for Surveillance of Vaccine-Preventable Diseases provides a surveillance worksheet for use by states and local jurisdictions as-is or modified for use in collecting surveillance data.
- NSSP does not collect laboratory data as part of Emergency Department records, but acquires de-identified laboratory data from national and regional laboratory service providers.
- The DoD Defense Medical Surveillance System, as well as other subsystems within the DoD, receives electronic records from Military Treatment Facility laboratories using the current "health level 7"

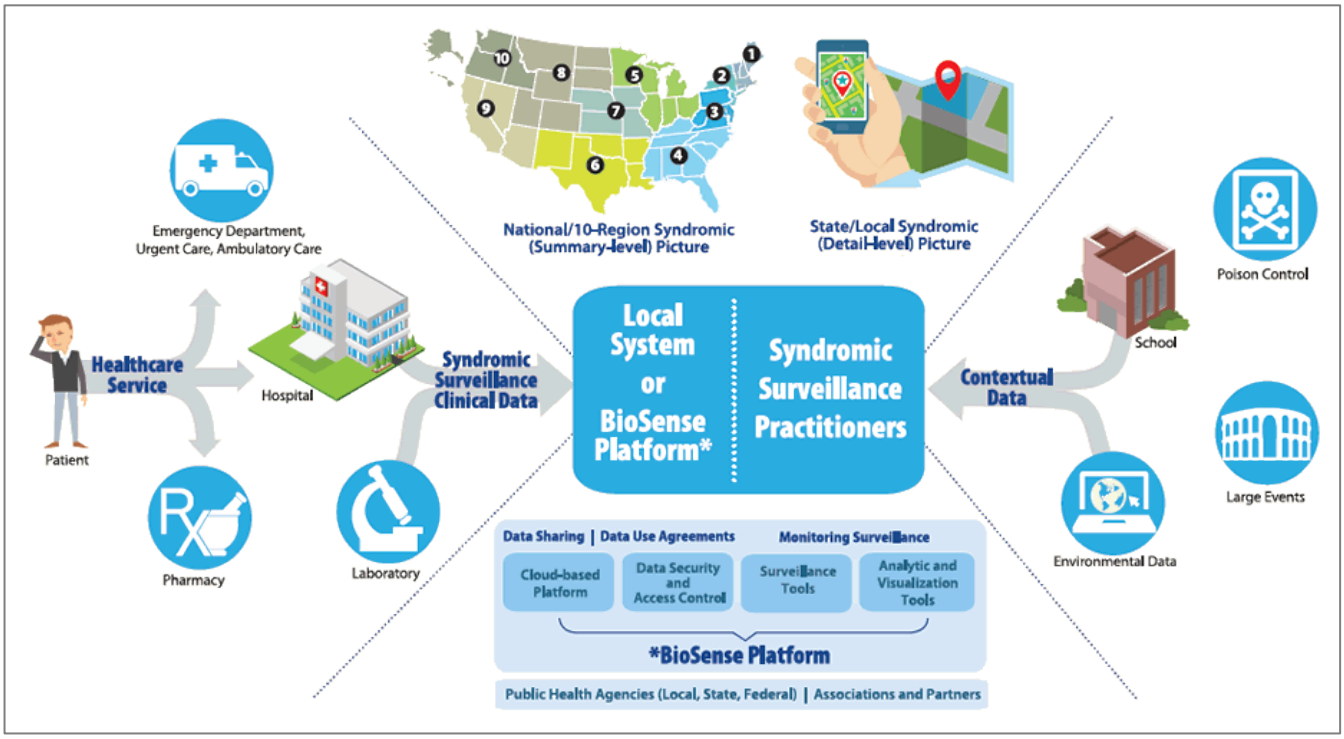
data format. The electronic medical record system for patient care is connected with the digital laboratory records in a seamless fashion. However, interpretation of laboratory data still requires significant expertise and public health professionals in the health centers must evaluate each case individually based on reporting criteria established by the jurisdiction and/or CDC.

- Laboratory results of approximately 150,000 specimens tested annually for influenza at state PHL are captured automatically from the laboratory information systems and sent to CDC using HL7 messages. These data can be available in real-time and represent a robust system not only for seasonal influenza surveillance, but also for routine detection of novel influenza virus infections and for use during a pandemic, as occurred in 2009.

■ ***Syndromic surveillance systems*** ***D2.4***

- CDC's NSSP operates the BioSense platform, which receives emergency room encounters information from state and local jurisdictions. NSSP supports collection of syndromic data by state and local jurisdictions for public health use. With introduction of additional tools, such as the SAS statistical software package (www.sas.com) and ESSENCE, the information from these data will contribute to rapid data visualization and development of a nearly real-time national picture.
- Health departments within each state/local/territorial jurisdiction decide on their syndromic surveillance system and are highly encouraged to participate in the NSSP. A total of 64 jurisdictions (45 states and 19 counties/cities) participate in NSSP. Most of them are contributing data while some are starting to establish connections so that the data can be submitted (Figure 2).
    - Patient encounters with the healthcare system (emergency response, hospitals, pharmacies, and laboratories) result in "syndromic surveillance clinical data" that can be analyzes (and sometimes visualized) by region (such as the 10 FEMA response regions) or at much more local levels of detail.
    - Other "contextual data" come from health-related programs (such as poison control centers) and publicly accessible information from schools, large public gatherings, or the environment that might suggest imminent health consequences from an otherwise undetected exposure.
    - Those two forms of data flow into the syndromic surveillance platforms, which can be used locally or nationally by those who are specially trained to evaluate such information and with the help of systems like Biosense that provided high-powered mathematical analysis.
    - Through data sharing and data use agreements, public health agencies and associated partners have access to only the amount and type of data that they need; and specialized surveillance, analysis, and visualization tools help everyone to use the data in similar ways.

Figure 2. Public health syndromic surveillance data flow in the United States [depicted by the CDC](#).



- The DOI National Park Service conducts syndromic surveillance at several of the large national parks. Data on employee absenteeism, clinic visits, and ill visitors are collected in near real-time via web-based platforms.
- The DoD operates ESSENCE, a combination of syndromic and indicator-based surveillance that takes advantage of the DoD's extensive digital record systems for personnel, health care, and military medical readiness.
- For animal health, syndromic surveillance is conducted on a limited basis. A collaborative effort within USDA allows for analysis of slaughter condemnation information for both swine and cattle, but does not link with laboratory data except for a few pilot efforts, such as a pilot project in Texas, which integrates clinical observations, slaughter (carcass) condemnations, and laboratory testing.

Conditions/pathogens included in the syndromic surveillance system

- Each jurisdiction can decide which syndrome (or pathogen) to monitor for their jurisdiction. This decision depends upon current circumstances and situation. There is no standardized list of syndromes that are detected or reported.

- NSSP reviews the top 10 syndromes occurring daily on the national and regional level for situational awareness purposes. Theoretically, these can also change based on situation. Five syndromes that are commonly reviewed on regular basis include "influenza-like illness," "gastrointestinal syndrome," "respiratory syndrome," "injury," and "rash."
- ESSENCE automated statistical detection algorithms test for anomalous increases in counts of encounters mapped to broad syndrome groups (e.g., influenza-like illness, gastrointestinal syndrome, febrile syndrome, hemorrhagic illness). ESSENCE receives automated electronic data feeds for Military Health System outpatient encounters (> 400 medical facilities worldwide).

Validation and reporting

- NSSP Data are validated against standardized syndromic surveillance Message Mapping Guides.
- Significant efforts have been made in the past to refine the definitions for syndromes used by the CDC and DoD.
- Each jurisdiction determines which reports are required based on their current situation and when reports are issued and updated. Some reports are shared publicly on state and locality websites. The state and local health department may share their reports and information with other jurisdictions.
- Staff members at the national level are responsible for monitoring their respective syndromic surveillance systems and, based on standard operating procedures, notify the lead epidemiologist or unit director of a potential health situation. Those personnel then determine, in consultation with leadership, whether or not additional actions (including reporting/notification) might be required.

National biosurveillance activities

- Several different departments and agencies have developed advanced biosurveillance capacities that go beyond traditional event- and indicator-based surveillance in order to develop epidemic intelligence and warnings more quickly and more efficiently. In July 2012, the White House released the National Strategy for Biosurveillance.
- The AFHSB's Integrated Biosurveillance Section uses multiple sources of public health information to provide information and coordinate other surveillance capacities within the DoD.
- The DHS also operates the BioWatch Program, which monitors the air for biological agents likely to be used in a bioterrorism attack. If a detection occurs, public health and other local and state officials use the information to determine if the signal is actionable, and, if so, coordinate an emergency response, including prompt medical care and other actions to protect public health and safety.

■ ***Additional sources of information for this section***

- "Evaluation of reporting timeliness of public health surveillance systems for infectious diseases." BMC Public Health. 2004; 4: 29).
- "Improvements in Timeliness Resulting from Implementation of Electronic Laboratory Reporting and an Electronic Disease Surveillance System." Public Health Rep. 2013 Sep-Oct; 128(5): 393–398.
- "Completeness and timeliness of electronic vs. conventional laboratory reporting for communicable disease surveillance--Oklahoma, 2011." Public Health Rep. 2014 May;129(3):261-6.

Best Practices, Challenges, Gaps, and Recommendations

The U.S. public health system is capable of rapidly detecting public health threats, conducting risk assessment, conducting notifications, and responding effectively. There are defined local-to-national surveillance roles and responsibilities in both public health policy and legislation. The long history of U.S. surveillance systems contributes to their strength while their different purposes and funding, largely in categorical intentions, has resulted in many parallel but highly effective systems. Substantial academic research and analysis continually occurs to keep pace with the rapidly changing public health and technological environment. However, in the United States, public health surveillance systems are largely not interoperable and electronic linkages are very limited, especially between various sectors. There are shortages of trained personnel at the subnational levels who are capable of collecting and analyzing large volumes of diverse data as well as integrating that information with non-clinical information source (i.e., news reporting, social media, or environmental testing) for biosurveillance purposes.

There are several opportunities for the U.S. departments and agencies to better exchange and integrate the results of their respective surveillance programs. Ongoing efforts at the federal level to increase the utilization and interoperability of electronic health care records, modernize the NNDSS, and digitalize records in the human and veterinary laboratory networks, presents an opportunity to develop wide-ranging biosurveillance capabilities for the United States. In a multisectoral approach, it would also be important to consider ways to integrate other forms of surveillance, such as food and the environment. Ideally, such systems would also have built-in utility for subnational jurisdictions, but training and coordination with personnel at the state and local levels would need to be developed and disseminated along with support for more qualified individuals where needed.

Reporting

Detect 3 (D3)

JEE Target

Timely and accurate disease reporting according to World Health Organization (WHO) requirements and consistent coordination with Food and Agriculture Organization (FAO) and World Organization for Animal Health (OIE).

Level of Capabilities in the United States

➢ Summary

The United States has an extensive network of epidemiologic, laboratory, and early warning surveillance mechanisms, many of which are identified throughout this section and other sections in this report. Several federal agencies, as well as all 50 states, engage in surveillance and reporting activities through crosscutting efforts. These U.S. systems are able to quickly identify nationally notifiable and unusual or unexpected health events for both human and animal populations, to include other IHR hazards, to ensure reporting obligations are fulfilled under the IHR and the standards promoted by OIE and FAO.

➢ Indicators

■ *D.4.1 System for efficient reporting to WHO, FAO, and OIE* *D3.1*

Contact points for international reporting

- The U.S. IHR NFP is located in HHS ASPR. Details on the organization and functions of the U.S. IHR NFP and communications with WHO are provided in the section on *IHR Coordination, Communication, and Advocacy*. Table 9 shows the various agencies that would normally be involved in a public health event assessment based on the type of event.
- The USDA serves as the U.S. Government focal point for OIE and is the U.S. focal point for the animal health component of One Health activities in the U.S. Government.
    - The Deputy Administrator of Veterinary Services, as the Chief Veterinary Officer manages U.S. animal health standard-setting activities related to the OIE.
    - Specifically, the USDA's National Surveillance Unit is the organization within APHIS tasked with coordinating activities related to animal health surveillance.

- USDA's International Animal Health Standards Team actively participates in helping shape the draft Animal Health standards proposed by the OIE.

- Points of contact for the FAO International Food Safety Authorities Network (INFOSAN) are:
  - FDA: Director of FDA's Emergency Operation Center;
  - CDC: Division of Foodborne, Waterborne and Environmental Diseases (DFWED) Senior Advisor for Food Safety and the Branch Chief of the Enteric Diseases Laboratory Branch;
  - USDA: FSIS Assistant Administrator for the Office of Public Health Science.

Table 9. Types of events that might require WHO, FAO and/or OIE reporting and the agencies typically involved in developing the initial risk assessment.

Type of event	Department – Agency
Agricultural incidents	USDA – APHIS HHS – CDC, FDA DoD FBI
Infectious diseases, vector borne or zoonotic diseases	HHS – CDC, NIH USDA – APHIS DOI – USGS, FWS, National Park Service DoD FBI
Food borne diseases	USDA – APHIS, FSIS HHS – FDA, CDC DoD FBI
Natural disasters (with cross-border consequences)	DOI –USGS, FWS HHS – ASPR, CDC DHS – FEMA DoD
Radiological or chemical events	DHS – FEMA HHS – ASPR, CDC, FDA EPA DOE DoD Nuclear Regulatory Commission FBI
Pharmaceuticals and other contaminated products	HHS – CDC, FDA DoD FBI

Mechanisms for information exchange

- INFOSAN and IHR reporting mechanisms are integrated to avoid redundancy or conflicting information. An agreement between FDA, USDA, CDC and the NFP (with concurrence from PAHO) outlines the pathway and process for information flow between the two notification systems. Those key agencies typically maintain, or assign as needed, liaison officers with one another.

- Examples of other information exchanges that have occurred in the United States:
  - OIE to WHO-IHR: detection of animal health events that pose a significant risk to humans such as avian influenza H5N1 (2005).
  - WHO-IHR to OIE: detection of an IHR-reportable disease in the human population with an implication for animal health, such as variant influenza A H3N2 (2012).
  - FAO-INFOSAN to WHO: A multistate outbreak of listeriosis linked to Blue Bell Creameries products in 2015 was linked to cases in several states.

Training for the IHR NFP, OIE, and FAO contact points

- IHR, OIE, and FAO contact points receive training through multiple formal and informal pathways.
  - Much of the understanding and competence in managing the respective obligations is a blend of knowledge transfer from outgoing incumbents, dialogue with existing domestic and international partners, on-the-job training, and reviewing and exercising of existing protocols and procedures.
  - Incumbents also travel to domestic and international meetings and workshops to expand their knowledge (e.g., INFOSAN regional meetings, OIE global meetings, previous WHO IHR Course).
- Contact points also manage stakeholder engagement and outreach for their respective detection and notification pathways; this includes trainings and refreshers for domestic stakeholders, and recirculating existing policies and processes as points of contact in the domestic and international networks turnover.

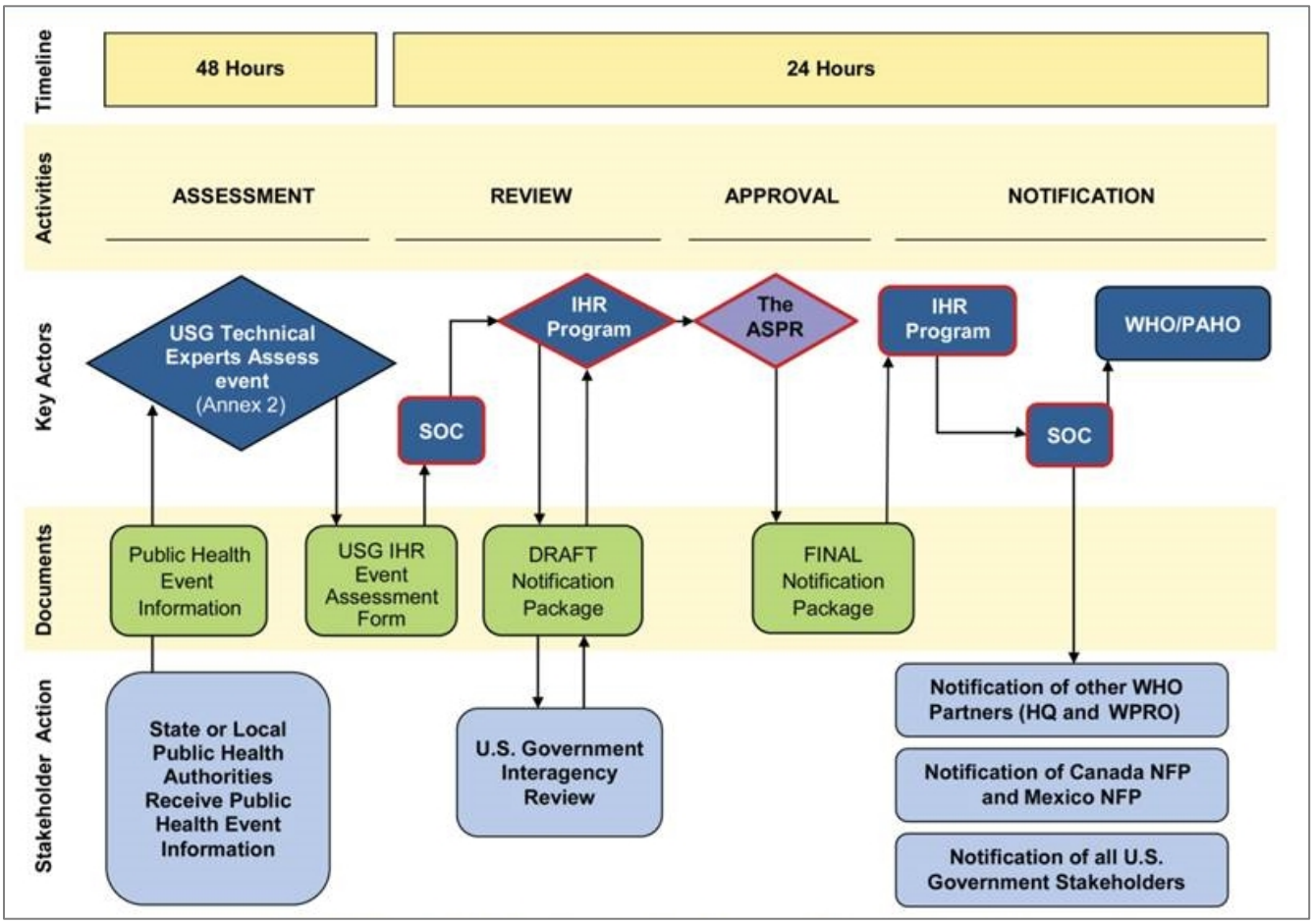
Mechanisms for public health, animal health, and security authorities to make decisions on reporting

- The United States process for IHR event assessment and notification has five general steps that are coordinated by the IHR Program and the HHS Secretary's Operation Center under the structure of the U.S. IHR NFP (Figure 3):

1. ASSESSMENT: Formal public health risk assessment
   - Conducted by a single agency and in some cases as a collaboration between technical agencies in a 48-hour timeframe.

- Departments and agencies address IHR-notification criteria (IHR Annex 2) in their event detection and assessment processes.

Figure 3. Approval and notification process for a potential public health emergency of international concern in the United States.



2. REVIEW: Review of the IHR event notification by the U.S. Government IHR Stakeholders (all U.S. Government agencies with an IHR point of contact)

   - If the IHR event notification meets the criteria for a PHEIC, it must be approved by the ASPR and reported to the WHO within 24 hours.
   - Stakeholders typically have two hours to provide input on the event being notified.
   - A stakeholder may make comments or suggest changes to either the event assessment or the notification messages based on information available.
   - Significant changes or concerns about the event assessment will need to be addressed by the responsible agency. If needed, the IHR Program will convene, via the Secretary's Operation Center, a teleconference with stakeholders to address issues related to the event.

3. APPROVAL: Approval by the Assistant Secretary in ASPR
4. NOTIFICATION: Transmission of the notification and the U.S. Government risk assessment to the WHO via PAHO
    - Courtesy copies are sent to others, including the NFP of Mexico and Canada and the IHR Contact Point for the WHO's Western Pacific Regional Office, which supports the U.S. territories.
5. Review and approval of the text for the WHO IHR Event Information Site

- A 2007 position statement by CSTE encourages health departments to report smallpox, polio, variant human influenza and severe acute respiratory syndrome (SARS) in accordance with the IHR. A 2008 position statement supported the United States adoption of the update IHR reporting requirements and agreed to officially modify the list of nationally notifiable diseases to be consistent with the IHR.

Multilateral, regional or bilateral reporting with neighboring countries

- The United States has developed multilateral regional and bilateral reporting agreements with neighboring countries. One example, the North American Plan for Animal and Pandemic Influenza (NAPAPI), is a trilateral agreement between Canada, Mexico, and the United States. The countries have agreed to simultaneously share notifications they send to WHO with each other. Additionally, countries also engage in information sharing at even lower thresholds than for reportable events through the development of a trilateral protocol for non-routine and emergency communications.

Informal consultation mechanisms with WHO (Article 8)

- The U.S. IHR NFP has used the consultation mechanism (Article 8) in numerous occasions:
    - Clarifying IHR reporting criteria and U.S. protocol for reporting human influenza infections with novel strains that are not seasonal, such as human influenza A variant H3N2;
    - Clarifying global communications, education, and outreach regarding the Hantavirus infections occurring at Yosemite National Park, in addition to updating and developing guidelines and other materials (clinical definition, clinical guidance, public messaging) to support the public health response;
    - Coordinating regional response preparedness and response planning for Ebola in the Americas and establishing U.S. Government *petite comité*. Clarifying and refining the U.S. process for Article 30 communications of high-risk travelers; and the separate process for low and moderate-risk travelers;

- Clarifying and coordinating U.S. Government Food Safety event reporting between WHO and FAO (INFOSAN);
- Clarifying IHR reporting criteria and U.S. notification protocol for Zika virus in response to the WHO declared PHEIC and subsequent WHO IHR Emergency Committee temporary recommendations, specifically data sharing required of WHO member states.

Bilateral exchange mechanisms with other IHR NFP

- The bilateral exchange mechanisms are used by the U.S. IHR NFP to exchange information with NFP of other countries and connect their public health authorities with those in the United States. There are many examples since 2007, including during the most recent Zika virus outbreak in the Americas, such as messages between the United States and Mexico, Colombia, Paraguay, and Philippines.
- Contact information on the WHO IHR Event Information Site for all NFP of WHO Member States has also been invaluable to U.S. federal agencies in:
  - Notifying health authorities about communicable diseases in travelers to/from the United States. While the U.S. IHR NFP may provide the appropriate contact information, these communications are not treated as formal messages that require NFP authorization.
  - Organizing international capacity -building missions with PAHO and in other regions.

■ ***Reporting network and protocols in country*** ***D3.2***

Example of an IHR event notification: Sexually transmitted Zika virus infection

- In mid-February 2016, a young woman living in the continental United States developed an acute rash. Although the patient had no history of travel, her male companion had recently been in South America where there was sustained transmission of Zika virus. With the awareness of the outbreak and similar symptoms in the male companion, a local clinician ordered Zika virus PCR testing on the patient. The urine specimen was positive but the serum samples were negative. This case met the WHO Emergency Committee definitions for a reportable case under the declared PHEIC. The U.S. IHR NFP, after following the protocol for consultation with U.S. IHR Stakeholders, submitted the notification developed by CDC to the Pan American Health Organization on March 2, 2016 under IHR Article 6. The suspected infection in the male companion was specifically not reported because he had traveled to a country in which there was already well-documented, widespread transmission. That case did not fall into a category of reportable illnesses under the PHEIC declaration.

Best Practices, Challenges, Gaps, and Recommendations

Integration of OIE, FAO, and WHO reporting requirements in the United States has created an efficient system that minimizes the potential for inconsistent or conflicting notifications. Agencies that most commonly identify notifiable events are well versed in working through their respective reporting requirements. Because the IHR itself does not account for every variation in biology, epidemiology or human behavior, the United States has developed informal though effective processes for deliberating among the relevant agencies and coordinating with the WHO Regional Office on interpretations of the reporting requirements in the IHR.

As was described in the sections on *National Legislation, Policy, and Financing* and *IHR Coordination, Communication, and Advocacy*, full understanding of the IHR is not universal among the U.S departments and agencies, and it is uncertain how state health officials perceive their roles in the federal obligations. The U.S. Government's ability to assess international public health risks and report them to WHO, OIE, or FAO accordingly is currently fully functional. However, one systematic weakness in the United States' current IHR implementation is the lack of institutional continuity and consistency within and among the agencies. A more explicit U.S. Government policies for international event reporting, as described in the *National Legislation, Policy, and Financing* section, could help to improve overall coordination among the agencies and subnational public health authorities by creating opportunities for dialogue, training, exercises and communication.

Another important opportunity is the further development of U.S. government programs that specifically address WHO, OIE, and FAO event assessment and reporting requirements. Such an effort would necessarily require a multiagency approach. As the national advocate for IHR implementation, the U.S. IHR NFP could consider ways to develop, coordinate, and promote the dissemination of a multiagency standard operating procedure that helps to guide agency and interagency activities related to the IHR. Such guidance could also serve as a more comprehensive resource for states and overseas territories that is complementary with other, existing international agreements.

