

15 Years of Preparedness: Are US Public Health Laboratories Ready?

A Report of the 2017 APHL
All-Hazards Preparedness Survey



MAY 2018

Background

Public health laboratories (PHLs) play a crucial role in protecting the public's health from various threats, providing services to prepare for and respond to all-hazards threats—chemical, biological and radiological—as well as incidents such as natural disasters and emerging infectious diseases. This past year, US PHLs have been very active, responding to ongoing effects of Zika virus, local outbreaks of various pathogens and multiple hurricanes. PHLs were able to respond because of their ability to maintain state of the art technology, a dedicated and skilled workforce and an established network of reliable peer laboratories and other key partners.

The Public Health Emergency Preparedness (PHEP) Cooperative Agreement, issued by the US Centers for Disease Control and Prevention (CDC), continued to provide much of the vital funding necessary to support PHL preparedness and response work. Public Health Laboratory Testing, one capability component of the PHEP Cooperative Agreement, is performed by state and local PHLs, many of which comprise the Laboratory Response Network (LRN) for Biological and Chemical Threats Preparedness (LRN-B and LRN-C). The LRN is the nation's laboratory emergency response system for biological, chemical and radiological threats and other public emergencies such as natural disasters. Founded by APHL, CDC and the Federal Bureau of Investigation (FBI) in 1999 to improve US readiness for bioterrorism, the LRN remains a valuable resource for law enforcement and public health officials. It links local, state and federal public health laboratories with sentinel clinical, food, veterinary, environmental and agricultural laboratories; and military and international laboratory centers.

This report provides a historical perspective on funding for laboratory preparedness in US PHLs and outlines progress towards maintaining a warm base to respond to the next threat.

Methods

APHL collected data for the 2017 All-Hazards Laboratory Preparedness Survey in the fall of 2017. The survey covered the 12-month period from July 1, 2016 – June 30, 2017, representing Fiscal Year 2016 (FY16) CDC PHEP Cooperative Agreement, Budget Period 5. The survey was distributed to every state PHL, as well as PHLs in the District of Columbia, Puerto Rico, New York City and Los Angeles County. Data was collected using Qualtrics®, a web-based survey tool and data repository. Each participant received an email with a unique survey link and a copy of the survey. 53 PHLs (98%) responded to this survey. The [APHL 2017 All-Hazards Laboratory Preparedness Survey Summary Data Report](#) presents aggregate survey assessment results for all questions.



Maureen Sullivan (Minnesota Department of Health PHL) provides instruction of motility media to a hospital laboratorian at a training workshop for sentinel clinical laboratories. Photo: MN DOH