Workforce Development

Detect 4 (D4)

JEE Target

State parties should have skilled and competent health personnel for sustainable and functional public health surveillance and response at all levels of the health system and the effective implementation of the IHR (2005).

Level of Capabilities in the United States

➢ Summary

The essential workforce requirements for public health surveillance, investigation and analysis, emergency response, laboratory, risk communication, and other disciplines, are adequately staffed at the federal level. With an extensive network of specialized professionals, employees are available across federal programs to mount a substantial surge during major public health responses, such as happened during the 2014-2015 Ebola virus outbreak. The National Disaster Medical System (NDMS), the U.S. Public Health Service (USPHS), the U.S. federal military services, and state National Guards have public health staff that can be mobilized in the event of an overwhelming situation.

Public financing for health departments and training programs comes from a combination of local budgets as well as federal grant programs. While public health workforce tracking is not comprehensive in the United States, there are systems in place to monitor the numbers of epidemiologists and clinical health professionals around the country. Schools of public health, and public health training in other colleges and universities, are common. There are Bachelor or vocational/technical, Bachelor, Master, and Doctoral level training programs for most disciplines, with appropriate forms of certification and accreditations that are routinely required by employers, especially in publicly financed billets.

➢ Indicators

■ *Human resources are available to implement IHR core capacity requirements* *D4.1*

Federal public health professionals

- At HHS, the Health Resources and Services Administration (HRSA), through its Bureau of Health Workforce, improves the health of underserved and vulnerable populations by strengthening the

health workforce and connecting skilled professionals to communities in need. The bureau provides strategic coordination, alignment, and enhanced communication between the various professional disciplines to increase the number of practicing primary health care providers to address shortages, increase health access, and develop ongoing strategies to monitor, forecast and meet long-term health workforce needs, especially in resource poor communities.

- CDC helps build the future public health workforce through management and delivery of fellowships with specific target audiences, including epidemiology, public health informatics, laboratory sciences, economics and decision sciences, public health policy and management, and other public health disciplines.
    - CDC also supports the current workforce with training through the CDC Learning Connection, which connects learners to quality public health and health care training opportunities and CDC TRAIN, a learning management system of public health learning products.
    - To assure skilled competent public health personnel at the national and subnational level, CDC's DSLR conducts an extensive training program for entry level public health emergency preparedness personnel by placing federal employees in state public health agencies for training. After completing two years of training, the employees transition to national or subnational employment.
- In the United States, the state-level public health departments all have epidemiology, laboratory, and case management capacity. The federal government supplements state capacity to prepare for and respond to any public health emergency through the CDC Division of State and Local Readiness (DSLR), which provides both technical assistance, training and funding.
    - DSLR, through the PHEP cooperative agreements, supports the public health workforce by providing funds to support full-time employees at the jurisdictional level. Awardees of the PHEP cooperative agreements adhere to a certain set of core public health preparedness capabilities, which includes hiring and training staff members to fulfill a wide variety of functions. More detail on the PHEP cooperative agreements is in the section on *Preparedness*.
    - DSLR has a more direct human resources role in ensuring capacity through placement of field staff in order to ensure that each awardee jurisdiction has some capacity in the various disciplines needed to support emergency preparedness and response. Currently, DSLR has 33 Career Epidemiology Field Officers, 23 Preparedness Field Assignees, 13 Public Health Associates and Medical Countermeasure Field Assignees, and 10 Temporary Epidemiology Field Assignees placed in jurisdictions around the country. During public health emergencies, DSLR has the ability to move or place resources where there is a demonstrated need.
- The APHIS Veterinary Services conducts two training programs, which target current veterinary epidemiologists. The veterinary field epidemiology program, which trains about 25 epidemiologists annually, provides trainees with the tools to effectively manage and direct surveillance and eradication programs, particularly focused on protecting animal health.

- Many other federal departments and agencies train and employ public health personnel who, under specific circumstances, are available to respond within their agencies and in temporary assignments to other agencies during public health emergencies. As mentioned in the section on *Preparedness*, those include the CDC, USDA, NIH, and FDA, with additional support from NDMS and the USPHS.

Monitoring national public health human resource capacity

- HRSA, through its National Center for Health Workforce Analysis, leads health professions workforce data collection, analysis, and evaluation efforts and acts as the national resources for workforce projections. The center examines issues that impact the supply, demand, distribution, and education of the nation's health workforce and provides policymakers the information necessary to make decisions regarding the health professions' workforce and provision of care
- The Council of State and Territorial Epidemiologists (CSTE) tracks the status of field epidemiology staffing in the United States. Since 2001, the CSTE has conducted a series of periodic standardized assessments of the epidemiology capacity of state and territorial health departments to estimate the number of state and local epidemiologists working in the United States.
- USDA APHIS tracks veterinary field epidemiology capacity.

Multi-level communication among public health professionals

- Regular and systematic communication between epidemiologists at the national, subnational, and local levels is conducted through surveillance systems (NNDSS, *PulseNet*), reports (including MMWR and influenza), scientific abstracts, and conferences.
- During an infectious disease outbreak, epidemiologists and other health professionals have access to a wide variety of information. CDC's Health Alert Network is the federal government's primary method of sharing cleared information about urgent public health incidents with public information officers, public health practitioners (federal, state, territorial, and local), clinicians, and PHL.
- The Clinician Outreach and Communication Activity (COCA) system prepares clinicians to respond to emerging health threats and public health emergencies by communicating relevant, timely information related to disease outbreaks, disasters, terrorism events, and other health alerts. Methods include phone calls and webinars, emailed reminders and updates, training events, and other continuing education activities.
- CDC publishes the MMWR, which is the agency's vehicle for scientific publication of timely, reliable, authoritative, accurate, objective, and useful public health information and recommendations.
- CDC has the Epi-X secure communications network, which supports postings and discussions about disease outbreaks and other public health events that could involve multiple jurisdictions.

- Overall, over 3,000 trained field epidemiologists support investigations throughout the country and supplement existing state-level field epidemiology capacity. In 2010, 2,476 epidemiologists worked at the state level for the 51 jurisdictions across the United States. An additional 1,278 epidemiologists employed or contracted by local health departments were identified in 2010.

■ ***Field Epidemiology Training Program or other applied epidemiology training program in place***

D4.2

Examples of federal public health training

- There are two main field epidemiology training programs currently implemented in the United States. These programs provide high-quality training experiences and to secure long-term career placement for field epidemiologists at the state or local level. Both programs provide robust mentorship from primary and secondary mentors.
- The Epidemic Intelligence Service (EIS) is an advanced level, two-year, on-the-job training and service fellowship conducted by the CDC. EIS trains physicians, veterinarians, scientists, and other health professionals that may come from a variety of settings, including academia, clinical practice, government, and non-governmental agencies, to apply epidemiology to solve public health problems.
- The Applied Epidemiology Fellowship is closely designed after the Epidemic Intelligence Service program but is conducted by CSTE. In that program, those who already have a master- or doctoral-level degree, and who are interested in public health practice at the state or local level, receive training in epidemiology or a related field.
- Over the years, EIS officers have deployed internationally and many EIS officers work hand-in-hand with residents of Field Epidemiology Training Programs (FETPs) in host countries. This is facilitated by ongoing accreditation through the Training Programs in Epidemiology and Public Health Interventions Network, which builds a global community of field epidemiologists.
- The USDA Outbreak Investigations program, conducted biennially, targets epidemiologists to provide them with a standard approach for performing proper disease outbreak investigations. Outbreak Investigations is a newer course, which has trained 34 epidemiologists to date. Additional details regarding the training of veterinary and animal health professionals are provided in the section on "Zoonotic Diseases."
- The Environmental Health Training in Emergency Response is conducted by CDC. The course helps prepare environmental health practitioners and others across the public health workforce by providing them with the necessary knowledge, skills, and resources to address the environmental health impacts of emergencies and disasters.

Examples of other public and private public health training

- Long-term training in public health occurs during and following academic preparation in the various disciplines.
  - For physicians, the U.S. medical school curriculum offers some exposure to concepts of population health and provides opportunities for public health rotations. CDC offers the Epidemiology Elective Program, a six- to eight-week rotation for a small number of senior medical and veterinary students. Physicians can pursue long-term training for public health careers through preventive medicine residencies, through other specialty fellowship programs such as EIS, and by earning the Master of Public Health degree. Over 80 medical schools sponsor activities for students to pursue the dual medical and public health degrees.
  - For nurses, all four-year baccalaureate schools of nursing require at least one semester of community health. Nurses can specialize in public health careers through masters and doctoral programs in nursing and through earning the Master of Public Health degree or dual degree with nursing. Nurses with advanced degrees and public health experience are also eligible for the EIS.
  - There are opportunities for veterinary students and veterinarians to receive public health training at the CDC, such as the Epidemiology Elective Program. Veterinary students may also intern at local, state, or federal public health or animal health agencies in order to gain real-world public health experience. The USGS National Wildlife Health Center veterinary externship program trains approximately six veterinary medicine students per year in wildlife disease investigation techniques, including wildlife pathology and epidemiology. Additional details regarding the training of veterinary and animal health professionals are provided in the section on *Zoonotic Diseases*.
  - For biostatisticians, U.S. schools and programs of public health offer concentrations or advanced degrees in biostatistics.
  - For laboratory scientists, a number of national fellowships exist, which provide training related to laboratory science, public health, and infectious diseases.
    - CDC has the Laboratory Leadership Service fellowship for early career fellowship for future leadership and management positions in PHL, with a focus on biosafety and quality.
    - The American Society for Microbiology/CDC Program in Infectious Disease and Public Health Microbiology Postdoctoral Research Fellowship supports the development of new approaches, methodologies, and knowledge in infectious disease prevention and control.
    - The APHL provide training to laboratory staff in PHL and in partnership with CDC conducts laboratory fellowships as a part of a national laboratory-workforce development effort.
  - The U.S. Congress established the Uniformed Services University of the Health Sciences in 1972 to educate, train, and prepare uniformed services health professionals, officers, and leaders who will directly support the Military Health System and the readiness of the Armed Forces.

- CDC offers long-term fellowships in public health informatics, economics and decision sciences, public health policy and management, and other public health disciplines. CDC also offers the CDC Learning Connection, which connects learners to quality public health and health care training opportunities, and CDC TRAIN, a learning management system of public health learning products.
- The HRSA Regional Public Health Training Centers Network offers high-quality training, tools, and resources for thousands of professionals engaged in advancing public health practice.

■ *Workforce strategy* *D4.3*

Routine training and hiring practices in the United States

- Federal, state, and local public health agencies, academic institutions and professional associations, and numerous partner organizations form a robust network of collaborators, and many have their own internal workforce strategy.
- Most commonly, federal and state public health offices retain epidemiologists, public health advisors, physicians (in various specialties and sub-specialties), public health nurses, public health laboratorians, pharmacists, environmental health practitioners, public health informaticians, health communications specialists, veterinarians, veterinarian and medical technicians, and wildlife professionals. Practicing clinical professionals, including doctors, nurses, pharmacists, nurses' aides, midwives, and non-allopathic healers interact with public health professionals and are considered important contributors to overall population health and control of communicable diseases.
- The median number of years that public health personnel have been on staff varies across various agencies, organizations, and positions. However, different reports indicate that 45 to 50 percent of public health employees will become eligible to retire in the next five years, indicating that public health staffs have worked for many years.
- Attrition is a concern for the public health workforce. A 2013 Association of State and Territorial Health Officials survey of state health agencies, combined with the latest numbers from a NACCHO survey of local health department job losses and program cuts, revealed that more than 50,600 state and local jobs have been lost since 2008. This represents about 22 percent of the total state and local health department workforce.
- A recent Public Health Workforce Interests and Needs Survey by the Association of State and Territorial Health Officials was the first nationally representative survey of individual state health agency workers. That survey obtained data from more than 10,000 public health workers from 37 state health agencies. Eighteen percent of respondents reported an intention to leave the government public health workforce in the next 12 months, either to retire or to pursue work elsewhere. Thirty-eight percent plan to leave government public health service before 2020. Furthermore, more than 30 percent of the CDC workforce will be eligible to retire by December 2017.

- Retention efforts for the public health workforce include focusing on career satisfaction and professional development opportunities. Characteristics related to supervisory and organizational support were highly associated with increased job satisfaction.
- There are specific incentives for some workforce specialties in the federal government, depending on the department or agency.
  - Direct hire authority exists for physicians at CDC and veterinarians at USDA.
  - The U.S. Public Health Service and DoD provides special pay incentives for physicians and several other categories.
  - The HHS Indian Health Service, HRSA, and USDA provide a significant quantity of tuition reimbursement for those studying for careers in the health professions; while USDA offers a veterinary medicine loan repayment program.
  - USDA also has scholarship programs and tuition assistance for undergraduate and graduate students to promote careers in a variety of disciplines, including veterinary medicine, food, agriculture, plant pathology, and other related disciplines. Additionally, USDA is implementing a new National Institute of Food and Agriculture Veterinary Services Grant Program to develop, implement, and sustain veterinary services, as well as to establish, equip, or expand veterinary practices in underserved areas.

Examples of Federal programs for emergency staffing

- NDMS teams are composed of pre-identified personnel including licensed and credentialed civilian medical personnel capable of performing a wide range of duties in the post-disaster phases. NDMS members are organized into state-level teams, which are activated as needed to respond throughout the country. Upon activation, team members take leave from their primary employers and become temporary federal employees for the duration of their assigned mission. The primary purpose of the NDMS is to supplement an integrated national medical response capability for assisting U.S. state and local authorities in dealing with the medical impacts of major peacetime disasters.
- The USPHS Commissioned Corps is composed of uniformed officers with qualifying degrees in health and public health fields. Members of the Commissioned Corps hold positions throughout the federal government workforce including the HHS, DHS, DoD, and the DOJ, and may be activated to deploy in response to domestic and international emergencies, as needed. The Commissioned Corps includes a Readiness and Deployment Operations Group, which consists of pre-identified teams capable of deploying within 12-36 hours of notification to provide mass care at shelters, distribute and/or administer medicines, and/or conduct community outreach and assessments, among other functions. As seen during the recent response to the Ebola epidemic in West Africa, Commissioned Corps officers may also be deployed internationally to handle specialized missions, which may include direct patient care.

Financing the public health workforce

- U.S. Congress appropriates funds to federal departments and agencies for public health workforce activities. The federal departments and agencies can then fund partner organizations and local governments through grants and cooperative agreements. Additionally, philanthropic organizations may fund special interest activities to strengthen the public health workforce.
- To increase the health professions workforce and the number of providers working in underserved communities, HRSA provides funds to accredited U.S. health professions schools, health centers and health care providers; and provides support to individuals in exchange for commitments to serve underserved communities.

Best Practices, Challenges, Gaps, and Recommendations

Following a long tradition of professional education, apprenticeship, and practical application of learning, the U.S. public health workforce has developed in parallel with its public health system. The public health workforce receives primarily public financing, and there are many opportunities for specialization, research, career advancement, and diverse career experiences, though not necessarily homogeneously across the country. Professional associations provide important support for the public health workforce in the United States, ensuring opportunities for professional development, establishing standards for accreditation, promoting fair remuneration and job opportunities, and maintaining a network for routine and emergency communications.

However, there remain several challenges with sustaining the public health workforce in the United States. Workforce data for public health professionals other than epidemiologists is inconsistent, making it difficult to establish priorities for education and professional development. While many federal agencies and states have human resource models for their public health offices, there is no overarching national capacity goal that helps to identify or predict shortages. As with other highly specialized professions, the extent to which jurisdictions that are socioeconomically disadvantaged are capable of recruiting and sustaining a workforce that meets the needs of their populations remains unknown.

With respect to the component of the U.S. workforce that is ready for public health emergency response, there appears to be little known about capacities at the jurisdictional level until an event occurs. Although some actions are being taken at the national level – the National Association of Country & City Health Officials recently launched a study to update the National Profile of Local Health Departments – there is yet no federal focus or policy on public health workforce. The PHEP cooperative agreements provide critical resources for 62 state and jurisdiction health departments, but that program does not typically include local workforce assessments. Notable needs include (1) an evaluation the size and effectiveness of workforce; (2) mechanisms to work with states to ensure there are a sufficient

number of public health practitioners and other public health professionals at the state and jurisdiction levels; and (3) more resources and local assistance for public health emergency exercises.

The U.S. Government could begin by commissioning a study of the existing public health workforce and gaps between human resource needs and staffing at state and local levels. At the same time, the existing programs could increase focus on recruitment and human resource development. With conclusion of the study, the U.S. could establish an overall workforce staffing and incentives model in collaboration with existing agency programs to reduce human resources gaps through either existing or new public support models.

RESPOND

Preparedness

Respond 1 (R1)

JEE Target

Preparedness includes the development and maintenance of national, intermediate and community/primary response level public health emergency response plans for relevant biological, chemical, radiological and nuclear hazards. Mapping of potential hazards, identification and maintenance of available resources, including national stockpiles, and the capacity to support operations at the intermediate and community/primary response levels during a public health emergency.

Level of Capabilities in the United States

➢ **Summary**

The Secretary of Homeland Security coordinates with Federal entities to provide for Federal unity of efforts for domestic incident management. To achieve a secure and resilient nation, The National Preparedness System, called for under Presidential Policy Directive 8 (PPD 8), provides the overarching doctrine for building, sustaining, and delivering the core capabilities identified in the National Preparedness Goal in order to achieve a secure and resilient nation. The National Planning Frameworks, key elements of the National Preparedness System, describe the roles and responsibilities for the whole community across all mission areas – prevention, protection, mitigation, response, and recovery. A series of major disasters and incidents – most notably the 9/11 and anthrax attacks in 2001 and hurricane Katrina in 2005 – triggered the comprehensive review and restructuring of national security policy and the domestic public health preparedness, response, and recovery system in the United States.

Within HHS, and as mandated by PAHPA, ASPR is the lead agency for coordination of domestic and international preparedness and response activities and in charge of maintaining and coordinating a number of national systems. Many other offices and entities within the federal government have specified roles in preparing for and responding to health emergency. Managed by ASPR, NDMS utilizes intermittent federal employees from around the country in conjunction with personnel from the USDA, CDC, FDA, NIH, and the USPHS (among others) to provide the bulk of the public health surge capacity across the federal government. In addition, there is a variety of organizations and entities in charge of

the development, procurement, and distribution of public health emergency medical countermeasures, which is also a key component of the national preparedness efforts (e.g., the NIH, the BARDA, the PHEMCE, the SNS managed by CDC, etc.). The USDA and DoD also maintain significant national readiness and response assets.

The U.S. national preparedness and response systems have been tested by multiple, concurrent public health situations, and those systems are continually reviewed, revised, and refined as real-world responses lead to new insights and challenges. The Strategic National Risk Assessment (SNRA) completed in 2011 provides U.S. policy makers and planners a foundation for domestic capacity development and a means for agencies to share information and planning considerations as well as to help align those policy/planning efforts towards a common goal.

➢ Indicators

■ *Multi-hazard national public health emergency preparedness and response plan is developed and implemented* *R1.1*

National preparedness response systems, plans, and frameworks

- The National Preparedness Goal, established as part of PPD 8, defines what it means for the whole community to be prepared for all types of disasters and emergencies: "A secure and resilient nation with the capabilities required across the whole community to prevent, protect against, mitigate, respond to, and recover from the threats and hazards that pose the greatest risk."
- The National Preparedness System, also established as part of PPD 8, outlines an organized process for the preparedness activities of communities, the private and nonprofit sectors, faith-based organizations, and the local, state, tribal, territorial, insular area (i.e. jurisdictional) and federal governments in the United States to achieve the National Preparedness Goal.
    - The National Preparedness System is comprised of six components: (1) identifying and assessing risk, (2) estimating the level of capabilities needed to address those risks, (3) building or sustaining the required levels of capability, (4) developing and implementing plans to deliver those capabilities, (5) validating and monitoring progress, and (6) reviewing and updating efforts to promote continuous improvement. The components provide a consistent and reliable approach to support decision-making and resource allocation, and to measure progress toward these outcomes.
    - To facilitate the achievement of the National Preparedness goal, the National Preparedness System also includes a number of frameworks, plans, and guidance documents separated into these general categories:

- The National Preparedness System describes roles and responsibilities to deliver the core capabilities required across the five mission areas: prevention, protection, mitigation, response, and recovery.
- Federal Interagency Operational (FIOP) Plans provide further detail regarding Federal roles and responsibilities, specify critical tasks, and identify resourcing and sourcing requirements for delivering core capabilities.
- Operational plans for individual departments and agencies to supplemental/implement the FIOP.
- Comprehensive planning guides support jurisdictions, nongovernmental organizations, and the private sector.
- The Threat and Hazard Identification and Risk Assessment process helps jurisdictions and organizations understand their risks and estimate capability requirements necessary to address those risks.

- The NRF, updated in 2016, is a foundational component of preparedness in the United States. It defines U.S. doctrine for managing any type of disaster or emergency regardless of scale, scope, complexity, and funding source.
  - The NRF is composed of a base document, Emergency Support Function (ESF) Annexes, and Support Annexes. The Annexes provide detailed information to assist with the implementation of the NRF. The ESF system provides the structure for coordinating federal interagency support for a federal response to an incident. They are mechanisms for grouping functions most frequently used to provide federal support to states and federal-to-federal support, both for declared Stafford Act disasters and emergencies and non-Stafford Act incidents.
  - ESF #8 – *Public Health and Medical Services* is led by HHS, with much of the responsibility subsequently delegated to the Assistance Secretary for Preparedness and Response. ESF #8 provides the mechanism for coordinated federal assistance to supplement subnational resources in response to a public health and medical disaster, potential or actual incidents requiring a coordinated federal response, and/or during a developing potential health and medical emergency.
  - Development of the HHS All-Hazards Plan began soon after the release of PPD 8 in September 2011 in conjunction with the development of the NRF and the FIOPs. The base plan was utilized on a number of occasions, including Hurricane Sandy in 2012, with completion of all of the functional appendices in April 2014. Scenario-specific annexes to this plan, such as pandemic influenza, hurricane, earthquake, anthrax, special events, and improvised nuclear device planning, describe how HHS will coordinate and conduct activities at the national level as the lead agency in the federal public health and medical response to an emerging threat. These annexes address HHS's capabilities, essential tasks, and resources by the phase of response.

They also specify requirements for ESF #8 and other federal partners who support HHS in carrying out its response mission.

- The National Incident Management System (NIMS) is an essential foundation for the National Preparedness System and provides the template for the management of incidents and operations in support of all five National Planning Frameworks. NIMS provides a comprehensive, nationwide, scalable, systematic approach to all-hazards incident management. It provides the core doctrine, concepts, principles, terminology, and organizational processes and is crucial in managing incidents, especially those that require the utilization of surge capacities.
- Additionally, the National Animal Health Emergency Management System is an integrated system and framework, building on the NRF and primarily supporting, along with the DOI, ESF #11 – *Agriculture and Natural Resources*, for managing foreign animal diseases and other animal health incidents that may or may not impact human populations.
- The SNRA, published in 2011, supports PPD 8 and ensures that national preparedness is based on core capabilities that support strengthening the security and resilience of the United States through the systematic preparation for the threats that pose the greatest risk to the security of the nation. The Secretary of Homeland Security led the effort to conduct the SNRA to help identify the types of incidents that pose the greatest threat to U.S. homeland security. Representatives from the offices of the Director of National Intelligence and the Attorney General, as well as other members of the federal interagency, supported this effort.

National public health preparedness and response

- The NHSS, as mentioned in the *National Legislation, Policy, and Finance* section, provides strategic direction to ensure that efforts exist to improve health security nationwide.
- Led by HHS, ESF #8 provides the mechanism for coordinated federal assistance to supplement state, tribal, and local responses to a public health and other disaster with health consequences.
    - The *Public Health and Medical Services* core capability provides lifesaving medical treatment via EMS and related operations to avoid additional disease and injury by providing targeted public health and medical support and products to all people in need within the affected area. Many other departments and agencies support the *Public Health, Healthcare, and Emergency Medical Services* core capability of ESF#8.
    - The *Public Health and Medical Services* critical tasks are to: 1) deliver medical countermeasures to exposed populations; 2) complete triage and initial stabilization of casualties and begin definitive care for those likely to survive their injuries; and 3) return medical surge resources to pre-incident levels, complete health assessments, and identify recovery processes.
    - The Response FIOP builds upon ESF #8, and describes the concept of operations for integrating and synchronizing existing national-level federal capabilities to support local, state, tribal,

territorial, insular area, and federal plans. The Response FIOP is supported by federal department-level operational plans, where appropriate.

  - Additional plans and guidance are available for all levels and partners in a response. For example, the *Medical Surge Capacity and Capability Handbook* describes a systematic approach for managing the medical and public health response to an emergency or disaster.

- When activated, the *Public Health and Medical Services* core capability follows three phases.
  - Phase 1: The Secretary of HHS reviews the readiness and deployment status of personnel and resources to support state and local response operations. Federal health officials coordinate directly with state health departments of the impacted states (by way of the incident management system) to determine resource needs. HHS, in coordination with FEMA, state, and local officials, identifies potential locations for Federal Medical Stations and Medical Staging Areas. HHS provides assessment teams and liaisons to EOCs if needed.
  - Phase 2: ESF #8 partners begin providing 24/7 support where needed to save lives, minimize adverse health and medical effects, and stabilize the public health and medical infrastructures. Once a determination has been made that the situation exceeds local or state capabilities, HHS deploys additional resources based on information from the assessment teams and the on-site managers. In this phase, concurrent aspects of recovery also begin within the *Recovery Health and Social Services* core capability.
  - Phase 3: As needed, ESF #8 resources are selectively released, going through demobilization, deactivation, and closeout in an effort to facilitate the complete transition from *Public Health, Healthcare, and Emergency Medical Services* to the *Recovery Health and Social Services* core capability. As response operations begin to diminish, incident managers demobilize federal agencies from their respective operations. Requirements for long-term post-incident health surveillance or investigation are determined, and continued assistance to states regarding the surveillance and monitoring efforts of disaster-related illness in the affected area may be necessary.

National/Federal public health medical assistance resources and assets

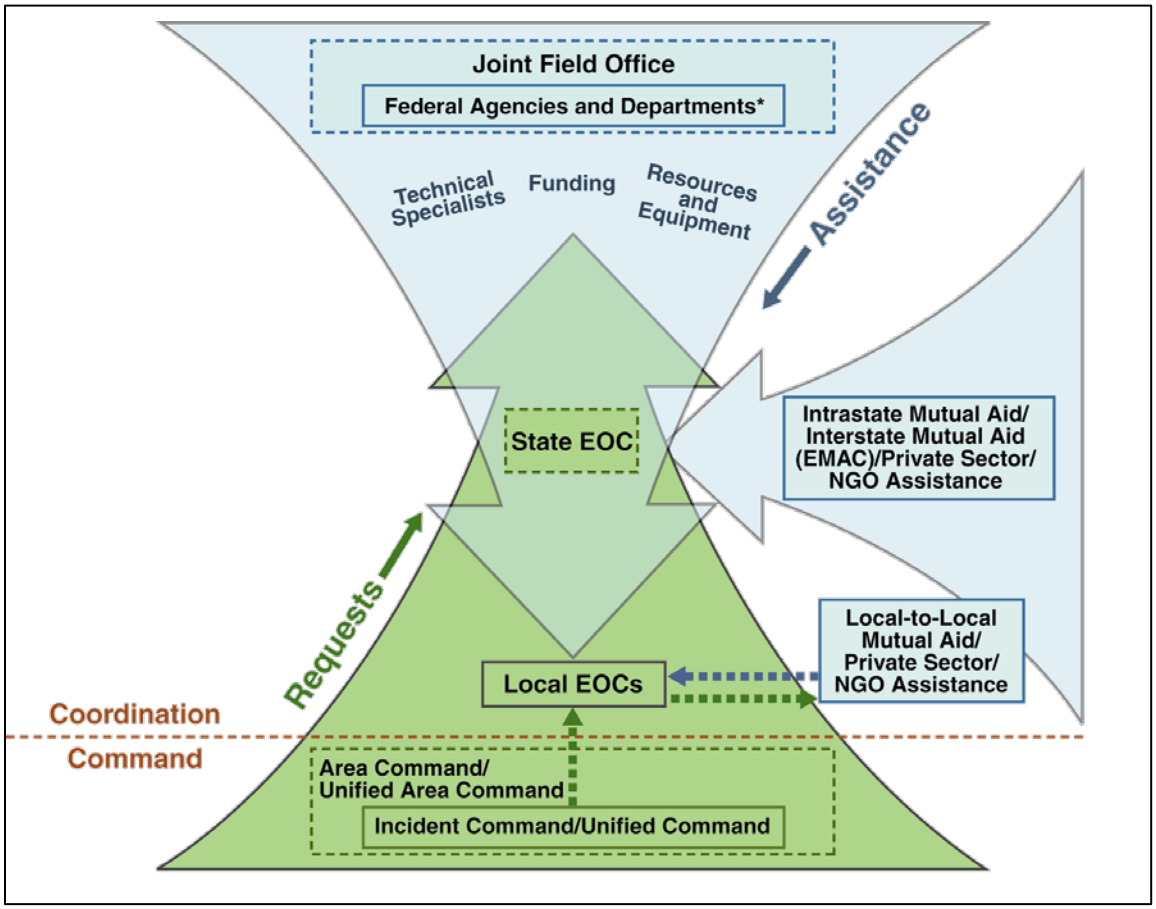
- Federal public health medical assistance consists of medical materiel, personnel, and technical assistance. ESF #8 resources may provide or facilitate the response capability for the triage, treatment, and transportation of victims or persons with special medical needs; evacuation of patients; infection control; mental health screening and counseling; environmental health services; and other emergency response needs. Some of these Federal public health and medical assets resources are:
  - The Commissioned Corps is the federal uniformed service of the U.S. Public Health Service (USPHS) and is one of the seven uniformed services of the United States. USPHS Officers support U.S. Government response efforts and can be deployed on an individual basis, such as

when specific skill sets are needed, or as part of a team, when large-scale responses are needed for any public health or medical event or incident.

- The NDMS is a federally coordinated system that augments the nation's medical response capability, which supplements the integrated national medical response capability for assisting state and local authorities in dealing with the medical impacts of major peacetime disasters. Key components include:
- Disaster Medical Assistance Teams from the NDMS
- Veterinary support from the National Veterinary Response Teams

- National stockpiles are an essential component of the National Preparedness System. The United States has a functional stockpile (repository) of medical countermeasures for both human and animal populations used to ensure states and local governments have the resources to respond to public health events in both sectors. Figure 4 shows the basic flow of requests from the state and local levels (for information or assistance) and the flow of federal assistance for all domestic emergencies in the United States.
  - In an emergency, local area commanders (whether incident command, area command or unified command) determine that local requirements for response cannot be met through local resources and transmit requests for assistance to the local and state EOCs.
  - If the requirements cannot be met within the state, including through coordination of local-to-local agreements, or through interstate agreements, the requests flow to the federal partners through the Joint Field Office.
  - The federal agencies involved respond according to the type of request based on the predetermined ESF structure. As needed, technical assistance, funding, and/or material resources and equipment can then be delivered back through the EOC chain and placed into the hands of the local responders through a combination of federal and state coordination mechanism.

Figure 4. Flow of domestic requests and assistance in the United States during an emergency.



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    - Disaster Medical Assistance Teams from the NDMS

    - Veterinary support from the National Veterinary Response Teams
  - National stockpiles are an essential component of the National Preparedness System. The United States has a functional stockpile (repository) of medical countermeasures for both human and animal populations used to ensure states and local governments have the resources to respond to public health events in both sectors.
    - The SNS, managed by CDC, includes resources like antibiotics, chemical antidotes, antitoxins, other life-sustaining medications, critical medical equipment, and supplies. The PHEMCE, described in the section on *Medical Countermeasures and Personnel Deployment*, determines the current and future content of the SNS.
    - The USDA manages the NVS as the repository of supplies, vaccines, equipment, and other veterinary resources to support state and local governments. The NVS staff helps states and local authorities plan, train, and exercise the logistical infrastructure required to receive, store, and deliver NVS resources during an emergency.
  - Federal Medical Stations (FMS) are an HHS deployable health care facility that can provide surge beds to support health care systems anywhere in the United States that are impacted by disasters or public health emergencies. Each FMS comes with the required medical equipment and personnel to establish and run an FMS. FMS are not mobile and must be deconstructed before being relocated.
  - The Medical Reserve Corps (MRC) is a national network of volunteers organized locally to improve the health and safety of their communities. They prepare for and respond to natural disasters, such as wildfires, hurricanes, tornados, blizzards, and floods, as well as other emergencies affecting public health, such as disease outbreaks. The MRC network comprises 987 community-based units and almost 200,000 volunteers located throughout the United States and its territories.
  - The Emergency System for Advance Registration of Volunteer Health Professionals (ESAR-VHP) is a federal program created to support states and territories in establishing standardized volunteer registration programs for disasters and public health and medical emergencies. The program, administered on the state level, verifies health professionals' identification and credentials so that they can respond more quickly when disaster strikes.
  - Many other resources exist, such as patient evacuation resources through the NDMS; Surge ambulances through the FEMA-administered National Ambulance Contract; Health situational awareness through the SOC and other key departments and agencies including CDC, FDA, and USDA; and technical assistance on a variety of public health and medical matters.

- During zoonotic events, HHS coordinates with USDA, the lead for ESF #11 – *Agriculture and Natural Resources*. Other departments and agencies also support as required per NRF support annexes.
  - For example, the National Animal Health Emergency Response Corps, established and managed by APHIS in 2001, is a federal volunteer recruitment and response program that supports U.S.

Government responses to exotic disease outbreaks and other disasters that affect livestock, poultry, companion animals, and wildlife.

- OSHA's Hazardous Waste Operations and Emergency Response standard provides for the employers responsibility for the protection of workers engaged in emergency responses to biological, chemical, radiological, and nuclear hazards. This standard requires an emergency response plan and training of workers that respond to public health emergencies.
- The NRF contains the hazard-specific Incident Annexes that outline the actions, roles, and responsibilities associated with a response to a human disease outbreak of known or unknown origin requiring federal assistance.

Reviewing, exercising and updating plans

- The United States conducts various types of exercises that occur frequently in the United States, often multiple times per year. All exercises involve some form of after-action review to strengthen the knowledge of existing systems, frameworks, mechanisms, and skills necessary to prepare for and implement a response in the United States. Revisions occur as needed based on lessons learned from exercises or real-world responses.
    - Examples of national preparedness capacity review examples include the 2016 National Preparedness Report and Government Accountability Office's *Opportunities Exist to Strengthen Interagency Assessments and Accountability for Closing Capability Gaps* [reissued on December 9, 2015].
- Disaster response specialists and policymakers at the local, state, and national levels participate in routine training and exercising through the DHS National Exercise Program. The National Exercise Program serves as the principal mechanism for examining the preparedness and readiness of the United States across the entire homeland security and management enterprise.
    - The purpose of the National Exercise Program is to design, coordinate, conduct, and evaluate exercises that rigorously test the nation's ability to perform missions and functions that prevent, protect against, respond to, recover from, and mitigate all hazards. The program provides a consistent method to examine and validate federal and whole-of-community partners' core capabilities.
    - Each program cycle consists of a two-year, progressive schedule of exercises selected based on their support of the National Preparedness Goal and a specific area of concern based on the national risk assessment. The types of exercises selected into the program may include facilitated policy discussions, seminars and workshops, tabletop exercises, modeling and simulation, drills, functional exercises, and full-scale exercises. All of these exercises may be sponsored by organizations from any level of government, the non-governmental and private sector, and the whole community.

- The apex of the two-year cycle is a National Level Exercise. The most recent national exercise was Capstone 2014, a complex, aggregated scenario consisting of:
  - Alaska Shield: FEMA and state emergency management agencies, including Alaska, commemorated the anniversary of the 1964 9.2 magnitude Great Alaskan Earthquake, with an exercise that tested response and mass casualty care.
  - Ardent Sentry 14: In conjunction with Alaska Shield and other exercises during the period, the DoD exercised its Defense Support to Civilian Authorities' mission.
  - Nuclear Weapon Accident/Incident Exercise: The DOE participated in the exercise with a scenario that tested response and recovery following an accident during the secure transport convoy of nuclear weapons.
  - Eagle Horizon 2014: During this exercise, many federal departments and agencies activated their continuity of operations and reconstitution planning to test their continuity plans and ensure that primary mission essential functions could take place from alternate facilities.
  - Silver Phoenix 2014: This exercise explored challenges associated with examining, prioritizing, and conducting recovery activities involving multiple geographically-dispersed and competing events using the National Disaster Recovery Framework.

- The Homeland Security Exercise and Evaluation Program (HSEEP) provides a set of guiding principles for exercise programs, as well as a common approach to exercise program management, exercise design and development, conducting exercises, post-exercise evaluations, and improvement planning.

■ *Priority public health risks and resources are mapped and utilized* *R1.2*

Public health risk assessment and resource mapping

- The SNRA participants characterized the risks in context with available national resources, grouping them into three categories: natural hazards, technological/accidental hazards, and adversarial, human-caused threats/hazards.
  - The specific results of the SNRA are largely classified. They include a comparison of risks for potential incidents in terms of the likelihood and consequences of threats and hazards, as well as an analysis of the uncertainty associated with those incidents.
- The public document about the assessment identifies that a wide range of threats and hazards pose a significant risk to the United States, affirming the need for an all-threats/hazards, capability-based approach to preparedness planning. Overarching themes include:
  - Natural hazards, including hurricanes, earthquakes, tornadoes, wildfires, and floods present a significant and varied risk across the country.

- A virulent strain of pandemic influenza could kill hundreds of thousands of Americans, affect millions more, and result in economic loss. Additional human and animal infectious diseases, including those previously undiscovered, may present significant risks.
- Technological and accidental hazards, such as dam failures or chemical substance spills or releases, have the potential to cause extensive fatalities and have severe economic impacts, and the likelihood of occurrence may increase due to aging infrastructure.
- Terrorist organizations or affiliates may seek to acquire, build, and use WMD. Conventional terrorist attacks, including those by lone actors employing explosives and armed attacks, present a continued risk to the United States.
- Within an all-hazards preparedness context, certain events with unique characteristics – such as nuclear attacks or chemical releases – require additional specialized preparedness (such as waste management planning) and response activities.
- Some events, such as explosives attacks or earthquakes, generally cause more localized consequences, while other events, such as human pandemics, may cause consequences that are dispersed throughout the country, creating different types of impacts for preparedness planners to consider.

Resources mapping for public health preparedness

- Resource mapping as a component of the U.S. National Preparedness System defines the logistics, stockpiles, experts, and funding needed to effectively respond to any type of emergency.
- The components of the National Preparedness System provide a consistent and reliable approach to support decision-making, resource allocation, and measure progress toward these outcomes.
- The National Preparedness System also defines a process for estimating capability requirements that allows consistent and reliable (and periodic review of) resource mapping.
- **The U.S. Government** regularly reviews and updates all capabilities, resources, and plans because U.S. risks and resources and preparedness efforts continue to evolve as do its preparedness efforts.

Best Practices, Challenges, Gaps, and Recommendations

The United States has developed and implemented a comprehensive, crosscutting, multihazard National Preparedness System that supports public health readiness and resiliency. The associated National Planning Frameworks and FIOPs organize specific requirements and tasks among the lead and supporting agencies, and define roles and responsibilities in a scalable and adaptive manner. The U.S. SRNA provides the ability to draw rough comparisons of the assessed events – within an order of magnitude – to view the broad differences in risk across events and plan accordingly.

FEMA's 2015 National Preparedness Report identified a number of specific challenges that are being addressed at various levels within the federal government. Among those, there are challenges in incorporating emergency preparedness into technology platforms and comprehensively assessing the impact of (attempted) corrective actions that ideally should have broad implications across the federal government. Recent public health events, including the epidemic of Ebola virus disease and regional outbreak of Zika virus, have highlighted challenges with coordinating the response to complex incidents that do not receive Stafford Act declarations.

There are opportunities for the federal public health system to examine its weaknesses in the context of technological systems and the ability to evaluate and implement corrective actions. Such an exercise would necessarily involve state and other local partners, including the private sector, and help to generate recommendations that are specific to public health. The recommendations from the National Preparedness Report should be seen as contextual guidelines for developing solutions to other gaps and challenges highlighted throughout this evaluation project.

Emergency Operations Centers

Respond 2 (R2)

JEE Target

Countries will have a public health Emergency Operation Center (EOC) functioning according to minimum common standards; maintaining trained, functioning, multi-sectoral rapid response teams and "real-time" biosurveillance laboratory networks and information systems; and trained EOC staff capable of activating a coordinated emergency response within 120 minutes of the identification of a public health emergency.

Level of Capabilities in the United States

➢ Summary

The United States has an extensive multiagency, multisectoral EOC network for coordinating information and resources to support public health incident management at all levels of government. This network is empowered, guided, and facilitated by authorities, systems and mechanisms previously identified in the section of this report on *National Legislation, Policy, and Finance* and *Preparedness*, such as PPD 8, the NRF, and NIMS. The existing authorities, systems, and mechanisms provide a foundation for the operationalization of the U.S. Government EOC network in accordance with specific plans and procedures and NIMS. Specific plans are in place for both general and specific threats and circumstances, with planning teams in multiple agencies ready to modify existing plans or begin new plans when the situations dictates.

The capability to effectively activate an EOC relies on federal government guidelines and frameworks for response structures that ensure operation centers have similar functional processes, terminologies, internal command structures, and coordination and communication protocols. Further, U.S. departments and agencies fulfill unique directives and responsibilities based on their capabilities, resources, staffing, and logistical considerations. Accordingly, the EOC operational scope and responsibilities reflect the department, agency, and sector-specific considerations in the context of the common national framework. Importantly, Federal EOCs maintain close contact with one another and, as needed, take the lead for national or international emergencies according to the NRF or as directed by the President.

Through national, state, and local EOC development and strengthening programs, U.S states maintain EOC capabilities configured to expand and contract as required to manage public health events. Additionally, most local jurisdictions, tribal governments, and territories have either a standing EOC facility or the ability to establish an EOC quickly if needed. The federal government also ensures that

from the national to local level, event -specific guidelines are available publically and disseminated throughout the EOC network and to response partners to support the domestic response. While some EOCs maintain standing watch teams, most EOCs below the national level activate to support or maintain situational awareness when an event or incident is occurring. During "steady-state," or the period between incidents, EOC activities and staffing levels may decrease significantly.

➢ Indicators

■ *Capacity to Activate Emergency Operations* *R2.1*

Triggers and activation levels for all-hazard EOC activation

- Public health EOCs have a range of scenarios, triggers, and activation levels. Triggers are developed using an all-hazard approach to preparedness and response and vary by department and agency. IHR, OIE, and FAO requirements are addressed by existing U.S. Government information requirements that prompt decision making and response activation.
- Examples of activation levels are:
  - In the HHS Secretary's Operation Center, there are four levels of activation: "1" is the highest level and indicates full activation with personnel deployed to the field; "4" is the lowest level, or the steady state. The EOC for the DOI uses a similar system.
  - CDC Division of Emergency Operations and FDA have a three-level system in place for the independent activation of their respective EOC. The EOC manager or higher-level staff in the chain of command determines the transition from one activation level to another initially. Sometimes, activation occurs in consultation with other coordinating entities, based on internal operating procedures and the nature of the incident.
- An EOC, such as the CDC and the HHS Secretary's Operation Center, frequently have multiple responses occurring simultaneously, each with their own incident management and appropriate activation levels.

Staffing and training of EOC personnel

- Most federal EOCs maintain some form of 24-hours-a-day, 365-days-a-year coverage. The EOC may only require a few personnel or an off-site duty officer to provide coverage when not activated for an event.
- EOC staff and associated multisectoral rapid response teams receive training for their roles during a response. This training also focuses on their agency's particular mission or role in the response. Departments and agencies determine the proper level of training for staff based on their roles.

Staffs also receive extensive training when hired or joining a specific response team and at regular intervals to maintain competencies and disseminate changes.

Surge staff availability and training

- Surge capabilities are essential to staffing EOCs during a response. Once an EOC is activated (or increases its activity level in some way), requests for additional personnel to be on stand-by or report for duty are disseminated first internally, and then externally, to the agency through the EOC manager or incident manager. In general, there is greater surge capacity at the federal level – see the *Preparedness* section for a description of various contingency human resource options – but than at the state levels.
- When called upon, surge personnel attend regular and just-in-time training to ensure their capability to staff and effectively manage the EOC. This training can take many forms, from specialized training provided by the EOC staff, online training, or formal training by external entities that specialize in emergency response.

■ *Emergency Operations Center Operating Procedures and Plans* *R2.2*

Emergency operations procedures

- Public health EOCs in the United States have clearly defined, yet flexible and scalable, procedures and processes in place in order to properly react to the complex reality of a response. EOC procedures account for the unique administrative requirements and staffing of the agency, bringing together the knowledge from their subject matter experts to best provide a clear and coordinated concept of operations on which to function.
- EOC plans and procedures, for example, take the form of standard operating procedures, guidance documents, protocols, checklists, flowcharts, position descriptions, terms of reference, and areas of responsibility. These documents form the central tenets of response activities for each agency and are reviewed on a regular and as-needed basis.
- Existing authorities, guidelines, and frameworks central to EOC function in the United States mandate the procedures for information sharing and dissemination. Many mechanisms, processes, and procedures for event information sharing are provided throughout this report.

Frequency of updates and records maintenance and distribution

- EOC plans and procedural documents are maintained and distributed in a number of different ways. Online or networked portal pages are commonly used, with internal permissions and controls that ensure that documents cannot be changed or lost.

- Hard copies are essential if the existing digital library is unavailable. Continuity of operations plans typically provide for a situation in which the EOC or portions of the incident management structure must transition for some reason (e.g., moving to another physical location).

EOC leadership, emergency management and situational awareness

- EOC directors or managers (depending on their administrative location within the agency) are responsible for ensuring the day-to-day readiness and staffing of the EOC. During the initial phase of a response, the same person may serve as the incident manager. If deemed necessary to ensure that the EOC itself continues to function during an incident, another qualified person within the agency may be selected as the incident manager, working alongside the EOC director/manager but ultimately responsible for decision-making with respect to the emergency response. While the incident manager role may rotate periodically, the EOC director/manager position is not likely to change.
- Alternatively, some agencies may pre-appoint a position within the EOC for the incident manager (automatically) when there is a recognized event.
- A public health EOC, depending on its activation level, typically publishes daily reports for the agency (through the Secretarial level) describing its present activation level(s) and detailing key activities. Other important situational awareness data such as extreme weather conditions, major public or political events, events being managed by another EOC, a list of situations under "watch" status, and the locations of deployed personnel are also included.
- Risk communication and public affairs specialists associated with the EOC or agency will be responsible for ensuring that the public is appropriately informed of situations and activities. The *Risk Communication* section of this report addresses these details.

■ ***Emergency Operations Program*** ***R2.3***

Examples of recent public health emergency operational exercises

- The U.S. Government has a very active and dynamic all-hazards exercise system that includes public health emergencies, and all levels of government and sectors.
  - The recurring (currently biennial) National Level Exercise is a mandatory, integrated continuity exercise for all federal executive branch departments and agencies. The focus of the exercise is to ensure national continuity in the face of all-hazards in order to ensure the preservation of our government and the continuing performance of essential functions.
  - In 2015, the annual National Level Exercises were:
    - Eagle Horizon

    - *Southern Exposure 15* was a full-scale exercise for the integration of organizations at all levels of government to demonstrate the ability to coordinate and conduct response and recovery activities during an incident at a nuclear power plant.
  - Beyond National Level Exercises and other federal exercises, departments and agencies partake in numerous regional, state, and local exercises as well as inter- and intra-agency exercises. This enables departments and agencies to further refine the mechanisms for coordination across sectors and down to the local level, which is essential to providing an effective all-hazards response.

Emergency activations within the last year

- The U.S. EOC network is extremely active, and is continually activated for one event or another. For example, between March 2014 and December 2015, the CDC's EOC alone monitored over 196 outbreaks in 127 countries in addition to Ebola and Zika.
- In 2016, U.S. Government EOCs have activated or maintained activation for events such as:
  - Zika Virus Disease Outbreak in Central and South America, the Caribbean, and Mexico.
  - Ebola Outbreak in West Africa.
  - Public drinking water contamination in Flint, Michigan.
  - Ongoing response to the wild-type poliovirus outbreak in parts of Asia.
- Relevant national, state and local EOCs have also been activated for National Special Security Events, such as Independence Day and the State of the Union Address, during which there are usually mass gatherings in Washington, D.C. and other parts of the country.

Improvement Plans, After-actions reports, and lessons learned

- Examples are:
  - CDC Ebola Response
  - Super storm Sandy Lessons Learned
  - H1N1 Improvement plan
  - H1N1 Lessons Learned
  - CDC Division of Emergency Operations scientific review board findings
  - Guidelines for public health EOC development

■ ***Case management procedures are implemented for IHR relevant hazards.*** ***R2.1***

Case management guidelines for priority diseases and IHR relevant hazards

- The management of individual cases during an emergency is coordinated according to the distribution of definitions and procedures through mechanisms for communication described in this section of the report as well as in the section on *Risk Communications*.

SOPs for management and transport of patients

- For human disease, case management guidelines are publically available for many disease conditions, including nationally notifiable (priority) diseases and IHR relevant hazards. A number of highly specialized guidelines were developed for patients with or suspected of having Ebola virus disease.
  - CDC's inter-facility transportation guidelines
  - CDC's air-to-ground patient handoff guidelines
  - DOT's guidelines for packaging of Ebola contaminated waste.
- Guidance documents for use by communities in handling patients affected by other IHR relevant health hazards (e.g. chemical and radiation events) are also available from federal agencies and national organizations.
- USDA provides similar guidelines for diseases in animals, such as highly pathogenic avian influenza.