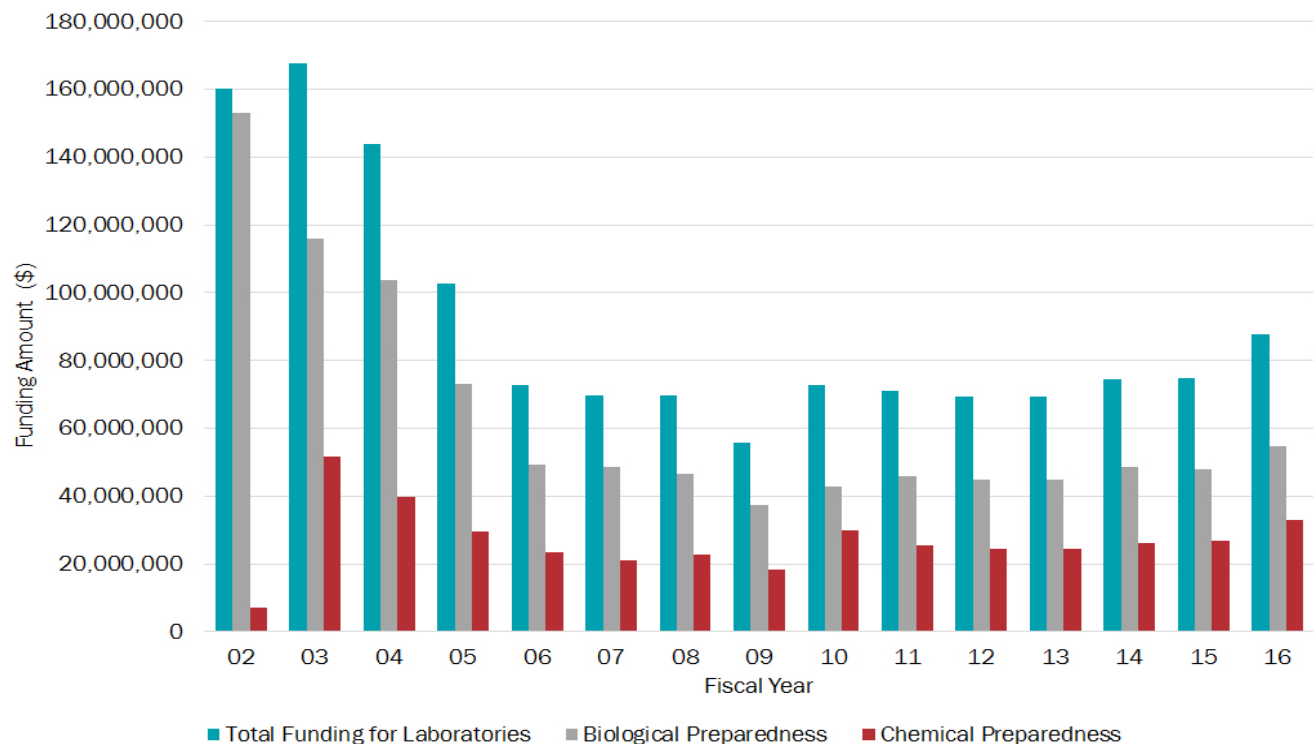
FUNDING

Over the past 15 years, CDC has provided funding via the PHEP Cooperative Agreement to strengthen preparedness across the US public health system. This funding source has been pivotal in ensuring that the public health infrastructure is poised to respond to various threats. In 15 years, via PHEP, CDC has provided nearly \$11 billion (see Figure 1). Approximately \$1.36 billion has contributed to:

- Renewed PHL workforce by supporting recruitment, hiring and training
- Implementation of modern technologies including the procurement of new laboratory equipment and maintenance contracts
- Safer facilities via renovations to ensure appropriate containment to protect workers and the public (e.g. biosafety level 3 (BSL-3) suites)
- Efficient data exchange by implementation of electronic messaging systems
- Communications Systems to facilitate rapid information sharing among PHLs, responders and other partners
- Transportation Systems, including couriers for faster and safer sample transport
- Collaborative approach where PHLs conduct outreach to diverse partners such as law enforcement, Civil Support Teams (CSTs), other first responders and clinical labs.

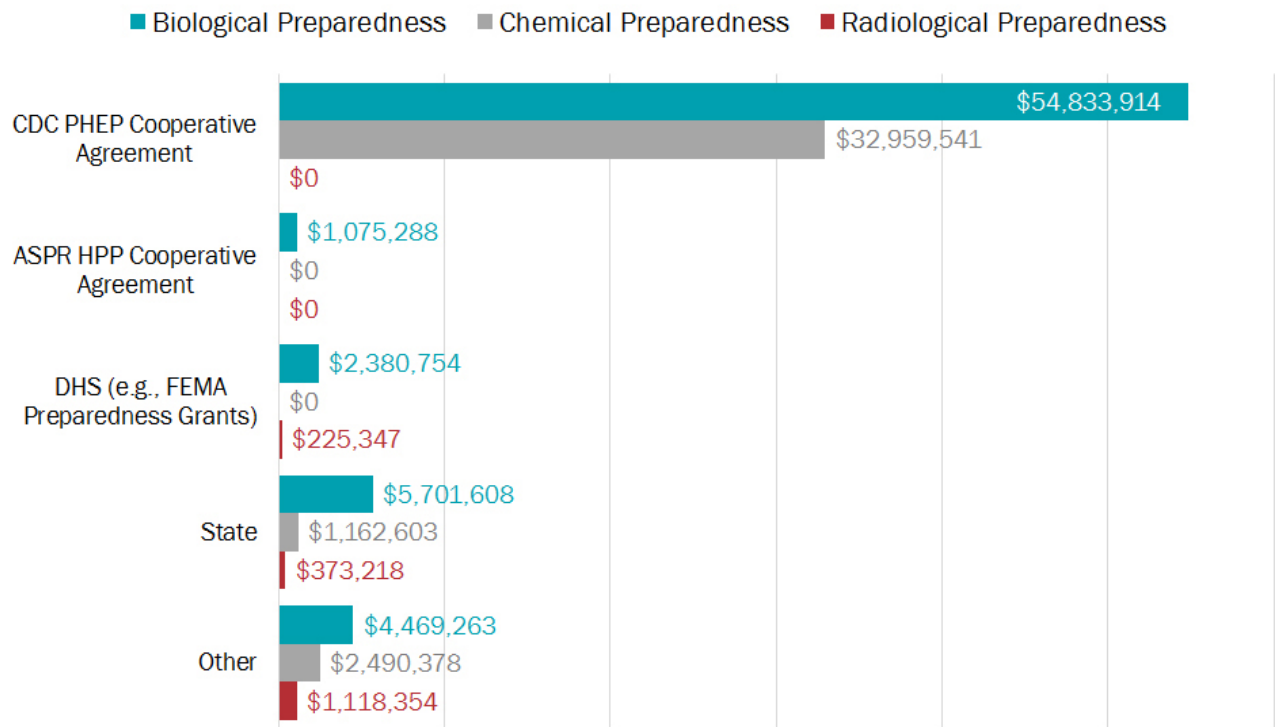
Together, these activities and resources ensure that the nation has a warm base poised to respond to the next threat. This funding enabled the US PHL system to be ready for whatever threat came its way—Anthrax, Brucellosis, Plague, Tularemia, Botulism, West Nile, Severe acute respiratory syndrome (SARS), Middle East respiratory syndrome (MERS), pandemic influenza, Ebola, Zika, multiple foodborne outbreaks and the recent hurricanes.