Patient referral and transportation mechanisms

- Guidelines are publically available for use by communities in handling patient referral and medical transport for many disease conditions, including nationally notifiable (priority) diseases and IHR relevant hazards.
  - Guidance for Emergency Medical Services[9] (EMS) for Ebola virus disease
  - EMS Pandemic Influenza Guidelines for Statewide Adoption
- The study "State EMS System Pandemic Influenza Preparedness" by the Federal Interagency Committee on Emergency Medical Services (2009) indicated that most communities likely have inadequate resources to safely handle the transport of EVD patients or patients affected by other priority diseases or health hazards. Specific gaps identified at that time included:

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[9] Emergency medical services is a phrase used to describe most pre-hospital, community-based ambulance and other types of healthcare aid and rescue services that can be called upon when needed under specific rules established locally.

- Integration with ongoing pandemic influenza preparedness efforts;
- Availability of appropriate personal protective equipment for EMS personnel;
- Medical oversight of EMS and 9-1-1 systems;
- Integration of EMS systems with community mitigation strategies;
- Planning for continuity of operations and surge capacity.

- A National Association of State EMS Officials in April 2015 identified a number of "lessons learned" following the Ebola virus disease outbreak that began in 2014 that indicates that there are still significant challenges for local pre-hospital medical services.
- The HRSA Emergency Medical Services for Children program funds pediatric emergency care improvement initiatives and projects in the United States. The Pediatric Emergency Care Applied Research Network demonstrates the value of an infrastructure or network designed to be the platform from which to conduct investigations on the efficacy of treatments, transport, and care responses in emergency care settings including those preceding the arrival of children to hospital emergency departments. A national assessment indicated that a significant number of hospitals did not have disaster plans that included special provisions for children. HRSA collaborated with other national organization to develop and disseminate a planning checklist for hospitals.

Best Practices, Challenges, Gaps, and Recommendations

Public health EOCs in the United States have become indispensable components of daily situational awareness within and among the agencies responsible for protecting public health. They stand ready to assist agency leaders and technical subject matter experts to quickly mitigate health threats in all forms. Every agency with a functional role in public health maintains an EOC structure and activation plan in some form. Multiple real-world events and the National Level Exercises have allowed Federal EOCs to refine their internal procedures and develop external relationships with one another as well as with states and local jurisdictions. Organizations such as ASTM International (formerly the American Society for Testing and Materials) and the independent, non-profit Emergency Management Accreditation Program (EMAP) provide an opportunity for national and subnational EOCs to standardize many of their practices and protocols. CDC and many of the state emergency management programs have already standardized their practices and protocols.

However, there continue to be a number of domestic public health emergency management challenges. Through the after-action review and analysis of lessons learned, the United States has consistently identified several categories of system-level challenges, including a misunderstanding of individual and agency roles, responsibilities, and capacities, as well as of activities that are inconsistent with existing plans, especially during the initial response period. There are opportunities to better integrate national public health priorities into communities' local decision-making, including the coordination and management of triage and emergency medical services. Novel public health threats, those that require

extended activation periods, and those that emerge from overseas, such as Ebola and Zika virus; and situations in which multiple activation are occurring simultaneous, present situations that are difficult to plan for and that require extensive interagency and federal-state coordination and cooperation.

The U.S. Government could consider a formal policy regarding emergency management program/EOC accreditation. The United States might further development its partnerships with existing professional societies and accreditation organizations, including the WHO, to ensure that all U.S public health management programs at all levels meet or exceed minimum standards. Federal public health EOCs could also begin to collaborate within their specialized domains to coordinate operating procedures, communication procedures, information and resource management systems, and personnel training plans; and redouble their efforts to implement flexible yet interoperable technology solutions across the public health EOC landscape.

Linking Public Health and Security Authorities

Respond 3 (R3)

JEE Target

In the event of a biological event of suspected or confirmed deliberate origin, a country will be able to conduct a rapid, multi-sectoral response, including the capacity to link public health and law enforcement, and to provide and/or request effective and timely international assistance, including to investigate alleged use events.

Level of Capabilities in the United States

➢ Summary

The capacity to link public health and law enforcement, including the investigation of alleged use events, is a strong component of the U.S. public health emergency preparedness and response system. In the United States, the foundation for linking public health and law enforcement is the Joint Criminal-Epidemiological (Crim-Epi) Investigation Model. The Crim-Epi model was developed to raise the awareness levels and increase collaboration between public health, law enforcement, and other sector professionals with respect to the identification, assessment, and response to biological threats, including intentional acts. The federal government has made efforts to improve public health, law enforcement, and multisectoral response by creating frameworks/protocols and conducting training and exercises on both a national, as well as a sub-national, level. Regularly contact on a weekly or more frequent basis, as needed, between national public health and law enforcement authorities ensures timely information sharing and the coordination of response operations.

The responsible agencies maintain relevant MOU to authorize and coordinate their respective subject matter areas. Similar arrangements exist between national and local law enforcement agencies. Enforcement systems are in place, including those at points of entry into the United States that help to prevent food, medical product, and environmental contamination, and ensure the necessary monitoring. Existing laboratory systems and networks are capable of identifying select and unknown agents.

➢ Indicators

- ***Public Health and Security Authorities, (e.g. Law Enforcement, Border Control, Customs) are linked during a suspected or confirmed biological event*** ***R3.1***

Plans, MOU and other agreements between national public health and law enforcement agencies

- In 2013, the CDC and FBI signed a MOU for the identification and response to biological threats, including bioterrorism incidents. Prior to this, CDC and FBI, as well as other U.S. departments and agencies, collaborated on some well-known incidents (such as the 2001 anthrax attacks) and jointly developed guidelines for state and federal agencies on being prepared for, and responding effectively, to suspected biological incidents.
- The FDA's Office of Criminal Investigations (OCI), the law enforcement arm of the FDA, is responsible for conducting investigations of criminal violations of the Food Drug and Cosmetic Act – Title 21 of the U.S. Code. OCI has a letter of agreement with the FBI that outlines participation of OCI Special Agents assigned to National Joint Terrorism Task Force investigations. That Task Force utilizes the collective resources of the participating agencies (federal, state, and local) for the prevention, preemption, deterrence, and investigation of terrorism and activities related to terrorism, including public health -related terrorism events. Additionally, FDA has an agent assigned full time to the National Counterterrorism Center in the Office of the Director of National Intelligence and can assign personnel to subnational FBI task forces as needed.
- The National Infrastructure Protection Plan – introduced in 2006 and updated in 2013 in response to PPD 21 – links HHS, DHS, and the FBI during an incident that threatens U.S. critical infrastructure. The 2013 Protection Plan increases focus on the cross-sector and cross-jurisdictional coordination and integration of information sharing as an essential component of the risk management framework. That plan also integrates efforts by all levels of government, as well as the private and non-profit sectors, by establishing an inclusive partnership framework.

MOU at the sub-national or state level.

- At the subnational level, several states have developed protocols/MOU between their health departments and the FBI. The FBI also has a WMD Coordinator assigned to each of its field offices. WMD Coordinators are responsible for managing the office's WMD program and serve as a point of contact for emergency responders and public health at the state and local level in a threat scenario or incident potentially involving a WMD. In such an incident, the WMD Coordinator serves as a conduit for obtaining federal assistance for operational response direction and threat evaluation support.
- The DHS Office of Health Affairs, Health Threats Resilience Division (State and Local Initiatives Branch) builds partnerships with members of the public and private sector to support the integration of health security activities that promote national medical readiness efforts across the federal, state, local, tribal, and private sectors. For example, the State and Local Initiatives Branch works with situational awareness units within law enforcement agencies to imbed public health analysts who can assist with interpretation of information with a public health dimension or consequence.

- DHS CBP provides cargo/import security at over 300 land, air, and sea ports across the United States. CBP works with CDC DGMQ at those points of entry to aid in the implementation of CDC quarantine authorities.
- A number of other resources are available to guide jurisdictions in establishing agreements for cooperation, collaboration, and mutual aid:
  - A Menu of Suggested Provisions for Public Health Mutual Aid Agreements
  - Joint Public Health – Law Enforcement Investigations: Model Memorandum of Understanding (MOU)
  - Joint Criminal and Epidemiological Investigations Handbook
  - Radiological/Nuclear Law Enforcement and Public Health Investigation Handbook

Incident identification and risk assessments

- CDC and the FBI have SOP for conducting joint/shared risk assessments consistent with the CDC/FBI MOU. These SOP guide their collaboration on the identification and response to biological threats, including bioterrorism incidents.
- The FDA maintains SOP for the identification of biological hazards that support the agreement between the FDA and the FBI WMD Directorate.
- DHS publishes risk assessments prior to National Special Security Events, which may be developed jointly with the FBI. The ASPR Office of Emergency Management ensures that public health and medical risks are captured in its risk assessments.
- HHS and DHS have established specific cooperation mechanisms, to include a MOU and SOP, as part of a broad framework for cooperation to enhance the nation's preparedness against the introduction, transmission, and spread of quarantinable and serious communicable diseases from foreign countries into the states, territories, and possessions of the United States.
- All situations involving the intentional use of a biological agent require a FBI-led Threat Credibility Evaluation. The purpose of this is to determine the likelihood of an intentional incident and identify the subsequent courses of action. For suspected or confirmed bioterrorism incidents that may affect the health of the public, subject matter experts from CDC are included on the evaluation.
- DHS conducts quantitative Terrorism Risk Assessments (TRA) of biological, chemical, radiological, and nuclear events that may have deliberate intent. The TRAs accomplish this by integrating the information derived from the intelligence and law enforcement communities with input from the scientific, medical, and public health communities.
  - TRAs establish the relative risk associated with specific chemical, biological, radiological, and nuclear agents and assist with understanding which agents pose relatively higher or lower threats. The Biological Terrorism Risk Assessment is a strategic level assessment designed to 1)

aide in identifying and prioritizing credible, high-impact threats, 2) aid in identifying and prioritizing vulnerabilities and knowledge gaps, and 3) provide a systematic, science-based, common framework for "what if" analyses.

  - TRAs also help inform BARDA's development and procurement requirements for medical countermeasures, including vaccines, therapeutics, diagnostics, and non-pharmaceutical countermeasures, against a broad array of public health threats, whether natural or intentional in origin. Once developed and acquired, they are placed in the SNS (more information about the SNS is in the section on Medical Countermeasures and Personnel Deployment).

- EPA's role in a deliberate biological incident is site- and situation-specific, driven by various factors including, but not limited to, the type and amount of agent released, the release scenario, the affected areas, the environmental persistence of the agent, and the capabilities and capacity of state/local authorities. In biological incidents, EPA's role may include actions to mitigate threats to human health and the environment including containment, environmental characterization, clearance sampling, decontamination, waste management, and responder health and safety. In preparing for potential responses, EPA focuses on the following key activities:
  - Develops operational/tactical guidance that relies upon the latest science and technology and addresses sampling, decontamination, and waste management, and health and safety;
  - Develops and provides response training focused on EPA's role in biological response;
  - Develops analytical capability and capacity to support processing environmental samples
  - Leads bench and applied field research aimed at improving existing technologies and developing new technologies applicable to sampling, analysis, and decontamination (including waste management); and,
  - Partners with federal, state, and local governments for tabletop and full scale exercises that address EPA's role in bio response.
- In addition to State and Local Public Health Departments, the National Guard "Civil Response Support Teams" located throughout the United States are available to support incident response.

Examples of training and exercises

- In 2008, the CDC and FBI implemented a training program based on the Joint Criminal and Epidemiological Investigations Handbook. The training is available to public health, law enforcement, and multisectoral (agriculture, food safety, military, and academia) personnel at the national and regional level. The purpose of the training is to build relationships between participants and promote the use of methodologies described in the handbook (information sharing, joint threat assessment, joint investigations/interviews) for the identification, assessment, and response to biological threats, including bioterrorism incidents. To date, CDC and FBI have conducted 50 workshops, training over 4,200 participants.

- The FDA Office of Regulatory Affairs and OCI routinely participate in joint public health and law enforcement training workshops and tabletop exercises that address WMD. FBI, DHS, USDA, and FDA have participated in multiple exercises that include information sharing and joint investigations/responses.
- EPA has collaborated with the FBI on developing guidance and conducting training and exercises to facilitate transitioning between the FBI's investigative phase of an incident to the clean-up and clearance processes overseen by the EPA.
- CDC, FBI, and DoD implemented joint investigation activities for the response to the 2015 DoD Anthrax Sample Investigation into the Inadvertent Shipment from Dugway Proving Ground of Live Anthrax Spores. Additionally, CDC and FBI utilized their 24/7 on-call duty officers/agents to respond to routine incidents (e.g., threat letters, ricin-related incidents, case reports of illness) involving biological threats.

Examples of legislation allowing detention and quarantine of persons for public health reasons

- The Secretary of HHS has statutory responsibility for preventing the introduction, transmission, and spread of communicable diseases from foreign countries into the United States or its territories, and from one state or territory to another. The legal foundations for these activities are Titles 8 and 42 of the U.S. Code and relevant supporting regulations.
- Under delegated authority from the Secretary of HHS, the Director of CDC has authority to detain, quarantine, and isolate individual(s) who are reasonably believed to be infected with certain diseases listed by the President by executive order. Title 42 U.S. Code Sections 264 – 272 (Public Health and Welfare) and Title 42 CFR Parts 70 (Interstate Quarantine) and 71 (Foreign Quarantine) specifically address this area of concern.
- Individual state and territorial legislatures establish laws and rules for detention and quarantine within their respective jurisdictions, establishing support agreements with Federal authorities where needed.

Information sharing and reporting

- HHS, CDC, DHS, DoD, FDA, EPA, and FBI develop reports (either for public or government use only) that are regularly shared between operations centers of the public health and security agencies during steady state conditions as well as during a response.
- CDC and FBI conduct weekly conference calls to share informational reports related to recent biological threats/incidents. For emergencies, the CDC and FBI utilize 24/7 on-call duty officers/agents to provide notification of incidents/threats that may affect public health and safety. The CDC-FBI MOU specifies the public health and law enforcement triggers, as well as a timeframe

for notification. As part of the weekly meeting, CDC provides a summary of LRN test results (clinical and environmental) for high priority biological threat agents.

- The DOI National Park Service produces reports for high-profile cases and outbreaks and shares them internally with the Offices of Public Health, Emergency Management, and Law Enforcement and Security.
- The FBI has created the International Biosecurity and Prevention Forum (IBPF) website to enable international sharing of biosecurity best practices across individuals working in law enforcement, public health, one health, academia, industry, government and policy.

Collaboration with International Criminal Police Organization (INTERPOL)

- The FBI has direct interaction with INTERPOL and maintains several liaison officers detailed there, to include a representative from the WMD Directorate responsible for preventing and responding to suspicious biological incidents. The FBI and INTERPOL hold weekly conference calls to provide updates on ongoing projects and recent incidents related to biological, chemical, and radiological matters, to include incidents with the potential to impact both public health and law enforcement.
- FDA OCI has full time Special Agents assigned to INTERPOL and the European Criminal Police Organization (EUROPOL).

Best Practices, Challenges, Gaps, and Recommendations

The United States has had considerable experience in the last few decades in dealing with health security threats, both naturally occurring and intentional. The responses to real-world events have resulted in strong collaborations between the public health sector, health systems, research scientists, laboratories, law enforcement, and other sectors (animal health, food safety, customs) at the national and subnational levels. Formal written agreements are in place among all of the relevant federal agencies, and the FBI has reached out to health and law enforcement offices at the state level to coordinate and align response protocols for biological threats. In addition to response activities, many of the federal agencies are engaged collaboratively through various program activities such as the CDC LRN, the Integrated Consortium of Laboratory Networks, and the DHS TRAs, which contribute to preparedness at the national level. The National Level Exercise program, which may include subnational entities, helps to support planning, develop capacities (information sharing, assessment, joint investigations), and test capabilities for the response to multiple types of threats. To assist with international law enforcement collaboration, the FBI and other federal law enforcement agencies maintain direct connections with the international security community.

While the United States has achieved the primary goal of implementing a multisectoral response to biological threats, there are still areas for improvement. Due to the normal turn-over in positions, there is likely to be a cadre of public health, law enforcement and other sector personnel who do not possess

a clear understanding of agencies' roles, responsibilities, and capacities. This lack of understanding may contribute to a delay in identification, assessment, and investigation of biological threats. Therefore, basic, advanced level, and recurring training in Crim-Epi is needed at the national and subnational levels. Another area for improvement is the development and refinement of written protocols at all levels that describe those roles and responsibilities specific to each jurisdiction. In the United States, public health authority is primarily at the subnational level. Therefore, the FBI and state/territorial/local/tribal public health departments need unique written protocols and MOU.

Medical Countermeasures and Personnel Deployment

Respond 4 (R4)

JEE Target

A national framework for transferring (sending and receiving) medical countermeasures (MCM) and public health and medical personnel among international partners during public health emergencies.

Level of Capabilities in the United States

➢ Summary

In recent years, many events have demonstrated the need for international public health and medical assistance, including the responses to the 2009 H1N1 influenza pandemic, the earthquake in Haiti in 2010, the earthquake and tsunami disasters in Japan in 2011, the Ebola outbreak in 2014, and the ongoing Zika virus outbreak. One of the lessons learned from these events is the need for the United States to have international preparedness and response policies and plans in place to strengthen the capacity for providing international assistance as needed.

The United States manages robust domestic systems for the development, stockpiling, distribution, and dispensing of medical countermeasures, as well as the deployment of federal public health and medical personnel when and where they are needed. However, despite these systems, the United States recognizes that no single country can afford to make available the wide variety of medical countermeasures required to prevent or mitigate all potential threats, or ensure enough qualified personnel are available for multiple, large-scale situations. As a result, building on the expertise developed through unprecedented domestic preparedness efforts, the U.S. Government has also developed corresponding policies to address the legal, regulatory, and logistical challenges associated with transferring these resources across international borders during public health emergencies.

While the United States has a robust domestic preparedness infrastructure and substantial experience with these issues, the complexity of the challenges related to international deployments of public health assets is now being addressed. The coordination required to solve these challenges is a clear example of the many opportunities for improvement. In recognition of this fact, the United States works continuously to exercise policies and plans to receive, consider, and respond to international requests for assistance during public health emergencies. Given that U.S. health security is fundamentally linked to global health security, these cross-border policies are developed and exercised in coordination with bilateral, regional, and multilateral partners where possible.

➢ Indicators

■ *System is in place for sending and receiving medical countermeasures during a public health emergency* *R4.1*

Medical countermeasures

- The foundation for the U.S. system of determining and prioritizing research, development, acquisition, stockpiling, and maintenance requirements for medical countermeasures is the PHEMCE, led by HHS ASPR. The PHEMCE brings together all federal agencies in charge of protecting the civilian population from potential adverse health impacts using medical countermeasures. Key roles and responsibilities within this system include:
  - The 2015 PHEMCE Strategy and Implementation Plan leverages multiple U.S. Government capacities and creates incentives for private industry to:
    - Identify, create, develop, manufacture, and procure critical medical countermeasures.
    - Establish and communicate clear regulatory pathways to facilitate medical countermeasure development and use.
    - Develop logistics and operational plans for the optimized use of medical countermeasures at all levels of response.
    - Address medical countermeasure gaps for all sectors of the American civilian population.
  - CDC maintains the SNS, which contains large quantities of pharmaceutical and non-pharmaceutical medical supplies that can augment local resources to protect the American population in the event of a public health emergency (e.g., terrorist attack, influenza outbreak, or earthquake). The logistics system is designed to provide adequate and rapid delivery of medical countermeasures for all types of incidents and includes antibiotics, antidotes, antitoxins, life-support medications, equipment for intravenous administration of drugs, airway-maintenance supplies, and other medical/surgical items in a large-scale emergency. The SNS also includes special products that are not commercially available.
  - HHS CDC and ASPR BARDA implement and maintain contracts with medical countermeasure manufacturers and distributors for the procurement of medical countermeasures for stockpiling prior to a public health emergency as well as for the rapid surge production and delivery of countermeasures during a public health emergency.
  - FDA works closely with CDC on legal and regulatory issues related to the stockpiling of medical countermeasures in the SNS. FDA also works closely with PHEMCE partners and manufacturers to approve, license, and clear medical countermeasures, or to authorize medical countermeasures for emergency use when appropriate (e.g., under the Emergency Use Authorization authority under section 564 of the Food, Drug, and Cosmetic Act) so that they are

available for stockpiling and response purposes. Additionally, FDA has entered into various MOU, cooperative agreements, and confidentiality commitments with international partners to facilitate the sharing of information to expedite the development and availability of medical countermeasures.

- In addition to the primary SNS, agencies such as DHS, DoD, and USDA maintain their own stockpiles unique to their areas of responsibility.
- As described in detail in the section on Linking Public Health and Security, the DHS TRAs inform development and procurement decisions made by BARDA.

U.S. policies for deploying medical countermeasures domestically

- The United States domestically deploys medical countermeasures from the SNS when local and state level resources prove inadequate for the event. The Secretary of HHS is the operational authority for release of the SNS, but depending on the scope of the event, this authority is delegated to the ASPR and the Director of the CDC. The process for managing requests for medical countermeasures from the SNS is identified in the SNS Emergency Operations Plan, which includes threat -specific annexes for planning considerations and logistical requirements associated with the countermeasures for each threat.
- Significant investments have been made through PHEP grant funding and federal programs for training, exercising, and evaluating medical countermeasure response functions. CDC's emergency operations plan for the SNS specifically addresses the logistics and security of transportation and delivery to the state and local levels. With forward-placed caches, CDC is able to rapidly deploy SNS inventory to any jurisdiction in the United States.
- Contracts with commercial third party logistics and transportation partners under CDC oversight and management are used to ship and deliver medical countermeasures from the SNS. The receipt and distribution of these medical countermeasures at the state and local levels is the responsibility of the receiving jurisdiction, and the responsibilities are identified in each jurisdiction's response plans and processes.
- CDC guidance to state and local partners (Receiving Distributing and Dispensing SNS Assets V.11) provides specific requirements for receiving, distributing, and dispensing medical countermeasures, and each state and locality is required to have jurisdiction-specific plans for carrying out these functions. These plans were most recently tested in August 2015 during a full-scale exercise, involving partners at the federal, state, and local levels, which tested plans, policies and processes in place to respond to a bioterrorism attack and allowed for the evaluation of anthrax response operations.
- The DoD also has an interagency memorandum of agreement with HHS/CDC/SNS regarding the sharing of assets and resources.

U.S. policies for deploying medical countermeasures internationally

- To address international requests for medical countermeasures from the SNS, HHS has developed and implemented a policy framework and an interagency process to receive, consider, decide on, and respond to such requests.
  - Requests for medical countermeasures are routed to the International Sharing of Medical Countermeasures Policy Group (ISMPG), a group of subject matter experts and stakeholders led by HHS. The ISMPG reviews and makes recommendations for senior leadership (Assistant Secretary or Secretary depending on the request) on each request for international medical countermeasure assistance using principles and criteria outlined in the framework.
  - The ISMPG considers and addresses legal, logistical, and regulatory concerns during the review and recommendation process to determine the feasibility of supporting the request for countermeasures in a clinically relevant timeframe. These considerations outlined in the framework include:
    - Legal limitations or barriers to international deployments of medical countermeasures;
    - Legal authorities and existing deployment mechanisms;
    - Liability protections for manufacturers and other stakeholders involved in the development and deployment of emergency medical countermeasures;
    - Funding issues including the cost of the deployment;
    - Regulatory authorization processes for public health emergencies;
    - Import and export requirements; and,
    - Logistical concerns (such as the maintenance of cold-chain requirements).
- While the preferred option for the shipment and delivery of medical countermeasures from the SNS is the use of commercial logistics and transportation partners, military or other U.S. Government transport options may be considered depending on the circumstances.
- For pandemic influenza, an additional framework, applicable to the entire U.S. government, has been developed to provide a whole-of-government approach to receiving and making decisions about requests for assistance during influenza pandemics. Among other functions, the framework's processes improve situational awareness, deconflict and/or adjudicate multiple international requests for the same assets across Departments, and create opportunities to weigh domestic versus international needs.

International collaborations related to medical countermeasure deployment

- In 2011, U.S. President Barack Obama and Canadian Prime Minister Stephen Harper launched the Beyond the Border Initiative. It seeks to identify and overcome specific legal, regulatory, and

logistical barriers to the cross-border deployment of medical countermeasures between the United States and Canada.

- NAPAPI is a trilateral partnership between the United States, Canada, and Mexico that outlines how the three countries intend to work together to prepare for and manage animal influenza or a novel strain of human influenza in the region. NAPAPI members are committed to addressing the persistent legal, regulatory, and logistical barriers to sharing pandemic influenza vaccines and therapeutics. They have agreed to share medical countermeasure strategies and requirements for animal and pandemic influenza.
- GHSI is an informal, international partnership among like-minded countries, which strengthens health preparedness and response globally against threats of biological, chemical, radiological, and nuclear terrorism and pandemic influenza. Through GHSI, the United States has led the development of policies and procedures that describe and address the considerations and mechanisms that countries could use to request vaccine from the international community and to receive deployments from potential donors. One key issue, for example, is the development of legal terms and conditions that donors – governments, manufacturers, or non-governmental organizations – will use to transfer products to requesting countries. Just as importantly, these terms address legal liability for any adverse events related to the distribution and use of a product. GHSI has worked to prepare model terms to avoid delays during an actual emergency.
- HHS has also identified the need to assist potential recipients to rapidly assess the quality, safety, and efficacy of novel or unlicensed medical countermeasures. The existing WHO prequalification procedures are not flexible or adaptable enough to be used for novel products or those that have not yet received approval by national regulatory authorities. As a result, HHS is funding WHO through a cooperative agreement to create a process for WHO to rapidly review available medical countermeasure data on quality, safety, and efficacy where possible.