Figure 1: PHEP Funding: 2002-2016 for CDC-funded Jurisdictions



In FY16, 53 PHLs reported receiving a total of \$107 million in funds, primarily from federal agencies, such as CDC and the US Department of Homeland Security (DHS), almost \$88 million of which came solely from the CDC PHEP Cooperative Agreement. Other sources of funding include the US Department of Agriculture (USDA) and Food Drug Administration (FDA) via the Food Emergency Response Network (FERN) (See Figure 2).

Figure 2: Sources of PHL Preparedness Funding (FY16)



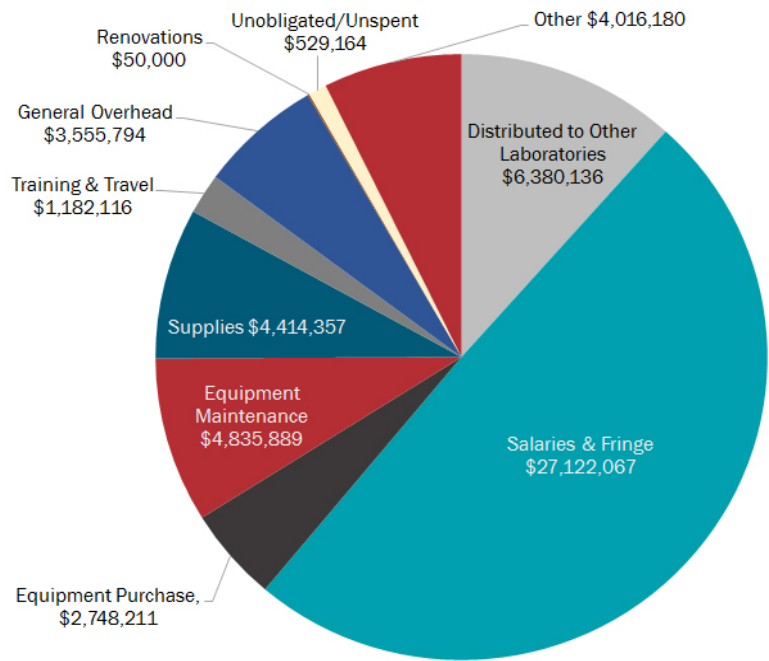
California Develops New Method for Testing Radiation in Drinking Water

Despite all-around limited funding for radiological threat preparedness, PHLs have found innovative ways to advance capabilities. Within the California Department of Public Health (CDPH), scientists in the CDPH Drinking Water and Radiation Laboratory Branch worked to develop a new testing methodology for the determination of gross alpha and gross beta radiation in drinking water using liquid scintillation counting technology. This new method advances detection capability by allowing for lower detection limits of analytes, shorter counting times, a reduction in biases due to matrix effects and calibration standards and employs state-of-the-art technology.

This method received approval by the US Environmental Protection Agency (US EPA) for use in testing drinking water sources for compliance with the Safe Drinking Water Act. Having also received approval by two consensus standards organizations—Standards Methods for the Examination of Water and Wastewater and the Annual Book of ASTM International Standards—it is at the forefront of methodologies that can help other PHLs ensure their municipality’s water is safe from radiological contamination.