Receiving medical countermeasures from international partners

- The United States may have requirements for medical countermeasures that may prevent them from being secured in the required time or quantity from the national stockpile or through contractual mechanisms. The International Assistance System (IAS), jointly managed by DHS FEMA and the DoS, is used to receive, review, and manage incoming offers of assistance from international partners during a domestic disaster in the United States. Per the IAS, FEMA may seek to fill requests for specific operational needs through either direct purchases or donations from international partners. In these cases, the International Resources Coordination Group is convened to coordinate and manage all aspects of these purchases or donations, from legal agreements and regulatory approval to logistical concerns. To manage these tasks, the Consortium will rely on technical representation from key government stakeholders as well as technical annexes to the document,

which includes processes and information requirements for moving both medical countermeasures and public health and medical personnel into the United States during emergencies.

- HHS is currently developing a companion framework to the IAS that will further describe roles, responsibilities, and procedures. An internal exercise is being planned for 2016 to test logistical, regulatory, and policy processes related to receiving medical countermeasures into the United States.

Lessons learned from international medical countermeasure deployments

- The U.S. Government engages in a continuous process of exercising policies and operational plans, and observing and implementing lessons learned from real-world responses to public health and medical emergencies. U.S. and international partners have identified the following gaps and best practices related to international medical countermeasure deployment:
  - Departments should work together prior to an event to identify all statutory, legal, and policy authorities that would impact deployment or receipt of medical countermeasures.
  - Model liability terms and conditions for the international deployment of medical countermeasures should be developed.
  - Appropriate regulatory body and develop processes (e.g. determine data requirements needed for emergency approval) should be identified to allow the emergency use of unapproved countermeasures or unapproved use of approved countermeasures during a public health emergency.
  - Import and export regulations that govern the movement of medical countermeasures should be identified, especially for those countermeasures that do not have the necessary regulatory authorization for use in the recipient country.
  - Logistical processes to move shipments of medical countermeasures rapidly should be identified and developed.
  - A comprehensive checklist of general required documents, licenses, and/or approvals necessary for the import and export of both approved and unapproved emergency medical countermeasures across the border should be developed.
  - Mechanisms for paying or accepting reimbursement for costs related to the deployment of medical countermeasures (e.g. logistics, replenishing the stockpile) should be identified.

■ ***System is in place for sending and receiving health personnel during a public health emergency***

R4.2

U.S. policies for domestic deployment of public health and medical personnel

- In the United States, the primary responsibility for emergency response rests with local governments. As a result, the federal government maintains a comparatively small number of public health and medical response teams. The primary mission of these teams is to support or supplement U.S. state and local responses as needed. Within HHS, these assets include deployable NDMS teams and USPHS Commissioned Corps.
- The Secretaries of the U.S. departments and agencies have the authority to send personnel on details and assignments as needed in order to assist with public health emergency responses. Prior to deployment of federal personnel, the U.S. government agencies coordinate with state and local jurisdictions to include official "invitations" from state officials.
- States may request short- or long-term personnel assistance for programmatic work, or short -term assistance with outbreaks. Personnel working in a state may be reassigned during emergencies under certain conditions

U.S. policies for international deployment of public health and medical personnel

- CDC is an important and active member of the WHO Global Outbreak Alert and Response Network (GOARN). A CDC expert is currently the Chair of the GOARN steering committee. Under GOARN, individual subject matter experts may be deployed for short periods to support epidemiologic investigations and health consultations.
- With respect to large-scale and longer-term surge response, most medical and public health response teams in the United States are designed, organized, and trained to respond domestically. If called to deploy across international borders, the United States and recipient country(ies) must address legal, regulatory, logistical, and funding issues.
- To address international requests for HHS public health and medical personnel, HHS has developed a policy framework and an interagency process to receive, consider, decide, communicate, and respond to such requests.
    - The personnel framework supports coordination between HHS and other U.S. departments when there is a request for international deployment of health personnel. Facilitated by ASPR, the HHS International Policy Group for Personnel Sharing (HIPPS) receives and reviews those requests and makes recommendations to federal leadership based on a number of predefined principles. The HIPPS has representatives in multiple U.S. departments and agencies.
    - The HIPPS considers legal, regulatory, and logistical concerns during the review and recommendation process to determine the feasibility of a deployment under the given circumstances. Considerations include issues such as:
        - Legal authorities and deployment mechanisms;
        - Identifying appropriate personnel and/or capabilities;
        - Impact deployment will have on primary duty locations' resources and operations;

  - Recognition of responders' medical credentials, licenses, and professional certifications, or obtaining waivers for those requirements from the host country;
  - Liability protections;
  - Availability/feasibility of logistical and operational support (including sustenance, lodging, command and control, and force protection);
  - Plans for medical evacuation of deployed staff in the event of illness or injury;
  - Plans for addressing mental and behavioral health of returning personnel, including plans for screening and re-integration into the workforce, the community, and their families;
  - Medical products, supplies, and equipment being deployed with personnel; and,
  - Funding sources.

- CDC's Emergency Management Program has a health and safety unit to address deployment safety and health concerns. The Deployment Risk Mitigation Unit is CDC's team that oversees and ensures the safety, resiliency, and well-being of responders to include safety and security while deployed.
  - CDC approaches addressing safety concerns for health personnel during an international deployment in many ways. For example, the *What to Know Before You Go* seminar provides a review of safety considerations and recommendations for deployed staff. The seminar and companion documents address resiliency and an option to link staff to the resources available at the Embassy, as needed.
  - In response to the increased number of lengthy and complex deployments, the CDC routinely places a safety officer in locations where CDC staffs are deployed. For example, during the 2014 Ebola Response, CDC located a safety officer in the Ebola affected countries to provide technical expertise, support to, and monitoring of responders. Other health monitoring of activities included medical monitoring upon return from deployment as required, and obtaining lessons learned from responders returning from deployment to update procedures and provide constant process improvement.

Bilateral and multinational collaborations related to international personnel deployment

- Similar to the development of mechanisms for sharing medical countermeasures, Beyond the Border seeks to identify and overcome specific legal, regulatory, and logistical barriers to the cross-border deployment of public health and medical personnel between the United States and Canada.
- ASPR co-leads the GHSA Respond-3 Action Package with the Ministry of Health of Chile. The United States, Chile, and PAHO have formed a working group to draft a background document and outline a work plan. The background paper describes the challenges to cross-border deployments of public health and medical personnel and compiles information about the variety of national and international efforts underway to address those challenges. As a next step in 2016, ASPR will use this preliminary research to develop a multi-year cooperative agreement with PAHO that will be

used to both implement the WHO International Emergency Medical Team Initiative in the Americas and address the five-year target of the Respond-3 Action Package.

Receiving public health and medical personnel during U.S. domestic disasters

- Jointly managed by FEMA and the DoS, the IAS is used to receive, review, and manage incoming offers of assistance from international partners during a domestic disaster in the United States. Similar to process used for the deployment of medical countermeasures, the International Resources Coordination Group coordinates and manages domestic deployment of foreign personnel, including legal agreements, logistical concerns, and operational coordination.
- HHS is currently in the process of developing a companion framework to the IAS that will describe the roles, responsibilities, and processes that HHS will use to manage international offers of public health and medical assistance. An internal exercise is being planned for 2016 to test logistical, regulatory and policy processes related to receiving foreign personnel into the United States.

Best Practices, Challenges, Gaps, and Recommendations

As a result of the large number of international requests to share medical countermeasures, medical assistance, and public health personnel during emergencies, the United States has established unique policies to receive, consider and respond to those requests. The policies are based on a strong domestic capacity for the stockpiling and deployment of medical countermeasures, and experience identifying and deploying health and medical personnel to respond to public health emergencies. The U.S. Government is also aware of the value of complementary policies and procedures that permit the receiving medical countermeasures and personnel from other countries in the face of an overwhelming, domestic public health emergency.

Aside from specialized public health rapid responders from CDC or GOARN, limited deployments of medical stockpiles for small outbreaks, and the experience in establishing the Ebola virus countermeasure clinical trials in West Africa, a number of gaps and challenges remain for the large-scale movement of material and personnel. While the U.S. response capabilities are well designed, organized, positioned, and funded for domestic response, moving them quickly to respond to an international emergency continues to present numerous logistical, administrative, legal, and financial difficulties. To move such assets across international borders during a public health emergency requires both donor and recipient countries to be prepared to address many complex issues very quickly.

For international medical countermeasure deployments, policy implementation actions could focus on securing rapid funding options for medical countermeasure procurement, transportation, and distribution in partnership with the United Nations system, private manufacturers, and potential donor nations. Furthermore, the United States could work with potential recipient countries, manufacturers, WHO, and non-governmental organizations to enhance the legal, regulatory, and logistical

preparedness at various levels to rapidly receive medical countermeasures, including novel or unapproved products. Similarly, to facilitate cross-border deployments of public health and medical personnel, the United States could begin working on explicit authorities and support for large-scale international missions. There is also an opportunity for the United States to play an active role in the creation of new global policies and systems for the procurement and distribution of medical countermeasures, as well as in the identification and deployment of public health and medical personnel.

Risk Communication

Respond 5 (R5)

JEE Target

State parties should have risk communication capacity which is multi-level and multi-faced real time exchange of information, advice and opinion between experts and officials or people who face a threat or hazard to their survival, health or economic or social well-being so that they can take informed decisions to mitigate the effects of the threat or hazard and take protective and preventive action. It includes a mix of communication and engagement strategies like media and social media communication, mass awareness campaigns, health promotion, social mobilization, stakeholder engagement and community engagement.

Level of Capabilities in the United States

➢ Summary

The United States is able to identify, develop, and disseminate public messages that rapidly and efficiently communicate risks, strategies, and actions to appropriate stakeholders through multi-level and multi-faceted mechanisms and processes. Risk communicators in the United States leverage new technologies, messages reach multiple, targeted populations, and feedback and rumors are quickly addressed. Agencies, especially those that might take the lead for a specific type of health emergency, have well developed risk communications teams that are integrated into leadership and operations through both strategic and tactical activities. In large and/or complex responses, including terrorist incidents, agencies are able to collaborate and coordinate through existing incident management structures and the Joint Information Center (JIC).

Recognizing that individuals are increasingly connected through large and distributed networks, risk communication offices in the United States frequently use social media, crowdsourcing, and other technology-based networks for information dissemination, service delivery, and behavioral modification. Community engagement before, during, and after a major public health event is a component of the national approach to public health security. The dissemination of key messages is facilitated through a number of public health readiness campaigns, websites, and social medial accounts that are specifically designated for communicating with the public about health emergencies. Numerous outlets for reliable health information have gained popular recognition including the National Public Health Information Coalition and the Health Alert Network, among others.

➢ Indicators

■ *Risk Communication Systems (plans, mechanisms, etc.)* *R5.1*

National risk communication plans and multiagency coordination

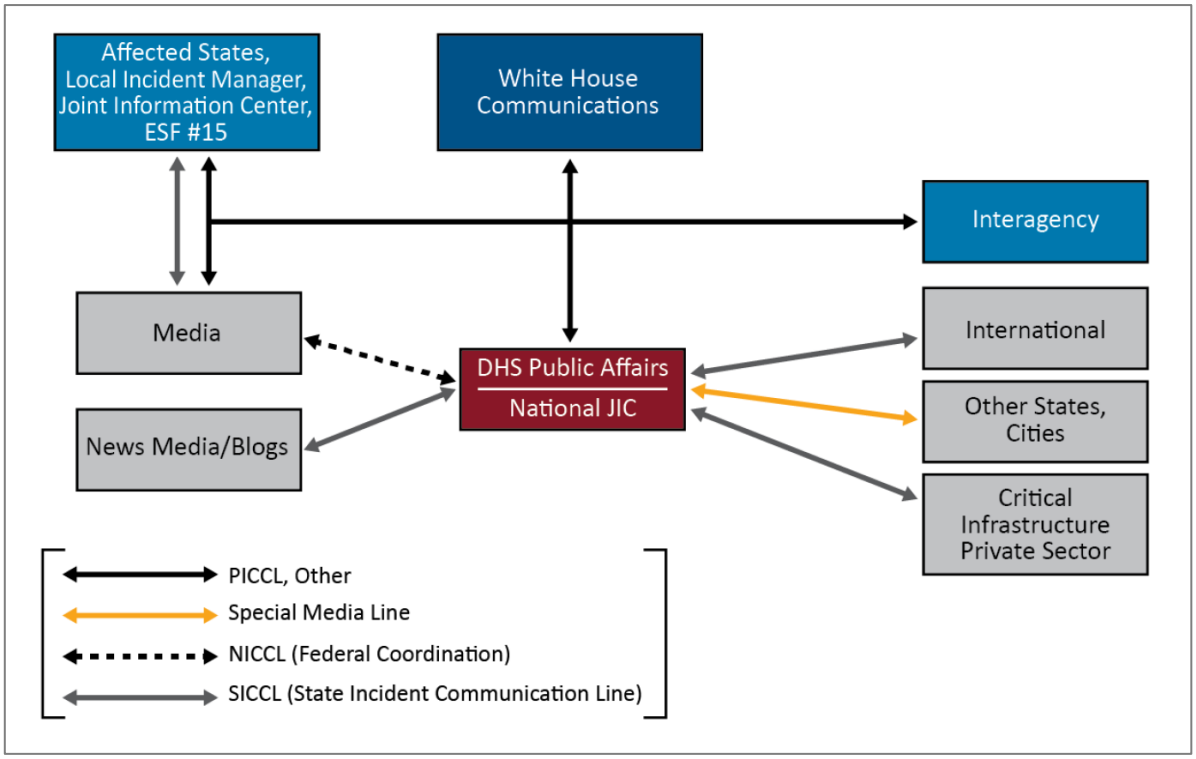
- The United States has a number of plans, mechanisms, and resources to coordinate and facilitate risk communication within individual departments and agencies, as well as across the entire U.S. Government during a public health event. The NRF Incident Communications Emergency Policy and Procedures (ICEPP) provide detailed guidance to federal incident communicators during a coordinated federal response.
    - The NRF ESF #15 - *External Affairs* (overseen by FEMA and, during an emergency, the National JIC (U.S. agencies have agreements, processes, and protocols in place for risk communications. The National Incident Communication Conference Line (NICCL) is an established network of lead communicators among the federal departments and agencies. The relationships between the federal government, components of the public, and the National, State and Private Incident Communication Conference Lines are shown in (abbreviated in the legend as NICCL, SICCL, and PICCL, respectively).
    - Staffing and budgets for risk communication
    - Communications is a primary component in response planning, staffing, and funding for U.S. departments and agencies. Examples include:

CDC maintains a JIC, a key component of CDC's EOC, which coordinates the activities of large numbers of communication personnel.

- The DoD's Military Health System, through the Defense Health Agency, has a communication division responsible for responding to public information needs.
    - Within DOI National Park Service, large national parks have full-time public information officers. Smaller parks may have staff members with collateral duties to provide public information or they rely on the regional support and capacity. The National Park Service Office of Public Health provides subject matter expertise in the development of all public information and messaging.
    - Figure 5 ensures that sufficient federal assets are available to provide accurate, coordinated, timely, and accessible information to audiences affected by an emergency through community engagement, social mobilization, and risk communication.
    - During emergencies, the U.S. Government provides pro-active, strategic communication plans and messages that anticipate and respond to public information needs. Public communications receive carefully vetting, which means that no communications are entirely informal, although they vary in the level of formality.

- During domestic public health emergencies, DHS and HHS collaborate as respective leads for ESF #15 and ESF #8. According to the ESF #15 SOP, HHS coordinates public health and medical messages across the federal government to ensure accuracy, consistency, and timeliness so that affected individuals and communities can make sound decisions about protecting health.
- In the event of a terrorist incident, the FBI would be consulted before issuing sensitive media/press releases.

Figure 5. Organization of the National Joint Information Center and lines of communication during an emergency response.



- U.S. agencies have agreements, processes, and protocols in place for risk communications. The National Incident Communication Conference Line (NICCL) is an established network of lead communicators among the federal departments and agencies. The relationships between the federal government, components of the public, and the National, State and Private Incident Communication Conference Lines are shown in Figure 5 (abbreviated in the legend as NICCL, SICCL, and PICCL, respectively).
  - In addition to the communication between the media and the DHS Public Affairs unit through the NICCL, the State Incident Communication Conference Lines provide the affected states and local incident managers, private industry (such as those responsible for critical infrastructure) and possible international stakeholders with similar access to the public.

- A Private Incident Communication Conference Line can be used to connect DHS, local incident managers, and other responding agencies with the White House communications office.
- Other special medical lines can be created as needed to advise non-affected states or cities about critical preparation and response activities.

Staffing and budgets for risk communication

- Communications is a primary component in response planning, staffing, and funding for U.S. departments and agencies. Examples include:
  - CDC maintains a JIC, a key component of CDC's EOC, which coordinates the activities of large numbers of communication personnel.
  - The DoD's Military Health System, through the Defense Health Agency, has a communication division responsible for responding to public information needs.
  - Within DOI National Park Service, large national parks have full-time public information officers. Smaller parks may have staff members with collateral duties to provide public information or they rely on the regional support and capacity. The National Park Service Office of Public Health provides subject matter expertise in the development of all public information and messaging.

Risk communication training and exercises

- The DHS National Exercise Program serves as the principal mechanism for examining the preparedness and readiness of the United States across the entire homeland security and management enterprise. The purpose of the National Exercise Program is to design, coordinate, conduct, and evaluate exercises that rigorously test the nation's ability to perform missions and functions that prevent, protect against, respond to, recover from, and mitigate all hazards. As a component of the National Preparedness System, the National Exercise Program provides a consistent method to examine and validate federal and whole-community partners' core capabilities. Departments and agencies also coordinate agency-specific and intra-agency exercises, workshops, and tests in addition to the National Exercise Program on regular and *ad hoc* schedules to ensure interoperability.
- CDC's *Crisis and Emergency Risk Communication* (CERC) is a validated approach to communicating effectively during emergencies described in detail below. Training material and other resources draw from lessons learned during public health emergencies and research in the fields of public health and emergency risk communication.
- The U.S. Government trains federal, state, private, and non-governmental partners, and other personnel to ensure that knowledge, skills, and abilities needed to perform key communication tasks are available during an emergency. Departments and agencies provide training based on information derived from the assessments, strategies, and plans developed in previous steps of the

preparedness cycle. The federal government coordinates with regions, states, and urban areas to review and establish priorities for training and exercises.

- Recording, reporting, and implementing lessons learned is a well-established part of preparedness and response in the United States, to include risk communications. Identifying lessons learned and innovative practices, analyzing recurring trends, sharing knowledge within departments and agencies and openly across public and private sectors are standard practices for both simulated exercises and after real-world events. Subsequent modifications to existing plans, processes, and practices are properly communicated to relevant staff and incorporated into existing training and guidance.

Supplemental information related to risk communication systems

- National response plans – communication sections
  - FDA Emergency Operations Plan (EOP) provides specific significant detail for risk communication and public affairs (March 2014)
  - Office of Public Health Preparedness and Response Division of Emergency Operations
  - CDC video: A New Era of Preparedness
- Crisis and risk communication tools and templates for state and local jurisdictions
  - CDC's CERC
  - Risk Communications for State and Local Agencies
  - CDC Mutual Aid Agreements
  - Using the Strategic Partner Framework
  - Clinician Outreach and Communication Activity (COCA)
  - Health Alert Network (HAN)
- Organizational Charts
  - USDA organizational chart
  - EPA organizational chart
  - CDC organizational chart
- Documenting lessons learned and refinement of communication activities
  - CDC's CERC "Shared Learning"
  - Emergency Preparedness and Response [video] *"A New Era of Preparedness"*

■ ***Internal and Partner Communication and Coordination*** ***R5.2***

Government-to-Government communications

- From initial notifications to final recovery actions, the federal government seeks to speak with a unified voice and consistent message that is coordinated not only with the different Federal authorities involved in an incident, but also with affected international, state, tribal, and local authorities. Federal-local coordination is achieved through mechanisms like NICCL as well as through the parallel State Incident Communication Conference Line.
- For international emergencies, relevant departments and agencies who maintain relationships with WHO, other international health organizations, and foreign ministries coordinate with their counterparts. In addition, if international content is going to be published or reported in U.S. publications, such as the MMWR, communication messages and publications are coordinated with international organizations and ministries. For example, HHS participates in the GHSI Communicator's network, a working group of the G7, Mexico, the European Commission, and WHO, which routinely and during emergencies share best practices, standard messages, and strategies for risk communications.
- The U.S. IHR NFP, located in ASPR, also serves as a mechanism for communication between other countries (through their respective NFP) and the WHO, receiving various types of questions related to both national public health events and international events to which the United States is responding.

Communication with the health system and civil society

- U.S. Government communication coordination systems, processes, and mechanisms activate and interact at various levels and times during steady-state and public health emergencies. Their purpose is to distribute pre-event and event-related information as widely as possible to the affected and potentially affected populations.
- Communication with the public and private organizations, hospitals, and the health care sector is a significant priority in strategic communication plans and is accomplished through multiple mechanisms. CDC's HAN is one of the critical mechanisms for rapidly sharing cleared information about urgent public health incidents with federal, state, territorial, and city/county partners (public information officers; federal, state, territorial, and local public health practitioners; clinicians; and PHL).
- Public messaging also considers community-specific needs like social, religious, cultural, political, and economic aspects related to the event. A key example of U.S coordinated public messaging and communication is CDC's Emergency Preparedness and Response site.
- The Private Sector Incident Communications Conference Line is similar to the NICCL but includes the private companies responsible for maintaining critical infrastructure in the United States.
- The National Public Health Information Coalition (NPHIC) supports communication and public affairs staff from state health departments and other health risk communicators. NPHIC participates

in national health promotion and risk communication activities, following public guidelines and recommendations from CDC.

Communication exercises

- Communication coordination tests and exercises are funded and performed with partner organizations and occur on small and large joint exercises as outlined in existing plans and according to situational needs. Both the State and Private Sector Communications Conference Lines are used for periodic engagement and exercises.

Collaborative planning

- Across the U.S. Government, it is common practice to complete an after-action assessment or report after completing a simulated exercise or responding to an actual emergency of the response, including the effectiveness of the communication accuracy and flow, whether it involves outside agencies and organizations or not.
- Departments and agencies coordinate with external partners and stakeholders to develop, review, and revise response plans. Needs identified through this coordination, including those for communication response, are incorporated in agency-specific annual budget requests to ensure a successful response.

Avoiding inconsistent or inappropriate messages

- Overlapping authorities and activities during an emergency response can cause public communications to be complex. The Ebola virus outbreak response presents an example of a recent challenging communication situation because of the large variety of PPE options and the regulation of manufacturing and occupational uses. Various aspects of PPE, from manufacturing to packaging to clinical use, are overseen by FDA, OSHA, the National Institute for Occupational Safety and Health, EPA, and CDC, with input from the WHO. This oversight requires unprecedented interagency and international coordination.
- The U.S. Government goes to great lengths to minimize the release of inconsistent or contradictory information. Efforts to avoid mixed messages include national teleconferences, press releases, updated webpages, informal conference calls, and behind the scenes coordination with state and local health departments. In the rare occasion that information is released that is inconsistent or contradictory, rapid coordination and information verification occurs between the lead and supporting agencies as outlined in the NRF ESF #15.

Supplemental documentations related to internal and partner communications

- Internal and external coordination events

  - Emergency Support Function 15: Standard Operating Procedures
  - External Affairs: A New Approach to Emergency Communication and Information Distribution
  - National Incident Management System Public Information Systems
  - Social Media in Emergency Management
- Response reports
  - Zika Response
  - MERS-CoV Response
- News stories during past emergencies
  - Example of news story: *Some say CDC failing crisis communications 101 in face of Ebola panic*
  - Example of news analysis: Analyzing the CDC's Crisis Communication in U.S. Ebola Outbreak
- Plans for communication coordination with external agencies
  - HHS communication toolkit for businesses and employers
  - CDC Clinician Outreach and Communication Activity (COCA)
  - CDC Health Literacy Training Resources
  - CDC website communication support
  - Frequently asked questions about CDC social media and syndication
  - DHS/FEMA disaster communications division coordination functions and capabilities
- After action reports from exercises or emergency responses
  - CDC Ebola Response
  - H1N1 Lessons Learned
  - Super storm Sandy Lessons Learned
  - A Public Health Perspective on the U.S. Response to the Fukushima Radiological Emergency

■ *Public Communication* *R5.3*

Communication resources and spokespersons during emergencies

- U.S. departments and agencies have formalized functions to communicate with the public that include trained spokespersons within communication offices or divisions. Most departments and agencies also have a formal media spokesperson training curriculum or program for their communications leaders and subject matter experts. In addition, dedicated and experienced communications personnel and teams trained in all forms of media outreach are in place within each department and agency to ensure successful external communications.