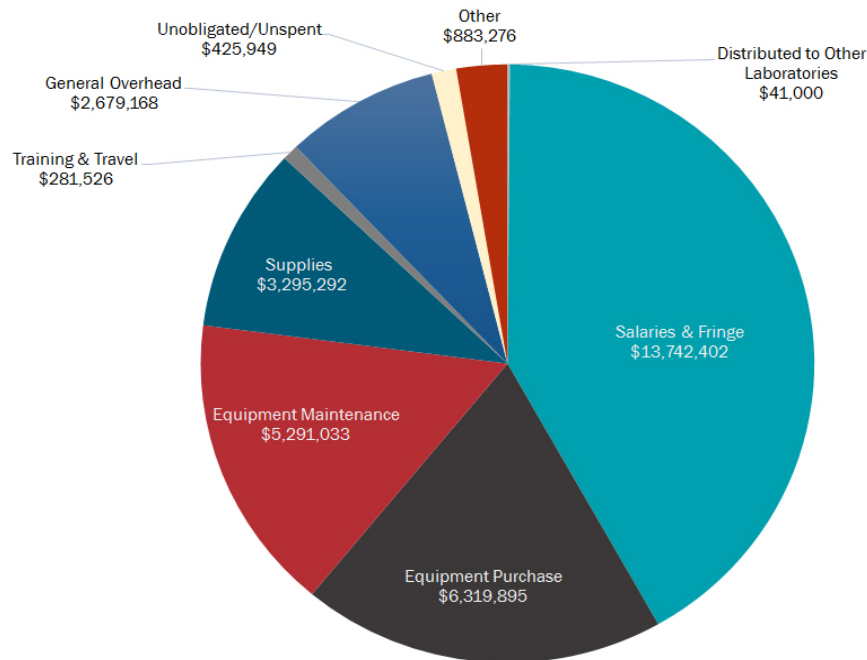
Figures 3 and 4 illustrate how CDC PHEP Cooperative Agreement funds were used in PHLs.

Figure 3: Allocation of FY16 CDC PHEP Funding for Biological Laboratory Preparedness (n=\$54.8 million)



Other major activities supported by preparedness funding included whole genome sequencing costs, on-demand courier fees, laboratory information management system (LIMS) support and communication services.

Figure 4: Allocation of FY16 CDC PHEP Funding for Chemical Laboratory Preparedness (n=\$32.9 million)



Other major activities included proficiency testing costs, courier fees and hazardous waste disposal.

While CDC has continued to resource biological and chemical threat laboratory preparedness, PHLs are woefully underfunded to prepare for a radiological or nuclear threat. In fact, there is no funding for CDC to support a network of laboratories to develop capability to prepare for a radiological or nuclear threat. Of the 53 PHLs that responded, only 8 (15%) reported receiving any funds for radiological preparedness. The eight laboratories reported receiving a total of \$1.7 million in FY16 primarily from the Department of Homeland Security (DHS) and FERN. Among all laboratories, issues with funding have left 47 (89%) laboratories unable to perform radiological testing in clinical samples and 28 (53%) laboratories unable to test environmental samples.

PERSONNEL

A core element of a prepared public health system is personnel. The highly skilled staff who support PHLs typically have years of experience and perform a variety of functions. In addition to the laboratorians and other scientists who perform testing of public health importance, there are key positions in a laboratory to ensure a well-prepared system to respond to all threats.

- **Biological Threat (BT) Preparedness Coordinator** –ensures the laboratory system has capacity to respond to biological terrorism and other health threats. They work with local PHLs, clinical laboratories, first responders and other partners to assure protocols, guidance and other resources are up to date.¹
- **Chemical Threat (CT) Preparedness Coordinator** –coordinates with their local health and medical community, first responders and other response groups to provide effective laboratory surge capacity for chemical events and other public health emergencies.²
- **Training Coordinator**–provides technical and training resources to local public health districts, clinical laboratories and other partners for response to biological and chemical threats, as well as other public health emergencies. They also provide guidance on regulations to assist laboratory partners with compliance.
- **Safety Officer and Biosafety Officer/Official (BSO)** – works to ensure the overall safety of the employees and facility. In some PHLs, these positions are combined. In recent years, the CDC's Epidemiology and Laboratory Capacity for Infectious Diseases (ELC) Program via Ebola Supplemental Funding has resourced the hiring of BSOs across US PHLs. The funding enabled the majority of US PHLs funded by CDC ELC to recruit and hire BSOs.