- Whether in steady state or response mode, departments and agencies devise and engage proactive communication strategies and tactics via various communication channels to amplify message dissemination to uniquely identified target audiences. Section 508 of the Federal Acquisition Regulations require Federal departments and agencies to provide access to information and data for people with disabilities.
- During emergencies, departments and agencies provide regular media briefings, and updates through agency-specific and joint internally maintained web sites and dedicated social media, such as Facebook, Twitter, Google+, and YouTube. In some cases, the federal government is required to provide only partial information or general statements to address rumors because of laws or regulations protecting personal privacy or commercial confidential information.
- Communications offices constantly monitor and audit internal and external communication channels for misinformation to quickly correct issues on a routine basis. Media trends are monitored to identify trends about the public's concerns, interests, and response to public health issues, including rumors and misinformation. By monitoring trends, communications staff can quickly respond to the public's concerns by addressing information gaps, increasing the accessibility and awareness of available information and resources, and ensuring just-in-time training is available for staff, media outlets, and the public.

Language and cultural competency

- The U.S. Government ensures that multiple languages are available, especially when media is targeting specific geographic locations or populations. For example, CDC Multilingual Services coordinates translation and interpretation in over 100 languages (including Sign Language), in-house translation to Spanish (including emergency services), and assistance with cultural adaptation. Many news releases and consumer updates are often translated into Spanish and alternate language translation services are always considered and offered, if warranted, during public meetings.
- Traditional media and social media teams across the government routinely conduct target audience analyses to better understand audience metrics and message-reach among target audience members in an effort to improve outreach and maximize preferred communication channels. For example, FDA has a message testing network with more than 500 FDA employee volunteers willing to review and provide feedback on documents and web content prior to public release. Communication messages and campaigns integrate findings into strategies to better deliver messages designed, directly or indirectly, to influence health behaviors of target audiences.

Developing evidence-based communications and new strategies

- To respond to communication challenges during public health emergencies, such as during the introduction of West Nile virus in the United States or the anthrax incident of 2001, CDC developed

and adopted the integrative model called CERC. It is based on experiential understanding and selected theories, and offers a phased approach to planning and response and encompasses the urgency of disaster communication with the need to communicate risks and benefits to stakeholders and the public. CERC emphasizes a participatory approach to communication, considering the social, psychological, and physical context of the crisis and proposes how to reduce harm to individuals and communities through communication.

- U.S. departments and agencies contribute in various ways to an evidence base of what communication methods best enable target audiences to change behavior during emergencies. Public affairs and communications offices and other relevant offices collaborate to share experiences and new strategies to continually improve communication response methods. Sharing information, tools, and links on health literacy research, practice, and evaluation for public health topics and situations is standard.
- Individual departments and agencies develop guidelines and teaching tools to improve cross-cultural communications skills, and deliver culturally and linguistically appropriate messages to diverse populations. Tools are also available to help evaluate the effectiveness of communications.
- Departments and agencies support research to help ensure appropriate behavior and outcomes, for example, regarding the public use of medical countermeasures through effective emergency communication.

Supplemental documentation related to public communications

- Community outreach
  - CDC Gateway to Health Communication & Social Marketing Practice
  - EPA social media page
  - Public CDC Health Literacy Training Resources
  - CDC web content in Spanish
  - FDA social media page
- Twitter pages
  - ASPR Twitter page
  - FDA Twitter page
  - CDC and CDC Emergency Twitter pages
  - USDA Twitter page
  - EPA Twitter page
  - DHS National Terrorism Advisory System Twitter page
- Communication research protocols and publications (formal/informal)

- CDC Clear Communication Index
- Health Communication and Social Marketing: Health Communication Campaigns That Include Mass Media and Health-Related Product Distribution
- CDC Health Literacy: Plain Language and Culture
- FDA Medical Countermeasures Initiative
- CDC Communicating With and About People with Disabilities
- FDA's Risk Communication Research Agenda

■ ***Communication Engagement with Affected Communities*** ***R5.4***

Social mobilization

- The U.S. Government departments and agencies have staff available to manage and conduct social mobilization, health promotion, or community outreach for at-risk populations as part of the overall U.S. national response plan.
- State and local level social mobilization, health promotion, or community engagement is also incorporated. Scalability is an integral part of the U.S. response system in all facets, including communications at all levels of government. In addition, state and local communications teams in any region or any emergency operation at the local level, per national guidelines and requirements, integrate in a vertical fashion to enable national level leadership to learn and freely apply best practices, updated messages, and information. For example, for the first diagnosed case of Ebola in the U.S., state, local and hospital officials joined a CDC national press conference within two hours of the positive lab results being shared internally.
- U.S. agencies responsible for protecting the health of the public have, to varying degrees, taken advantage of new mechanisms to raise the awareness and readiness of the general public. CDC's "Ready Wrigley" campaign and the DHS's *Ready* website are examples of work that prepares the public to receive and react appropriately to risk communication messages.
- During an emergency, the activation of supporting departments and agencies—and the usage of established systems like CDC's National Contact Center, and coordination networks like NPHIC – ensure public health communicators, social marketers, media relations professionals, and other resources are available to reach affected or at-risk populations. Additionally, departments and agencies have individual surge capacity. For example, CDC maintains a database of trained health communication professionals who can deploy during emergencies.

Community listening and feedback

- The U.S. Government engages in broad-based information sharing and provides training opportunities on a recurring and an "as needed" basis with various interagency and community

partners in preparation for a potential event of an emergency. Departments and agencies also prepare risk communication by monitoring ongoing and *ad hoc* feedback loops between at-risk or affected populations and response agencies.

- The U.S. Government coordinates internally and externally on public affairs to regularly and rapidly adapt messages to address internal and external audience feedback, misinformation, or questions. Community outreach, social media, information from established coordination networks (e.g., NICCL, the State Incident Communication Conference Line, or NPHIC) are used to identify and reach vulnerable (or potentially vulnerable) populations during emergencies.

■ ***Dynamic Listening and Rumor Management*** ***R5.5***

- Departments and agencies have formal and informal functions and methods to monitor and address rumors and misinformation. To ensure accurate and responsive information, communications offices and teams use media monitoring to identify trends in public's concerns, interests, and response to public health issues, including rumors and misinformation. The U.S. Government utilizes both planned and *ad hoc* methods to address rumors regarding public health issues through town halls, website updates, webinars, media tool kits, staff meetings, telephone hotlines, and email portals.
- It is a common practice to evaluate communication processes used to determine what actions had the most impact on changing behavior and/or stopping the rumor from spreading. Additionally, by monitoring media and the trends in public concern, communication departments and agencies can quickly address information gaps, increase the accessibility and awareness of available information and resources, and ensure just-in-time training is available for staff, media outlets, and the public. For example, the CDC Info contact center regularly performs analysis of calls and concerns to alert for rumors and misinformation during public health emergencies. Departments and agencies also consider and regularly evaluate communication feedback regarding rumors and misinformation from all internal and external sources in strategizing the process to improve communication.

Best Practices, Challenges, Gaps, and Recommendations

The United States has a sophisticated and multifaceted system for public health risk communication. As a professional discipline and critical component of public health emergency response, agencies have all established some level of risk communication and public affairs infrastructure. In the United States, CDC generally takes the lead for risk communication for public health emergencies in close coordination with other agencies in HHS and the other departments. The concept of the JIC has been incorporated into all-hazards disaster planning and is a focal point that is aligned with the activities of the EOC. Risk communicators in the United States are prepared to identify communication needs, craft messages appropriate to the situation, help to proactively guide community behaviors, evaluate the

effectiveness of community outreach and social mobilization (when needed), address rumors, and contribute to lessons learned.

Because risk communication is a highly specialized field, maintaining sufficient numbers of trained personnel who can be called upon to surge during a large-scale emergency (or when there are multiple emergencies) is a challenge throughout the country. In today's mega-media environment, an incredible volume and variety of communication channels require a highly adaptive approach to risk communication. Communicators are capable of leveraging technologies to multiply messages through syndication services and social media, as well as continuing to use traditional media formats. However, experience indicates that additional numbers of trained and experienced risk communicators are needed during novel, large-scale or special-hazard emergencies. The limited number of personnel currently experienced in communicating radiation information and data across the United States, for example, would not be able to meet the overwhelming demand for information after a large-scale radiological event.

The federal government could seek to evaluate the existing risk communication staffing models and develop options to surge/repurpose staff in times of emergencies. This could mean establishing agreements with state health departments to "borrow" their risk communicators; or agreements among agencies to temporarily detail risk communication staff to the lead agency JIC. As part of a broader "risk communication and social mobilization strategic development plan," staff development could include ways to expose risk communicators to various real world or scenario-driven (exercise) situations that allow them to gain functional knowledge around various public health and emergency management disciplines and lexicons.

Other IHR Related Hazards and Points of Entry

Points of Entry

Points of Entry 1 (PoE1)

JEE Target

States Parties should designate and maintain the core capacities at the international airports and seaports (and where justified for public health reasons, a State Party may designate ground crossings) which implement specific public health measures required to manage a variety of public health risks.

Level of Capabilities in the United States

➢ **Summary**

The United States employs an effective system to detect and limit the introduction of communicable diseases and other health risks into the United States through points of entry (PoE), synonymous with "ports of entry" in many U.S. documents. In coordination with DHS, the CDC has strategically placed U.S. Quarantine Stations at designated PoE where the majority of international travelers must enter the United States. Public health activities at those locations include coordination and collaboration among local public health departments, area medical providers, law enforcement, emergency medical services, airlines, and port operators. Importantly, the staffs at the Quarantine Stations are also required to engage with other PoE within their assigned geographic region to support planning and safe port operations. Public health personnel from the federal agencies as well as local health officers provide public health consultations and investigations, medical examinations and immediate treatment, and facilitate the transfer of sick travelers to definitive care.

Effective public health responses at PoE are achieved through the coordinated activities among multiple entities. CDC issues guidelines for the protection of travelers and to prevent introduction of communicable diseases into the United States. USDA is responsible for inspection of specific food items, and FDA is responsible for inspections of all other food and ingredients as well as medical products. Both agencies have specific authorities to detain, test, or confiscate material to prevent hazardous or contaminated material from entering the United States. CDC, the United States Coast Guard (USCG) and U.S. Navy are authorized to issue Ship Sanitation Control Certificates and Ship Sanitation Control Exemption Certificates. The DHS, DOT, port operators, and transportation companies are also critical players in port safety and sanitation. Law enforcement personnel and the air and ship

crews receive training on identifying sick travelers or other public health risks and are required to report problems immediately.

➢ **Indicators**

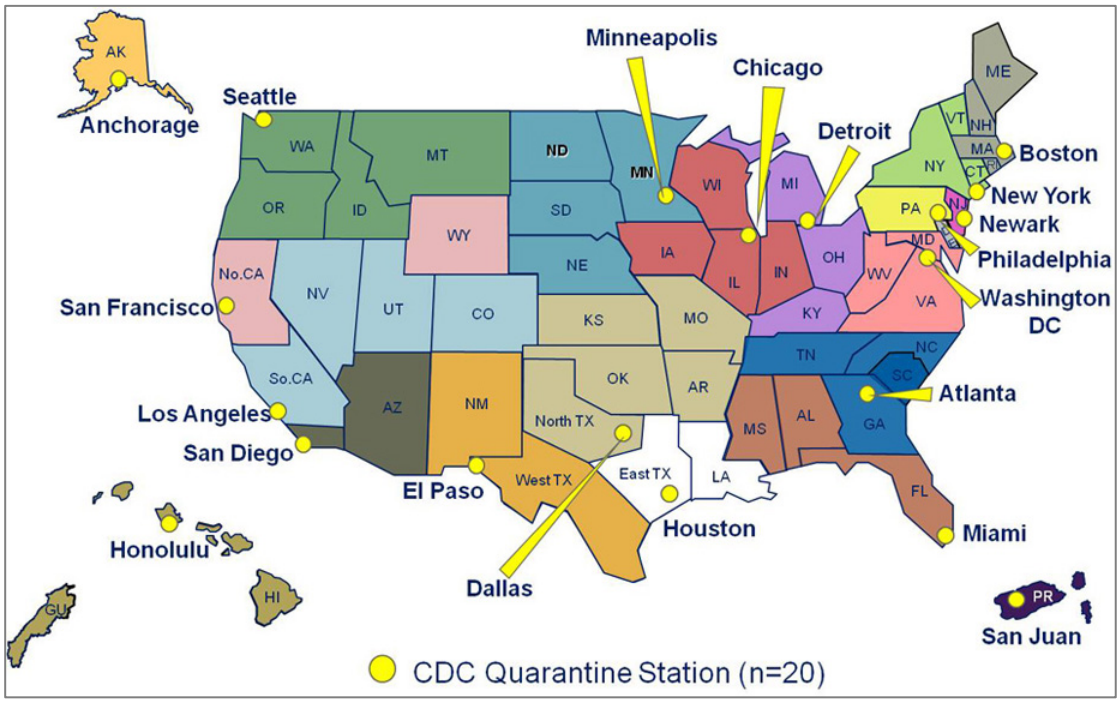
■ ***Routine capacities are established at points of entry*** ***PoE1.1***

Identification, quarantine and transfer to medical care at PoE

- CDC, DHS CBP, DHS Immigration and Customs Enforcement (ICE), and the USCG, established a MOU in 2005 to develop mechanisms for information sharing, travelers' health and medical services, and disease reporting. Those agencies coordinate inspection and entry requirements, quarantine enforcement and detention, transportation between ports and medical facilities, employee health, worker protection, and disease prevention.
- CBP coordinates with the CDC Quarantine Stations (Figure 6) to have SOP in place to transfer travelers to the appropriate nearby medical facility as needed. CBP does not maintain a medical or public health capability for PoE. All medical issues, if no CDC personnel are collocated at the PoE, are referred to the local medical system.
    - As shown in Figure 6, U.S. federal Quarantine Stations include Anchorage, Honolulu, Seattle, San Francisco, Los Angeles, San Diego, El Paso, Dallas, Houston, Minneapolis, Chicago, Detroit, Boston, New York, Newark, Philadelphia, Washington, DC, Atlanta, Miami, and San Juan.
    - Of those, Dallas and Boston are not currently staffed full time but have part-time coverage from nearby Stations
- The Secretary of HHS is authorized under section 361 of the U.S. Public Health Service Act (42 U.S.C. § 264) to take other measures to prevent the entry and spread of communicable diseases from foreign countries into the United States and between states. In practice, the application of such measures would be in consultation and coordination with DoS.
- CDC has the responsibility and authority to isolate, quarantine, or conditionally release persons arriving into the United States reasonably believed to be infected with a quarantinable disease. It also includes the authority to conduct risk assessments at PoE for travelers deemed to be at risk for communicable disease spread, among other authorities. CDC issued a Direct Final rule on December 12, 2012 that went into effect on January 13, 2015 to clarify definitions within 42 CFR Part 71, Control of Communicable Diseases: Foreign Quarantine.
- At the Quarantine Stations, quarantine public health officers conduct activities including screening and reporting illnesses; screening cargo, animals and animal products; and monitoring the health of, and collecting medical information from new immigrants, refugees, asylum-seekers, and parolees. Upon a report of suspected illness from a partner (e.g., an airline or Customs and Border Protection

(CBP) agent), health officers determine if the traveler requires further health assessments before departure from the PoE, as well as appropriate measures to prevent the spread of infectious diseases.

Figure 6. Map of the United States Quarantine Stations located at the 20 points of entry where most international travelers arrive.



- In the Quarantine Station system, all of the staffed facilities have defined geographic coverage areas and provide support to the (non-designated) PoE as well as non-international airports for communicable disease control, health emergencies, or other types of public health responses.
- United States law (42 CFR Part 71.21[b]) requires that "[t]he commander of an aircraft destined for a U.S. airport shall report immediately to the quarantine station at or nearest the airport at which the aircraft will arrive, the occurrence, on board, of any death or ill person among passengers or crew." However, paragraph 8.15 Annex 9 to the Convention on International Civil Aviation requires that "[t]he pilot-in-command of an aircraft shall ensure that a suspected communicable disease is reported promptly to air traffic control, in order to facilitate provision for the presence of any special medical personnel and equipment necessary for the management of public health risks on arrival." The FAA and CDC have had a Memorandum of Agreement in place since October 2010 to address how the two agencies will handle notifications of reports that they receive of deaths, suspected cases of communicable disease, and other public health risks, on board aircraft. The occurrence of deaths and certain illnesses suggestive of a communicable disease (defined in the regulation) on international flights arriving to the United States (at any PoE) must be reported to CDC's Division of Global Migration and Quarantine.

- Air cabin crews on U.S. flights have a critical role in public health. Guidance for those crews in general, as well as for specific infectious disease, is provided by the CDC.
- Title 42 CFR Part 70.4 requires that "[t]he master of any vessel or person in charge of any conveyance engaged in interstate traffic, on which a case or suspected case of a communicable disease develops shall, as soon as practicable, notify the local health authority at the next port of call, station, or stop, and shall take such measures to prevent the spread of the disease as the local health authority directs." Reporting to CDC fulfills this requirement.

PoE inspections and public safety

- Federal agencies on-site, (e.g., CBP, ICE, and if present, CDC) participate in their own PoE inspection programs related to public health under their respective legal authorities.
- The control of vectors and vector reservoirs in and near PoE is managed by state and local entities in coordination (as needed) with airport authorities.
- For maritime conveyances, CDC may require that certain measures be taken to mitigate the spread of disease aboard cruise and other vessels traveling to the United States. CDC works with the maritime conveyance staff to ensure these measures are implemented. The Vessel Sanitation Program assists the cruise ship industry to prevent and control the introduction, transmission, and spread of gastrointestinal illnesses on cruise ships. The program operates under the authority of the Public Health Service Act (Title 42 U.S.C 264).
- The OSH Act of 1970 does not typically give OSHA jurisdiction over workers on an aircraft in operation[10]. In a 2014 MOU, the FAA and OSHA agreed that OSHA could apply its standards regarding hazard communication, bloodborne pathogens exposure, and occupational noise exposure to the working conditions of aircraft cabin crewmembers[11] while they are on board aircraft in operation (except flight deck crew).
- CDC is the "Competent Authority" under the IHR (2005) to issue Ship Sanitation Control Certificate (SSCC)/Ship Sanitation Control Exemption Certificate (SSCEC).

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[10] An aircraft is "in operation" from the time it is first boarded by a crewmember, preparatory to flight, to the time the last crewmember leaves the aircraft after completion of that flight, including stops on the ground during which at least one crewmember remains on the aircraft, even if the engines are shut down.

[11] An aircraft cabin crewmember means a person assigned to perform duty in an aircraft cabin when the aircraft is in operation (other than flight crewmembers).

  - The CDC Vessel Sanitation Program may issue SSCC/SSCEC upon request during inspections of cruise ships. Ships under the jurisdiction of the CDC program include those that carry 13 or more passengers and have a foreign itinerary with U.S. ports.
  - Authority to issue SSCC and SSCEC has been delegated to the U.S. Navy and USCG, which may conduct inspections and issue certificates for vessels of their services, respectively, and those of the National Oceanic and Atmospheric Administration.
- The FDA has inspection authority over regulated food and medical products imported through U.S. PoE. Under the Federal Food, Drug, and Cosmetic Act, the FDA may take a range of enforcement and compliance actions with respect to imported products, including:
  - Examination and collection of samples for testing;
  - Refusing admission of products that are, or appear to be, in violation of FDA rules;
  - Issuance of import alerts for detention of similar products without examination.
- The FDA and DHS CBP may take a number of other specific actions such as seizure, civil money penalties, bond actions, requesting state embargo/stop sale, food importer debarment, and prosecution.

■ *Effective Public Health Response at Points of Entry* *PoE1.2*

Support for public health emergency response at PoE

- CDC has developed communicable disease response plans (CDRP) for the 18 PoE with quarantine stations. Each plan is highly variable because of the unique stakeholders and partners, specific structures, and logistics systems at each airport. They have been developed with state and local public health departments, emergency responders, airlines, airport operations and many additional stakeholders.
- CDC Quarantine Stations conduct a variety of exercises both internally and externally with local, state, and federal emergency response, and airport partners. These exercises assist Quarantine Stations in identifying strengths and gaps in communicable disease response plans and SOP used to protect travelers and employees during an event/incident. Exercises include, but not limited to, drills, workshops, tabletop exercises, and functional and full-scale exercises.
- A December 2015 U.S. report by the Government Accountability Office entitled "Air Travel and Communicable Diseases" concluded that the United States needs a comprehensive national aviation-preparedness plan aimed at preventing and containing the spread of diseases which would include PoE not already covered by the CDC. Additional effort is needed to determine how best to address the GAO findings.

Systems in place to safely transfer patients for medical care

- A 2010 agreement between CDC and the FAA describes the roles and responsibilities of CDC and FAA when they receive reports of deaths, suspected cases of communicable diseases or other public health risks on aircraft destined for the United States. The FAA notifies the CDC Emergency Operations Center via the FAA's Domestic Events Network when an FAA air traffic services unit receives such a report. CDC is responsible for notifying the aircraft operator or its designated representative, and the departure and destination airport operators (for airports in the United States), as well as for arranging for an appropriate public health response at departure or destination airports located within the U.S.
- CDC has agreements with over 170 hospitals located near PoE that have agreed to assist CDC in the assessment of ill travelers to determine if further public health measures are needed. The agreements set standards for communication and coordination between CDC and the hospital, and define roles and expectations for both CDC and the hospitals when a traveler under federal isolation orders requires hospital admission.

■ ***Other relevant references and documentation for Points of Entry***

- Quarantinable diseases in the United States
- Specific screening criteria for travelers who may be reportable to public health authorities
- FDA Import Program

Best Practices, Challenges, Gaps, and Recommendations

The United States has established a robust, full-time public health capacity at designated points of entry that receive the majority of international travelers. CDC personnel, trained specifically for their duties at the U.S. Quarantine Stations, collaborate closely with the collocated CBP and ICE teams and are available during all operating hours. Local communicable disease response plans integrate the complex requirements for protecting the health of the public, ensuring legal entry through a U.S. international border, providing medical care for travelers, and protecting the health of employees. Agreements have been established with local medical transport services and hospitals to ensure the quick and safe transfer of affected personnel to a location for definitive diagnosis and treatment. The Quarantine Station health officers are also responsible for coordinating with PoE within their jurisdictions that do not have full-time Federal public health personnel.

The limited on-site access to specialized public health officers and an uncertain readiness status among the hundreds of other (non-designated) air-, land-, and seaports around the United States and its territories suggests a potential gap in the overall protection related to international travel and transport. CDC trains and collaborates with port partners to detect signs and symptoms of illness in travelers who are arriving at all PoE, including those that do not have full-time CDC staff. Detection at the PoE is only one part of the layered system of detection of ill travelers. Reporting ill passengers or deaths during

travel as required by domestic U.S. regulations and international standards is an additional layer of protection against the introduction of communicable diseases or other hazards into the United States. In response to such reports, CDC coordinates with local and state health departments to utilize quarantine authorities (as needed) and other local health resources. However, more public health officers at (or covering) PoE that are not currently designated under IHR could assist the local port operators, law enforcement personnel, and health departments to develop and refine their own public health emergency response plans. Those federal officers would also be available to advise, assist, and coordinate during exercises, emergency preparations (i.e., in response to a communicable disease threat somewhere else), or in response to local emergencies.

Chemical Events

Chemical Events 1 (CE1)

Target

State parties should have surveillance and response capacity for chemical risk or events. It requires effective communication and collaboration among the sectors responsible for chemical safety, industries, transportation and safe disposal.

Level of Capabilities in the United States

➢ **Summary**

The United States has substantial preparedness and response capacity for chemical events with functioning mechanisms established for detecting and responding to emergencies. Most federal government responses to actual or threatened chemical releases or oil discharges to the environment are carried out by EPA and USCG under the National Oil and Hazardous Substances Pollution Contingency Plan (NCP), with the support of 13 other federal departments and agencies, including HHS. Chemical and oil responses can also be part of a federal response coordinated by FEMA under the Stafford Act. In that case, EPA and USCG typically lead the environmental response under the NRF ESF #10 - *Oil and Hazardous Materials Annex* and other federal agencies would lead other aspects of the response as needed, such as HHS leading the public health and medical response under the ESF #8 – *Public Health and Medical Annex*. HHS may also respond to chemical incidents involving a significant risk to public health under other authorities, such as the Public Health Service Act of 1944, and the FBI would take lead actions for a suspected terrorist incident or other federal crime. Relevant departments and agencies maintain specific operational plans and procedures for chemical event responses. The United States also participates in a number of international treaties, protocols, and conventions for the control of hazardous chemicals and materials, as well as non-proliferation.