Laboratory personnel from the Virginia Division of Consolidated Laboratory Services (DCLS) discuss nucleic acid extraction options. Photo: VA DCLS

The Biosafety Officers in public health laboratories “will ensure adequate biosafety training and practices to avoid potential hazards associated with the handling of biological materials, the spread of multi-drug resistant pathogens and threats of emerging pathogens, and acts of biological terrorism. The person in this position develops and monitors adherence to laboratory biosafety programs, provides related workforce training for biosafety for the agency and sentinel clinical laboratories, assists public health and clinical laboratories with biosafety risk assessments and risk mitigation plans, and works cohesively with key system partners and public health officials to improve communications and emergency management and response practices. Efficient communication skills, knowledge of microbiology and general laboratory practices, and experience in laboratory safety, training and outreach, and quality management systems are necessary for this position.”³

- Laboratory Director—oversees all functions of the laboratory and is ultimately responsible for the safety of employees and execution of services. In addition to performing a broad assortment of management and administrative duties, this individual acts as the direct contact with other governmental leaders.⁴

In 2001, 65% of state PHLs noted that they lacked adequate staff, such as a BT Coordinator, to manage major all-hazards events, and noted the need for additional staff to handle managerial, clerical, information sharing, communications, training and worker safety duties. During this same year, funding was not yet in place to help establish a CT Coordinator position. As of 2017, those numbers have improved, with only 42% (n=22) of labs indicating non-competitive salaries and 45% (n=24) stating a lack of qualified applicants, affecting their ability to carry out preparedness activities. While these figures show a reduction in staffing issues, challenges still remain in ensuring laboratories have an adequate workforce.

As funding dwindles, many states have combined functions with one person bearing the responsibility for internal safety as well as for building partnerships externally. Responding to natural disasters, emerging threats, chemical events and major national events such as sporting activities, it is ultimately up to a small workforce to be the first line of defense from disease outbreak.

Preparing for Politics in Pennsylvania

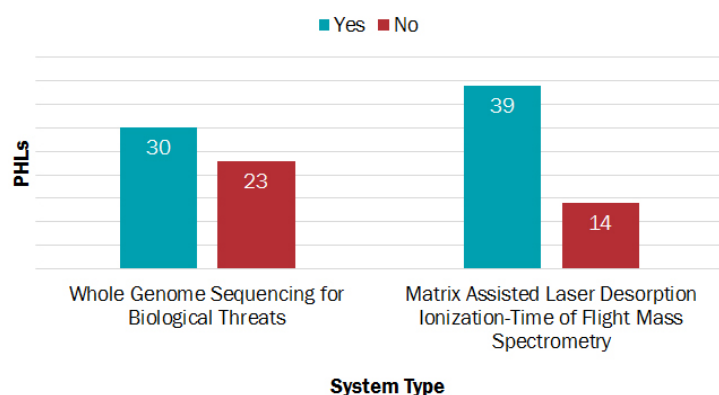
In July 2016, the Pennsylvania Bureau of Laboratories (BOL) was tasked with helping prepare for the Democratic National Convention. BOL, which houses routine daily testing for the DHS BioWatch program, supported enhanced BioWatch testing during the convention over a six-day period. Additional staff from other BioWatch sites traveled to BOL to provide the necessary support to perform molecular testing for bioterrorism agents, protein testing and radiological testing over three shifts per day. Established in 2003, the DHS-managed BioWatch Program provides air-monitoring, analysis, notification procedures and risk assessment to more than 30 large metropolitan areas across the country with the ultimate goal to have an early warning of a bioterrorist attack.⁵

To meet increased testing demands, Select Agent-registered space was needed for sample processing. Meeting the security requirements of the Federal Select Agent Program (FSAP) was challenging since the visiting BioWatch staff were not approved to access the BOL's registered space. BOL's Responsible Official and Alternate Responsible Officials consulted FSAP and developed a plan to convert a portion of the Select Agent Laboratory suite into unrestricted space where no Select Agents would be accessible. Once testing for the convention was completed, BOL underwent a FSAP inspection and received approval to convert a portion of the Select Agent Laboratory suite into unrestricted space for special situations. In the end, the result provided BOL with a space for future surge testing capability while adhering to federal regulations. BOL successfully adapted their laboratory to perform increased testing in support of surveillance during the Democratic National Convention.