The U.S. Government conducts baseline public health assessments to inform national, state, and local strategies, guidelines, plans, and protocols for chemical event response. Active and passive surveillance can be put into place to help determine the scope, impact, and evolution of a chemical event in the affected populations. Using direct response resources as well as statistical modeling, the federal government assists impacted state and local jurisdictions in responding to chemical events. The federal government also provides resources in support of state and local preparedness, which is especially important for state and local capabilities and capacities to respond to the fast-acting aspects of a chemical incident, before federal response resources arrive. Preparedness resources include clinical and

other response guidance, medical countermeasures, training, laboratory analytical capabilities, and others. The U.S. has dealt with many chemical event responses domestically and internationally and lessons learned from these responses are used to improve plans and develop new approaches.

➢ **Indicators**

■ ***Mechanisms are established and functioning for detecting and responding to chemical events or emergencies*** ***CE1.1***

Incident detection

- Sentinel surveillance, environmental monitoring, and consumer product monitoring with regard to chemical hazards occurs frequently through full and cross-cutting interagency and public-private engagement.
- Federal law (the Comprehensive Environmental Response, Compensation, and Liability Act [CERCLA] and Clean Water Act) requires that oil discharges and releases of reportable quantities of listed hazardous substances (which include chemicals) be reported to the National Response Center, which is managed by the USCG. These notifications are forwarded to EPA and USCG field offices to determine whether a federal response under the NCP is needed.
- Federal funding supports 62 states, territories, and metropolitan areas in the United States through the PHEP cooperative agreements. In the 2010 survey, 53 laboratories within these jurisdictions provided emergency response capabilities for their local areas, the nation, or both, as a component of the LRN for Chemical Threats (LRN-C).
    - CDC can analyze clinical samples for numerous threat agents and metabolites. Many analytic methods target metabolic products as biomarkers of exposure in either blood or urine. In recent years, CDC also has developed analytic methods that target protein adduct biomarkers.
    - All 53 laboratories in the LRN-C have Level 3 capacity. These laboratories work with hospitals and other first responders within their jurisdiction to maintain competency in clinical specimen collection, storage, and shipment.
    - Thirty-four labs are designated as Level 2 laboratories. Chemists in these laboratories are trained to detect exposure to a number of toxic chemical agents. Analysis of cyanide, nerve agents, and toxic metals in human samples are examples of Level 2 activities.
    - Ten laboratories currently participate in Level 1 activities. These laboratories, which serve as surge-capacity laboratories for CDC, are able to detect not only the toxic chemical agents that Level 2 laboratories can detect, but also can detect exposure to an expanded number of chemicals, including mustard agents, nerve agents, and other toxic industrial chemicals. Using unique high-throughput analysis capabilities, they expand CDC's ability to analyze a large number of patient samples when responding to large-scale exposure incidents.

- Automated systems, like the National Poison Data System, immediately alert American Association of Poison Control Centers and CDC toxicologists, supporting the timely detection of incidents of potential public health significance.
- EPA's mobile Portable High-Throughput Integrated Laboratory Identification System is available nationwide for rapid turnaround, high throughput analysis of environmental samples (water, soils, surfaces, air) that are potentially contaminated with a variety of chemicals, including chemical warfare agents. The portable system is an accredited confirmatory laboratory.

International treaties, protocols and standards

- The United States participates in a number of international agreements related to chemical hazards, including:
  - Montreal Protocol on Substances that Deplete the Ozone Layer (greenhouse gasses)
  - Minimata Convention on Mercury
  - Basel Convention on Hazardous Wastes
  - Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade
  - Strategic Approach to International Chemicals Management
  - Convention for the Prohibition of the Development, Production, Stockpiling, and Use of Chemical Weapons and on Their Destruction

National chemical response plans

- The EPA and USCG have primary authority under the NCP for monitoring and response to chemical threats that involve an actual or threatened release to the environment. The NCP is a federal regulation that implements CERCLA and section 311 of the CWA, as amended by the Oil Pollution Act of 1990. The NCP provides a framework for preparedness and response with participation from local, state, tribal and federal governments and parties that manage oil and hazardous substances. Thirteen other federal agencies with responsibilities and expertise in oil and hazardous materials incidents support EPA and USCG in preparedness and response. The federal agencies also maintain "special teams" with specific expertise in assisting response efforts, including environmental remediation techniques, health and safety assistance, risk assessment, environmental monitoring, and incident management. The NCP also serves as an operational supplement to the NRF.
- The Stafford Act may be used to provide support to state and local government agencies in response to a broad array of natural and man-made incidents, which depending on the circumstances, may include chemical incidents. The NRF and supporting Response FIOP describe how FEMA coordinates federal responses under the Stafford Act. EPA and USCG would typically lead the environmental response under ESF #10, with other agencies leading other aspects of the

response under other ESFs. The public health and medical response would be led by HHS under ESF #8. Federal agencies may also implement their own independent authorities during Stafford Act responses.

- Many other agencies (e.g., USCG, CDC, DHS, DoD, etc.) have individual chemical incident response plans that are activated during localized or smaller scale events (depending on local threats and capacities).
- The Emergency Planning and Community Right-to-Know Act (EPCRA) of 1986 was created to help communities plan for emergencies involving hazardous substances, including the creation of state-level Emergency Response Commissions and Local Emergency Planning Committees .
  - *Sections 301 to 303. Emergency Planning* - Local governments are required to prepare chemical emergency response plans, and to review plans at least annually. State governments are required to oversee and coordinate local planning efforts. Facilities that maintain extremely hazardous substances on-site in quantities greater than corresponding threshold planning quantities must cooperate in emergency plan preparation.
  - *Section 304. Emergency Notification* - Facilities must immediately report accidental releases of extremely hazardous substances in quantities greater than corresponding reportable quantities defined under the Comprehensive Environmental Response, Compensation, and Liability Act to state and local officials. Information about accidental chemical releases must be available to the public.
  - *Sections 311 and 312. Community Right-to-Know Requirements* - Facilities manufacturing, processing, or storing designated hazardous chemicals must make Material Safety Data Sheets (MSDS) available to state and local officials and local fire departments. MSDS describe the properties and health effects of these chemicals. Facilities must also report, to state and local officials and local fire departments, inventories of all on-site chemicals for which MSDS exist. Information about chemical inventories at facilities and MSDS must be available to the public.
  - *Section 313. Toxics Release Inventory* - Facilities must complete and submit a toxic chemical release inventory form (Form R) annually including each of the over 600 chemicals that are manufactured or otherwise used above the applicable threshold quantities.
  - *Section 322. Trade Secrets* - Facilities are allowed to withhold the specific chemical identity from the reports filed under sections 303, 311, 312 and 313 if the facilities submit a claim with substantiation to EPA.

Risk assessment and exposure monitoring

- U.S. departments and agencies have programs and offices that conduct and utilize risk assessments to appropriately scale their responses to a chemical event. Some of these offices and tools are listed below:

  - CDC ATSDR Assessment of Chemical Exposures
  - CDC Community Assessment for Public Health Emergency Response
  - EPA Hazard Ranking System
  - EPA Risk Management Plan Program
- CDC's National Center for Environmental Health collaborates with the American Association of Poison Control Centers via the National Poison Data System. This collaboration allows the monitoring (passive and active) of regional and national trends in human exposure and real time toxico-surveillance.

Mitigation and treatment

- An inventory of health care facilities and emergency contacts for specific capabilities for chemical hazard safety are publically available.
  - Chemical hazard emergency contacts
  - Fifty-five National Poison Control Centers
- There are 1,960 chemical hazards resource containers called *CHEMPACKs* strategically placed in more than 1,340 locations in all states, territories, island jurisdictions, and the District of Columbia. Most *CHEMPACK* containers are located in hospitals or fire stations to support a rapid hazmat response. More than 90 percent of the U.S. population is within one hour of a *CHEMPACK* container location, and if hospitals or first responders need them, they can be accessed quickly. The delivery time ranges from a few minutes to less than two hours.
- Protocols and guidelines for case management with regard to chemical hazards are publicly available, in addition to treatment guidance that can be issued by the Poison Control Center when consulted about an incident.
  - NLM and ASPR Chemical Hazards Emergency Medical Management
  - NLM Wireless Information System for Emergency Responders
  - CDC Agency for Toxic Substance & Disease Registry
  - CDC National Institute for Occupational Safety and Health
  - American Chemistry Council, Chemical Transportation Emergency Center (CHEMTREC®)
  - DHS/ASPR Patient Decontamination in a Mass Chemical Exposure Incident: National Planning Guidance for Communities
  - EPA – EPA's Office of Resource Conservation and Recovery website on "Managing Materials and Wastes from Homeland Incidents"

■ ***Enabling environment is in place for management of chemical Events*** ***CE2.2***

Chemical safety and hazard regulations

- The Chemical Facility Anti-Terrorism Standards program, initially authorized by Congress in 2007, identifies and regulates high-risk chemical facilities to ensure they have security measures in place to reduce the risks associated with these chemicals. On December 18, 2014, the President signed into law the Protecting and Securing Chemical Facilities from Terrorist Attacks Act of 2014, laying the foundation for the maturation of that program.
- The Federal Interagency Working Group led by the DHS Assistant Secretary for the Office of Infrastructure Protection, the DOL's Assistant Secretary for OSHA, and the EPA Assistant Administrator for the Office of Land and Emergency Management issues Fact Sheets to update the group's progress. A report to the President, published May 2014, summarizes interagency actions to date, findings, and lessons learned, challenges, and short and long-term priority actions. The report, entitled "*Actions to Improve Chemical Facility Safety and Security – A Shared Commitment*", includes with an aggressive Action Plan focused on changing the national landscape of chemical facility safety and security.
- Comprehensive authorities and regulatory frameworks are in place in the United States at all levels. These regulations and authorities provide the foundation for national doctrine, preparedness and response planning, regulatory authorities, and requirements. Some examples are provided below:
  - Presidential Executive Order on Improving Chemical Facility Safety and Security (EO 13650)
  - Occupational Safety and Health (OSH) Act of 1970 (Pub. L. 91-596).
  - Executive Order (EO) 12196 extends to civilian federal employees protections provided under the OSH Act to private-sector workers.
  - EPA SUPERFUND Program
  - EPA Incident Reporting
  - EPA chemical safety and pollution prevention
  - EPA SUPERFUND Program List of Priority Sites
  - EPA Hazardous Waste Program
  - EPA - EPA's Office of Water
- The Hazardous Materials Transportation Act provides the U.S. Government (via the DOT) with the comprehensive authority to regulate hazardous materials being transported in commerce domestically and in or out of the United States. This includes requirements regarding classifying, marking, labeling, packaging, and describing shipments of hazardous materials, training, creating and adhering to transportation security plans, reporting incidents, and requiring registration before

a person transports certain types, quantities, and configurations (e.g. large bulk shipments) of hazardous material.

- The joint U.S. Army - DHS/FEMA Chemical Stockpile Emergency Preparedness Program provides resources and technical assistance to communities adjacent to the Army domestic stockpile of chemical weapons. Extensive guidance on adopting shelter-in-place as a public protective action strategy and locally implementing the national Integrated Public Alert and Warning System, as well as a range of videos for emergency planners (e.g., sheltering-in-place, persons with access and functional needs, animals in emergencies, emergency public information, and exposure and contamination) are publicly available on the program's portal (login not required).

Funding support for emergency response

- Funding to support state and local government emergency response activities would be available for Stafford Act responses in accordance with the provisions of that law. Funding would be available for NCP responses in accordance with the provisions of the NCP, CERCLA, and the CWA as amended by the Oil Pollution Act of 1990.
- The United States, through a combination of federal, state and local resources, supports chemical emergency responses and related activities. The federal government funds the development and acquisition of medical countermeasures through BARDA, stockpiles resources in the SNS, and ensures that *CHEMPAKs* are staged around the United States. Individual states and jurisdictions provide the majority of logistics support for distribution of chemical and medical countermeasures, providing logistical support when an event occurs.

Exercises, simulations, and real-world responses

- U.S. Government response organizations participate in required and *ad hoc* hazardous material exercises every year, including many that relate to chemical events. Five recent national-to-local level exercises called the Chemical Defense Project Capstone Tabletop Exercise were sponsored by DHS and local government emergency management agencies in Baltimore, Maryland; Boise, Idaho; Houston, Texas; Nassau County, New York; and New Orleans, Louisiana. That exercise assessed the communities' preparedness capabilities and helped them to develop a comprehensive, community-wide, interdisciplinary, multiagency concept of operations for chemical event response.
- The FEMA National Exercise Division oversees the conduct of the National Level Exercise and has a robust system for evaluation and lessons learned. Also, as a public resource, DHS FEMA has developed a chemical event exercise template. Other organizations also conduct their own targeted or agency-specific exercises, which typically follow the methodology of FEMA for evaluation and corrective actions. Each agency has its own emergency preparedness division that creates exercise objectives, conducts evaluations, and produces after-action reports.

- Examples of recent real-world responses include:
  - Deepwater Horizon in 2010 – a massive oil spill from a ruptured well in the Gulf of Mexico.
  - Paulsboro, New Jersey, Train Derailment and Vinyl Chloride Release in 2012 – the accidental derailment of chemical cars results in toxic exposure in the community.
  - Elk River, West Virginia, January 9–20, 2014 – A chemical spill into the Elk River in Charleston, West Virginia, resulted in a "do not use" order for residents of nine counties, affecting 300,000 people. A laboratory in the LRN tested 581 drinking water samples and provided PHEP-funded epidemiology support from CDC.
  - Others environmental emergency responses are listed on the EPA website.

Best Practices, Challenges, Gaps, and Recommendations

The United States has a well-developed system for the regulation of chemical hazards, with resources available for chemical emergency management. National, state, and local organizations employ, or have access to, chemical experts and resources for chemical event preparedness and response. Multiple departments and agencies collaborate to develop public response guidelines for managing and responding to chemical and other hazardous material events. A network of Poison Control Centers across the country, linked through a federal database, provide information quickly about situations that might not be part of an obvious chemical release. Agency-specific lists and mechanisms are in place to identify and contact the appropriate experts across the U.S. government, when necessary. However, challenges and opportunities for improvement exist.

State and local level planners have challenges maintaining overall readiness due to lack of resources for training and staff in their chemical safety and emergency response offices. Depending on the specific location, states are experiencing a shortage of trained personnel who are familiar with chemical emergency management plans and can respond to larger-scale emergencies. To address all of the challenges in the chemical hazard sector, the Federal Interagency Working Group, led by the DHS, DOL, and EPA, in coordination with DOJ, DOT, and USDA, performed an analysis of the current operating environment, existing regulatory programs, and stakeholder feedback. From this analysis, the Working Group developed a consolidated Federal Action Plan in May 2014 to address five elements: (1) strengthening community planning and preparedness; (2) enhancing federal operational coordination; (3) improving data management; (4) modernizing policies and regulations; and, (5) incorporating stakeholder feedback and developing best practices. Recovery and resiliency are key areas that need to be explored and developed with respect to chemical response. The development of multiagency plans and strategies will vary depending on the chemical properties and hazards. In addition, specific guidance for clearance and re-entry criteria will need further exploration.

Radiation Emergencies

Radiation Emergencies 1 (RE1)

JEE Target

State parties should have surveillance and response capacity for radio-nuclear hazards/events/emergencies. It requires effective communication and collaboration among the sectors responsible for radio-nuclear management.

Level of Capabilities in the United States

➢ **Summary**

The United States follows a robust, multiagency approach to prepare for and respond to radiological and nuclear emergencies based on several decades of experience and refinement. A rigorous program for radiological emergency preparedness was established following the Three Mile Island accident in 1979 (which created organizations and cooperative structures for emergency response to nuclear power plant accidents) and other incidents at fuel cycle facilities, as well as transportation accidents. In the post-9/11 era, preparedness activities have expanded beyond fixed-facility accidents to include potential terrorist attacks. The federal government provides assistance to state and local governments as needed on the premise that events would be handled at the local level until they exceed the capability of the local jurisdiction.

The U.S. system of response is determined by the specific nature of the incident, utilizing those agencies that have the response capabilities or statutory authority for the materials involved in the release. The NRF contains the Nuclear Radiological Incident Annex (NRIA), which outlines the roles, responsibilities, and authorities for the federal agencies that have responsibilities during an emergency response. The capabilities of local governments vary widely across the United States, with the greatest resources found in states that have nuclear facilities. While some federal assets are regionalized, others may be deployed for events anywhere in the United States and its territories. As described in the NRIA, the overall coordination of the consequence management response to a significant radiological/nuclear emergency would be carried out by DHS and FEMA, in close coordination with the White House NSC Staff. The FBI would also take lead actions if the incident were the result of terrorism or other federal crimes. Other agencies may lead respective radiological responses under their own authorities and maintain specific internal operational plans and procedures for radiological responses

The United States generally has adequate resources to respond to emergencies at fixed facilities. However, as with any country, the United States would be challenged to respond to a large-scale,

catastrophic nuclear emergency. In a large-scale incident, the United States may rely on assistance from international partners. The United States is a signatory to the *Convention on Early Notification of a Nuclear Accident* and the *Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency* coordinated by the International Atomic Energy Agency (IAEA). Additionally, the CDC National Center for Environmental Health (Division of Environmental Hazards and Health Effects/Radiation Studies Branch) is and the DOE Radiation Emergency Assistance Center/Training Site are Collaborating Centers for radiation emergencies with the WHO Radiation Emergency Medical Preparedness and Assistance Network.

➢ Indicators

■ *Mechanisms are established and functioning for detecting and responding to radiological and nuclear emergencies* *RE1.1*

Radiation incident detection

- EPA has the national-level responsibility for routinely monitoring radiation in the environment (air, precipitation, and drinking water). The nationwide RadNet system monitors the nation's air, precipitation and drinking water to track radiation in the environment. RadNet has more than 130 stationary air monitors located across all 50 states. RadNet also has 40 deployable monitors that can be sent anywhere in the United States if needed. RadNet stationary monitors run 24 hours a day, 7 days a week, and send near-real-time measurements of gamma radiation to EPA's National Analytical Radiation Environmental Laboratory. A full description of this system and its data are available to the public on the RadNet website.
- A pilot project to develop a new capability for the early detection of radiation releases that have no obvious indicators is a partnership between DOE and EPA using the DHS BioWatch system. BioWatch is described in more detail in the *Real-Time Surveillance* section.
- Multiple agencies share the responsibility for monitoring consumer products (both food and other goods) for radioactivity, including the FDA, USDA, and DHS CBP. More information on the detection of radiation and other threats in food and consumer products is described in the sections on *Food Safety* and *National Laboratory System*.
- DOE has national-level responsibility for leading the Federal Radiological Monitoring and Assessment Center (FRMAC), which coordinates all Federal environmental radiological monitoring following an incident.
- Federal law (CERCLA) requires that releases of reportable quantities of listed hazardous substances (which include certain radionuclides) be reported to the National Response Center, which is managed by the USCG. These notifications are forwarded to EPA and USCG field offices to determine whether a federal response under the NCP is needed.

National radiation response plans

- The NRIA describes the overall framework for federal response and recovery to a wide range of radiological/nuclear incidents, and supplements the Response and Recovery FIOP. As indicated in the NRIA, a variety of response authorities may apply, including the Stafford Act, CERCLA/NCP, Atomic Energy Act, and Price-Anderson Nuclear Industries Indemnity Act. Individual agencies develop and maintain their own emergency response plans to carry out their responsibilities as described in the NRIA. In total, these plans represent a full range of functions that would be required in a radiological or nuclear crisis.
- The EPA Radiological Emergency Response Plan represents EPA's concept of operations for a radiological emergency consistent with the federal policies, planning considerations, and response provisions outlined in the 1994 National Oil and Hazardous Substances Pollution Contingency Plan, the 2013 NRF, and the 2011 National Disaster Recovery Framework.
- The 2010 Planning Guide for Response to a Nuclear Detonation, the 2014 Response and Recovery FIOP, and the NRIA provide additional interagency guidance for nuclear detonations.
- Departments and agencies, like DHS, USDA, FDA, and EPA, prepare and publish Protective Action Guides (PAG) that would trigger public safety measures, such as evacuation or staying indoors, to minimize or prevent radiation exposure during an emergency. The PAG are for emergency responders, and do not change federal, state, or local environmental standards. The PAG contain radiation dose guidelines that would trigger public safety measures to minimize or prevent radiation exposure during an emergency. States and nuclear power plant emergency response organizations are required to use the guidance in the PAG Manual in their emergency response planning and exercises.
- The Advisory Team for the Environment, Food, and Health is a federal interagency group of radiological health experts whose mission is to provide protective action recommendations to decision makers at all levels following accidents or incidents that result in the release of radioactive material to the environment, from the early phase through the late phase. The Advisory Team includes representatives from EPA, FDA, CDC, and USDA that works closely with the FRMAC (described below), which provides the data used to make recommendations. The Advisory Team coordinates at multiple levels of federal, state, and local governments to provide guidance where needed in matters of the environment, food, water, and both human and animal health.

Risk assessment and radiation exposure monitoring

- CDC is responsible for assisting local governments with monitoring exposed populations and for post-incident health surveillance. Guidance, education, communications, and training resources are available on CDC's Radiation Emergencies website. There is limited capacity for the analysis of human clinical samples including radiobioassay for the assessment of internal radioactive

contamination and biodosimetry for the assessment of external radiation exposure (i.e., dicentric chromosome assay). CDC is currently working to develop improved capacity for radiobioassays.

- The FRMAC is a DOE-led, federal interagency group that is responsible for coordinating the collection and assessment of radiological data immediately following emergencies through late-phase response. FRMAC plans are implemented in real-world events and frequently exercised, leading to continuous improvement. Plans are formally updated when needed based on significant accumulation of lessons learned or methodological changes.
- Several laboratory networks in the United States contribute to risk assessments. The ICLN (described in detail in the *National Laboratory System* section) provides a framework and coordination structure for laboratory procedures and capacities.
    - ICLN includes the Environmental Response Laboratory Network (ERLN) and the FDA/USDA FERN, as well as the NAHLN, the LRN, the FDA Veterinary Laboratory Investigation and Response Network, the USDA National Plant Diagnostic Network, and the DoD's Laboratory Network. Those laboratory systems have developed and maintain the capacity to test for radiological contaminants in various scenarios, and would coordinate during an event to ensure the rapid availability of information for risk assessments.

Mitigation and treatment following radiation events

- The Interagency Modeling and Atmospheric Assessment Center (IMAAC) coordinates and disseminates Federal atmospheric dispersion modeling and hazard (biological, chemical and radiological/nuclear) prediction products. These products provide the federal position during actual or potential incidents involving hazardous material releases. Through plume modeling analysis, the IMAAC provides emergency responders with predictions of hazards associated with atmospheric releases to aid in the decision-making process to protect the public and the environment.
- The FDA has published guidance documents for responses to radioactive contamination in food and protection of the thyroid following ingestion of radioactive iodine.
- The United States has established the Radiation Injury Treatment Network to care for patients who have been severely injured by a radiological event. The network is a consortium of hospitals and physicians with primary expertise in radiation oncology and bone marrow transplantation. The network maintains the inventory of available beds for injured patients. HHS, through the NIH National Library of Medicine, has developed a reference website, Radiation Emergency Medical Management, which provides extensive information to clinicians on radiation, radiation protection, radiation injury, and treatment. The website provides guidelines for the following situations:
    - Nuclear Detonation (weapons and improvised nuclear devices)
    - Radiological Dispersal Devices, Dirty Bomb
    - Nuclear Power Plant/Reactor Incidents

  - Radiological Exposure Devices (hidden, sealed radioactive source)
  - Transportation Incidents

- Other federal organizations, including the DOE's Radiation Emergency Assistance Center/Training Site and the DoD's Armed Forces Radiobiology Research Institute also have internationally recognized programs in radiobiology and radiation medicine to serve as medical resources. These groups also provide significant training to medical personnel worldwide and support the national biodosimetry mission.
- EPA also supports a number of national Special Teams that are capable of providing assistance in situations domestically and internationally. Those teams provide a wide range of resources, including remediation, risk assessment and monitoring, and consequence management.
- The FEMA RadResponder Network is a "whole community" solution for the management of radiological data. It is a product of collaboration with the DOE National Nuclear Security Administration and EPA and is provided free of charge to response organizations at all levels. The online RadResponder architecture enables organizations to rapidly and securely record, share, and aggregate large quantities of data while managing their equipment, personnel, interagency partnerships, and multijurisdictional event spaces. The system can be accessed through applications on smartphones and tablets, and via the web. Through multiple methods for access and interaction, the RadResponder Network can be seamlessly and rapidly employed at all levels of government during a response to a radiological or nuclear emergency.
- During most types of disasters, OSHA can lead the implementation of the NRF Worker Safety and Health Support Annex to protect the safety and health of response and recovery workers.

■ ***Enabling environment is in place for management of Radiation Emergencies*** ***RE1.2***

National plans for radiation safety

- The Federal Radiological Preparedness Coordinating Committee is a FEMA-led interagency group of federal agencies that have specific capabilities or stakes in radiological/nuclear response. There are also a number of committees that are led by the White House NSC Staff. FEMA also coordinates response across multiple sectors of federal, state, and local governments.
- The National Alliance for Radiation Readiness is a consortium of federal, state, and local public health organizations, including non-governmental organizations. The Alliance helps to coordinate planning for the public health response to radiation incidents at all levels and helps to organize radiation professionals at the state and local levels.

Hazard regulation

- Nuclear power plant licensees are required by NRC regulations to have emergency plans for radiation incidents/accidents/events at the power plant. Those plans typically include MOU with local response officials for support in various areas, such as fire and medical response. NRC oversees exercises and the evaluation of on-site responses, while FEMA oversees exercises and the evaluation of off-site responses.
- The DOT is responsible for the safe transport of radioactive materials in commerce. The NRC is responsible for certifying the design of packages that will be used to safely transport radioactive material. In 1979, the DOT and NRC signed a MOU describing each agency's role with regard to regulation of the transport of radioactive material. The transportation of radioactive materials would follow the regulations of the DOT and CBP, as well as the *ICAO Technical Instructions for Dangerous Goods*. During emergencies, special permits are available to facilitate transportation of samples and other radioactive materials if compliance with the DOT Hazardous Material Regulations requirements is not feasible. New mechanisms would likely be required to handle larger volumes of radioactive materials, waste, and samples generated from a multi-jurisdictional emergency.

Funding support for emergency response

- The United States has a number of mechanisms for funding the response to a radiation emergency. Those include both federal and private sources from statutory authorities and private insurance funds. However, in a large-scale radiological or nuclear emergency, additional supplemental funding may be needed (e.g., Congressional authorizations) based on the scale of the response and the extent of recovery. A Stafford Act declaration (as described in the *National Legislation, Policy and Financing* section of this Report) could make federal resources immediately available to support state and local government response.

Examples of exercises and simulations

- The U.S. radiological and nuclear emergency response community participates in five to 10 exercises and drills of different types each year. There are also regular exercises that examine other threat scenarios. The most recent fully integrated exercise, sponsored by DOE, FEMA, NRC, the state of South Carolina and Duke Energy in July-September 2015, was *Southern Exposure 2015* (SE-15). This exercise was based on a nuclear power plant emergency involving a simulated release of radiological contamination over a widespread area outside of the site boundary. SE-15 included over 2,000 participants. The exercise was unique in that it followed response actions from the immediate response phase through late-phase recovery.
- The FEMA Radiation Emergency Preparedness Program coordinates the national effort to provide state, local, and tribal governments with relevant and executable planning, training, and exercise guidance and policies. These are necessary to ensure that adequate capabilities exist to prevent,

protect against, mitigate the effects of, respond to, and recover from incidents involving commercial nuclear power plants.

Best Practices, Challenges, Gaps, and Recommendations

The United States has comprehensive systems of protection in place for radiological and nuclear hazards, as well as a scalable national response plan that integrates all civil sectors under the NRF. Regular exercises allow Federal agencies and subnational jurisdictions, as well as the nuclear power plant operators, to test both national and local plans and maintain a level of readiness through integrated communication and capabilities across the levels and sectors. U.S. Government policy makers and independent advisors have used lessons from domestic and international radiological events to refine U.S. strategies for radiological emergencies and set priorities for capacity development, system testing, and technological improvements. The FRMAC, IMAAC, the RadResponder Network, and the ICLN are examples of best practices in the United States that help the country to prepare for and respond to radiation events.

There are a number of challenges and opportunities to improve the United States capacity to handle a large-scale radiation emergency. Currently, few laboratories can conduct bioassays for internal radioactive contamination or biodosimetry for the assessment of external radiation exposure. Without those capabilities, it would be very difficult in a large-scale incident to determine an appropriate initial course of medical treatment as well as to make optimal use of limited medical resources. Research and development are needed to create novel, high-throughput systems that are capable of performing biodosimetry in mass casualty situations, as well as novel medical countermeasures that can be manufactured and stored in large quantities. In addition, new triage systems should be networked with the existing public health and clinical systems in order to provide a national capacity for continuity of care and treatment. On the environmental side, there are some laboratory capabilities for the detection of radiological contamination in food, water, and other environmental sources, but those are not widespread.

Another challenge for the United States is a decline in the availability of radiation and radiobiology professionals similar to that observed in the rest of the world. In a large-scale response situation, incident managers at various levels and operational teams may not have immediate access to people with the training and experience to accurately assess a dynamic situation and make recommendations. Additionally, there are not enough scientists in the "development pipeline" to replace those who have retired or will retire soon. Such a shortfall foreshadows a significant gap in the U.S. research and development sector. To address the gaps in the availability of qualified radiation professionals, the National Council on Radiation Protection and Measurements suggested the need for a national effort to increase research funding for low-dose radiation research to spur interest in advanced degrees among baccalaureates. The Council also suggested that existing radiation science laboratories could look for opportunities to support a larger number of trainees earlier in the educational cycle, such as through

internships and fellowships, to provide radiation-degree candidates with opportunities to gain hands-on experience.

APPENDICES

Appendix 1. U.S. IHR NFP procedural supplement for reporting variant influenza viruses.

Notifying the World Health Organization of Human Infections with Novel Influenza Viruses

Purpose

This procedural supplement describes when and how the United States will notify the World Health Organization (WHO) of human infections with recurring, novel influenza A viruses while adhering to the terms of the International Health Regulations (IHR).

Background

Since 2005, human infections with novel "variant" influenza A viruses[a] have been nationally notifiable within the United States using a rapid-reporting system overseen by the U.S Centers for Disease Control and Prevention (CDC). During 2012, a significant increase in the number of H3N2v infections in humans occurred, partially due to improvements to the surveillance system itself. Although there were several hospitalizations and two deaths, the 2012 cases did not represent a change to the overall public health risk. The variant did not lead to worsened clinical severity (on average), increased human-to-human transmission or other concerning virologic characteristics (such as markers for antiviral resistance).

Parallel to the development of U.S.-based reporting, ratification of the IHR in 2007 required that the United States notify the WHO of each confirmed case, or cluster of cases, of variant influenza infection as if it were a new potential public health emergency of international concern (PHEIC). Through the end of 2012, the United States had conducted 32 PHEIC notifications for novel influenza infections, mostly due to the same H3N2 variant. Consistent with the CDC determination, there were no changes to the international public health risk assessment assigned by the WHO. With increased incidence, but no change in risk, the amount of effort involved in those notifications (for all stakeholders, including the WHO) greatly outweighed the benefit to public health.

In August 2012, the CDC, the Assistant Secretary for Preparedness and Response (ASPR) and the Pan American Health Organization (PAHO) convened to discuss a protocol to reduce the number of

[a] "Variant" is used by convention to indicate viruses detected from humans that are known to be genetically similar to viruses circulating in swine.

redundant notifications for influenza cases caused by recurring (though still non-seasonal) variants. The stakeholders agreed to sending/receiving notifications for the first case (or cluster) caused by a recognized influenza variant *in each calendar year* (as a potential PHEIC under Article 6) followed by updates (as needed) for new cases during the remainder of the year. In addition to being posted on the WHO's secure, online Event Information System (EIS), such cases would also continue to be reported as part of CDC's weekly *FluView*.

Despite the reduced number of potential PHEIC notifications to the WHO, the CDC continues to closely monitor infections with variant influenza viruses for indications of increase public health risk. The majority of confirmed cases today continue to be caused by H3N2v and typically result from contact with swine; and most are mild illnesses. No changes in average disease severity or human-to-human transmission have been observed, but the virus remains a cause of non-seasonal (sporadic) cases.

CDC, the IHR Program and PAHO met again in 2015 to determine the effectiveness of the novel influenza virus notification process, resulting in additional refinements to the notification protocol reflected below.

NFP Procedural Supplement: Notifying WHO of Human Infections with Novel Influenza Viruses

1. The first detection of a variant virus **already known to infect humans** (such as H3N2v and H1N2v) in **each calendar year** will be notified as a potential PHEIC using the standard procedures.

2. Subsequent cases of infection with the same variant will be included in the weekly *FluView* update, as well as added to the CDC's influenza A surveillance website at http://www.cdc.gov/flu/swineflu/variant-cases-us.htm. Countries will be referred to those websites in the initial notification, and the NFP will provide the WHO with additional updates (from those websites) upon request.

3. Detection of truly novel influenza variants will follow the standard notification pathway.

4. A case or cases caused by a known influenza variant will trigger urgent notification to WHO under Article 6 (even if, in the same calendar year, a notification has already occurred) if it is determined that:

    a. Epidemiologic or clinical evidence suggests increased severity of disease;

    b. There is evidence of sustained human-to-human transmission;

    c. There are changes to the virus associated with an increased risk to public health, including increased pathogenicity, increased transmissibility (e.g. acquisition of a gene segment that is important in species specificity or has mutations associated with human adaptation), or resistance to influenza antiviral drugs.

Appendix 2. USDA proposed National List of Reportable Animal Diseases.

List of proposed nationally notifiable and monitored diseases among multiple animal species.

Notifiable Multiple-Species Diseases

- Akabane
- Anthrax
- Aujeszky's disease (Pseudorabies, PRV)
- Bluetongue (non-endemic)
- Brucellosis (Brucella abortus)
- Brucellosis (Brucella melitensis)
- Brucellosis (Brucella suis)
- Chronis wasting disease
- Crimean Congo hemorrhagic fever
- Epizootic hemorrhagic disease (EHD)
- Equine encephalomyelitis (Eastern)
- Equine encephalomyelitis (Venezuelan)
- Foot-and-mouth disease
- Glanders (Burkholderia mallei)
- Heartwater
- Japanese encephalitis
- Melioidosis (Burkholderia pseudomallei)
- New and Old World screwworms
- Rabies
- Rift Valley fever
- Rinderpest
- Surra (Trypanosoma evansi)
- Tuberculosis (M. bovis, M. tuberculosis)
- Vesicular stomatitis
- West Nile fever/virus

Monitored Multiple-Species Diseases

- Bluetongue (endemic types 2,10,11,13,17)
- Echinococcosis/hydatidosis (E. granulosis, E.multiocularis, E. oligarthrus, or E. vogeli) spirosis
- Paratuberculosis (Johne's disease)
- Q fever
- Trichinellosis
- Tularemia

List of proposed nationally notifiable and monitored diseases among cattle.

Notifiable Cattle Diseases

- Bovine babesiosis
- Bovine spongiform encephalopathy
- Contagious bovine pleuropneumonia
- Bovine genital campylobacteriosis (Campylobacter fetus venerealis)
- Hemorrhagic septicemia
- Lumpy skin disease
- Theileriosis (East Coast fever)
- Trichomoniasis
- Infectious bovine rhinotracheitis/infectious pustular vulvulvovaginitis (IBR/IPV)
- Trypanosomosis (tsetse transmitted)

Monitored Cattle Diseases

- Anaplasmosis (A. marginale, A. centrale)
- Bovine viral diarrhea (BVD, mucosal disease)
- Enzootic bovine leucosis (BLV)
- Malignant catarrhal fever

List of proposed nationally notifiable and monitored diseases among swine.

Notifiable Swine Diseases

- African swine fever
- Classical swine fever
- Nipah virus
- Swine vesicular disease
- Vesicular exanthema
- Porcine epidemic diahrrea
- Porcine Deltacorona virus disease

Monitored Swine Diseases

- Porcine cysticercosis
- Porcine reproductive and respiratory syndrome
- Swine erysipelas
- Transmissible gastroenteritis (TGE)

List of proposed nationally notifiable and monitored diseases among sheep and goat.

Notifiable Sheep and Goat Diseases

- Contagious caprine pleuropneumonia
- Enzootic abortion of ewes (ovine chlamydiosis, Chlamydia psittaci)
- Nairobi sheep disease
- Peste des petites ruminants
- Scabies
- Scrapie
- Sheep pox and goat pox
- Salmonellosis (Salmonella abortusovis)

Monitored Sheep and Goat Diseases

- Contagious agalactia
- Caprine arthritis/encephalitis (CAE)
- Maedi-visna
- Ovine epididymitis (Brucella ovis infection)

List of proposed nationally notifiable and monitored diseases among equine species.

Notifiable Equine Diseases

- African horse sickness
- Contagious equine metritis
- Dourine
- Equine encephalomyelitis (Western)
- Equine infectious anemia (EIA)
- Equine piroplasmosis
- Equine rhinopneumonitis/equine herpesvirus-1 myeloencephalopathy (EHV1-EHM)
- Hendra

Monitored Equine Diseases

- Equine influenza (Virus Type A)
- Equine rhinopneumonitis (non-EHM)
- Equine viral arteritis

List of proposed nationally notifiable and monitored diseases among avian species

Notifiable Avian Diseases

- Duck viral hepatitis
- Exotic (virulent) Newcastle disease per OIE definition
- Fowl typhoid (Salmonella gallinarum)
- Highly pathogenic AI and low pathogenic AI in poultry as defined in Chapter 10.4, Terrestrial Animal Health Code
- Avian mycoplasmosis (M. gallisepticum)
- Avian mycoplasmosis (M. synoviae)
- Pullorum disease (Salmonella pullorum)
- Turkey rhinotracheitis

Monitored Avian Diseases

- Avian chlamydiosis
- Avian infectious bronchitis
- Avian infectious laryngotracheitis
- Infectious bursal disease (Gumboro disease)

List of proposed nationally notifiable and monitored diseases among fish.

Notifiable Fish Diseases

- Epizootic hematopoietic necrosis
- Epizootic ulcerative syndrome (EUS)
- Gyrodactylosis (Gyrodactylus salaris)
- Infectious haematopoietic necrosis (IHN)
- Infectious salmon anemia (ISA)
- Oncorhynchus masou virus disease (herpesvirosis of salmonids)*
- Red sea bream iridoviral disease
- Spring viremia of carp (SVC)
- Viral encephalopathy and retinopathy*
- Viral hemorrhagic septicemia (VHS)

Monitored Fish Diseases

- Bacterial kidney disease (Renibacterium salmoninarium)*
- Infectious pancreatic necrosis*
- Koi herpesvirus diseases
- Piscirickettsiosis (Piscirickettsia salmonis)*
- Whirling disease (Myxobolus cerebralis)*
- White sturgeon iridoviral disease*

*under APHIS review

List of proposed nationally notifiable and monitored diseases among amphibians.

Notifiable Amphibian Disease

- Infection with ranavirus

Monitored Amphibian Diseases

- Infection with Batrachochytrium dendrobatidis

List of proposed nationally notifiable and monitored diseases among molluscs.

Notifiable Mollusc Disease

- Infection with abalone herpes-like virus
- Infection with Bonamia exitiosa/roughleyi
- Infection with Bonamia ostreae
- Infection with Marteilia chungmuensis*
- Infection with Marteilia refringens
- Infection with Marteilia sydneyi*
- Infection with Ostreid herpesvirus-1 microvar (OsHV-1 microvar)
- Infection with Perkinsus olseni/atlanticus
- Infection with Vibrio tapetis*
- Infection with Xenohaliotis californiensis

- Monitored Mollusc Diseases
- Infection with Haplosporidium costale
- (seaside organism)*
- Infection with Haplosporidium nelsoni (MSX)*
- Infection with Mikrocytos mackini*
- Infection with Perkinsus marinus
- Infection with Quahog parasite unknown (QPX)*

*under APHIS review

List of proposed nationally notifiable and monitored diseases among other crustaceans.

Notifiable Crustacean Disease

- Crayfish plague (Aphanomyces astaci)
- Infectious hypodermal and haematopoietic necrosis
- Infectious myonecrosis
- Necrotizing hepatopancreatitis
- Spherical baculovirosis (Penaeus monodon-type)
- Taura syndrome
- Tetrahedral baculovirosis (B. penaei)*
- White spot disease
- White tail disease
- Yellowhead disease

Monitored Crustacean Diseases

- None at this time

*under APHIS review

List of proposed nationally notifiable and monitored diseases among bees.

Notifiable Bee Diseases

- None at this time

Monitored Bee Diseases (under review)

- Acarapisosis of honey bees
- American foulbrood of honey bees
- European foulbrood of honey bees
- Small hive beetle infestation (Aethina)
- Tropilaelaps infestation of honey bees
- Varroosis of honey bees

List of proposed nationally notifiable and monitored diseases among lagamorphs.

Notifiable Lagamorph Diseases

- Myxomatosis
- Rabbit hemorrhagic disease

Monitored Lagomorph Diseases

- None at this time

List of proposed nationally notifiable and monitored diseases among other (individual) animal species.

Notifiable 'Other' Disease

- Camel pox
- Leishmaniosis

Monitored 'Other' Diseases

- None at this time

Appendix 3. United States list of Nationally Notifiable Diseases (as of 1 April 2016).

Anthrax
Arboviral diseases, neuroinvasive and non-neuroinvasive
- California Serogroup Virus Diseases
- Chikungunya Virus Disease
- Eastern Equine Encephalitis Virus Disease
- Powassan Virus Disease
- St. Louis Encephalitis Virus Disease
- West Nile Virus Disease
- Western Equine Encephalitis Virus Disease

Babesiosis
Botulism / *c. botulinum*
- Botulism, Foodborne
- Botulism, Infant
- Botulism, Other
- Botulism, Wound

Brucellosis
Campylobacteriosis
Cancer
Carbon Monoxide Poisoning
Chancroid
Chlamydia trachomatis infection
Cholera
Coccidioidomycosis / Valley Fever
Congenital Syphilis
Cryptosporidiosis
Cyclosporiasis
Dengue virus infections
- Dengue
- Dengue-like illness
- Severe dengue

Diphtheria
Ehrlichiosis and Anaplasmosis
- *Anaplasma phagocytophilum* Infection
- *Ehrlichia chaffeensis* Infection
- *Ehrlichia ewingii* Infection
- Undetermined Human Ehrlichiosis/Anaplasmosis

Foodborne Disease Outbreak
Giardiasis
Gonorrhea
Haemophilus influenzae, invasive disease
Hansen's disease / Leprosy
Hantavirus infection, non-Hantavirus pulmonary syndrome
Hantavirus pulmonary syndrome (HPS)
Hemolytic uremic syndrome, post-diarrheal (HUS)
Hepatitis A, acute
Hepatitis B, acute
Hepatitis B, chronic
Hepatitis B, perinatal infection
Hepatitis C, acute
Hepatitis C, chronic
HIV Infection (AIDS has been reclassified as HIV Stage III) (AIDS/HIV)
Influenza-associated pediatric mortality
Invasive Pneumococcal Disease (IPD) / *Streptococcus pneumoniae*, Invasive Disease
Lead, Elevated Blood Levels
- Lead, Elevated Blood Levels, Adult (≥16 Years)
- Lead, Elevated Blood Levels, Children (<16 Years)

Legionellosis / Legionnaire's Disease or Pontiac fever
Leptospirosis
Listeriosis
Lyme disease
Malaria
Measles / Rubeola
Meningococcal disease
Mumps
Novel influenza A virus infections
Pertussis / Whooping Cough
Pesticide-Related Illness and Injury, Acute
Plague
Poliomyelitis, paralytic
Poliovirus infection, nonparalytic
Psittacosis / Ornithosis
Q fever
- Q fever, acute
- Q fever, chronic

Rabies, animal
Rabies, human
Rubella / German Measles
Rubella, congenital syndrome (CRS)
Salmonellosis
Severe Acute Respiratory Syndrome-Associated Coronavirus Disease (SARS)
Shiga toxin-producing *Escherichia coli* (STEC)
Shigellosis
Silicosis
Smallpox / Variola
Spotted Fever Rickettsiosis
Streptococcal toxic shock syndrome (STSS)
Syphilis
- Syphilis, Early Latent
- Syphilis, Late Latent
- Syphilis, late with clinical manifestations (including late benign syphilis and cardiovascular syphilis)
- Syphilis, Primary
- Syphilis, Secondary
- Syphilitic Stillbirth

Tetanus / *c. tetani*
Toxic shock syndrome (other than Streptococcal) (TSS)
Trichinellosis / Trichinosis
Tuberculosis (TB)
Tularemia
Typhoid fever
Vancomycin-intermediate *Staphylococcus aureus* and Vancomycin-resistant *Staphylococcus aureus* (VISA/VRSA)
Varicella / Chickenpox
Varicella deaths
Vibriosis
Viral Hemorrhagic Fever (VHF)
- Crimean-Congo Hemorrhagic Fever virus
- Ebola virus
- Lassa virus
- Lujo virus
- Marburg virus
- New World Arenavirus – Guanarito virus
- New World Arenavirus – Junin virus
- New World Arenavirus – Machupo virus
- New World Arenavirus – Sabia virus

Waterborne Disease Outbreak
Yellow fever
Zika Virus Disease and Zika Virus, Congenital Infection
- Zika Virus Disease
- Zika Virus, Congenital Infection

Appendix 4. HHS and USDA Biological Select Agents and Toxins

HHS SELECT AGENTS AND TOXINS

Abrin
Bacillus cereus Biovar *anthracis*
Botulinum neurotoxins*
Botulinum neurotoxin producing species of *Clostridium**
Conotoxins (Short, paralytic alpha conotoxins containing the following amino acid sequence $X_1CCX_2PACGX_3X_4X_5X_6CX_7$)[a]
Coxiella burnetii
Crimean-Congo haemorrhagic fever virus
Diacetoxyscirpenol
Eastern Equine Encephalitis virus[c]
Ebola virus*
*Francisella tularensis**
Lassa fever virus
Lujo virus
Marburg virus*
Monkeypox virus[c]
Reconstructed replication competent forms of the 1918 pandemic influenza virus containing any portion of the coding regions of all eight gene segments (Reconstructed 1918 Influenza virus)
Ricin
Rickettsia prowazekii
SARS-associated coronavirus (SARS-CoV)
Saxitoxin
South American Haemorrhagic Fever viruses:
- Chapare
- Guanarito
- Junin
- Machupo
- Sabia

Staphylococcal enterotoxins A,B,C,D,E subtypes
T-2 toxin
Tetrodotoxin
Tick-borne encephalitis complex (flavi) viruses:
- Far Eastern subtype
- Siberian subtype
- Kyasanur Forest disease virus
- Omsk hemorrhagic fever virus

Variola major virus (Smallpox virus)*
Variola minor virus (Alastrim)*
*Yersinia pestis**

*Denotes Tier 1 Agent

OVERLAP SELECT AGENTS AND TOXINS

*Bacillus anthracis**
Bacillus anthracis Pasteur strain
Brucella abortus
Brucella melitensis
Brucella suis
*Burkholderia mallei**
*Burkholderia pseudomallei**
Hendra virus
Nipah virus
Rift Valley fever virus
Venezuelan equine encephalitis virus[c]

USDA SELECT AGENTS AND TOXINS

African horse sickness virus
African swine fever virus
Avian influenza virus[3]
Classical swine fever virus
Foot-and-mouth disease virus*
Goat pox virus
Lumpy skin disease virus
Mycoplasma capricolum[c]
Mycoplasma mycoides[c]
Newcastle disease virus[b,c]
Peste des petits ruminants virus
Rinderpest virus*
Sheep pox virus
Swine vesicular disease virus

USDA PLANT PROTECTION AND QUARANTINE (PPQ) SELECT AGENTS AND TOXINS

Peronosclerospora philippinensis (Peronosclerospora sacchari)
Phoma glycinicola (formerly Pyrenochaeta glycines)
Ralstonia solanacearum
Rathayibacter toxicus
Sclerophthora rayssiae
Synchytrium endobioticum
Xanthomonas oryzae

a. C = Cysteine residues are all present as disulfides, with the 1st and 3rd Cysteine, and the 2nd and 4th Cysteine forming specific disulfide bridges; The consensus sequence includes known toxins α-MI and α-GI (shown above) as well as α-GIA, Ac1.1a, α-CnIA, α-CnIB; X1 = any amino acid(s) or Des-X; X2 = Asparagine or Histidine; P = Proline; A = Alanine; G = Glycine; X3 = Arginine or Lysine; X4 = Asparagine, Histidine, Lysine, Arginine, Tyrosine, Phenylalanine or Tryptophan; X5 = Tyrosine, Phenylalanine, or Tryptophan; X6 = Serine, Threonine, Glutamate, Aspartate, Glutamine, or Asparagine; X7 = Any amino acid(s) or Des X and; "Des X" = "an amino acid does not have to be present at this position." For example if a peptide sequence were XCCHPA then the related peptide CCHPA would be designated as Des-X.

b. A virulent Newcastle disease virus (avian paramyxovirus serotype 1) has an intracerebral pathogenicity index in day-old chicks (Gallus gallus) of 0.7 or greater or has an amino acid sequence at the fusion (F) protein cleavage site that is consistent with virulent strains of Newcastle disease virus. A failure to detect a cleavage site that is consistent with virulent strains does not confirm the absence of a virulent virus.

c. Select agents that meet any of the following criteria are excluded from the requirements of this part: Any low pathogenic strains of avian influenza virus, South American genotype of eastern equine encephalitis virus , west African clade of Monkeypox viruses, any strain of Newcastle disease virus which does not meet the criteria for virulent Newcastle disease virus, all subspecies Mycoplasma capricolum except subspecies capripneumoniae (contagious caprine pleuropneumonia), all subspecies Mycoplasma mycoides except subspecies mycoides small colony (Mmm SC) (contagious bovine pleuropneumonia), and any subtypes of Venezuelan equine encephalitis virus except for Subtypes IAB or IC, provided that the individual or entity can verify that the agent is within the exclusion category. 9/10/13

Appendix 5: Acknowledgements for Production of the JEE Self-Assessment Report First Draft.

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