FACILITIES, EQUIPMENT AND SUPPLIES

PHLs rely on modern resources and practices in order to operate effectively. The laboratory itself is an essential structure in which laboratorians perform their public health duties. Good biosafety practices are necessary in order to ensure that personnel are protected from the dangerous pathogens that they handle, while biosecurity standards ensure that pathogens aren't removed from the safe confines of the laboratory. Understanding the importance of these practices, 50 PHLs (94%) reported having biosafety professionals that oversee guidance and trainings on these important principles to PHL staff and external sentinel clinical laboratories. For some BSOs,

Figure 5: Implementation of Advanced Technology in PHLs



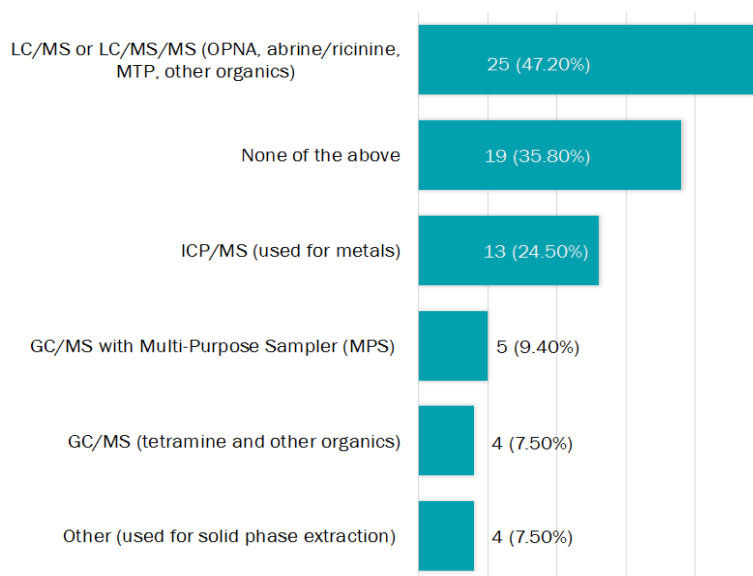
duties also included acting as the Responsible Official to FSAP, ensuring compliance with stringent regulations that protect employees and the public from dangerous pathogens.

Advancing technology has helped laboratories with faster identification of pathogens and detection of chemical exposures and threats. But equipment purchase and maintenance agreements have continued to demand significant amounts of funding, accounting for \$19.2 million (22%) of FY16 PHEP funded laboratory expenditures for both biological and chemical preparedness. Every laboratory reported having automated nucleic acid extraction platforms, with many planning to procure new instruments in the near future. Thirty-nine (74%) laboratories had or planned to purchase MALDI-TOF MS instruments, which is now being commonly utilized in public health and clinical laboratories (see

Figure 5). While implementing the newest technology may help with faster sample turnaround, leading to quicker test confirmation and treatment for affected individuals, there are significant safety concerns and performance issues which must be addressed during the evaluation of new technologies. Laboratories which comprise the LRN-B and LRN-C work collaboratively with federal agencies and other laboratories to evaluate new technologies such as MALDI-TOF MS.

Last year, 17 PHLs (32%) indicated an increase in LRN-C capabilities, resulting from expanded equipment, personnel and the addition of new LRN-C methodologies. This resulted in faster analytical turnaround time for analyzing urgent samples such a public concerns of lead poisoning incidents and biomonitoring investigations. Only four PHLs (7.5%) experienced a decrease in capability, occurring from the loss of staff, equipment and reduction in approved LRN-C methods. Updated laboratory equipment is also critical to ensure the most advanced technology is used, as 25 (47%) of laboratories indicated intent to replace liquid chromatography-mass spectrometry (LC/MS) or liquid chromatography tandem-mass spectrometry (LC/MS/MS) equipment while 13 (25%) plan to replace inductively coupled plasma mass spectrometry (ICP/MS) instruments in the near future (see Figure 6).

Figure 6: LRN-C Equipment Replacement Plans



Testing for Chemical Hazards in Iowa

The State Hygienic Laboratory (SHL) at the University of Iowa is well-prepared to handle possible chemical threats. In July 2016, SHL's capabilities were called into action when a local hazardous materials (HAZMAT) team reported the unexpected spraying of an unknown chemical substance in a residential area of Marion, IA from a crop duster plane. The substance left a white residue on cars and houses, and it was also sprayed onto the local swimming pool. Although it was anticipated that the substance was a broadleaf herbicide, SHL left nothing to chance. Analyzing three sample disks using a qualitative LC/MS/MS method, the emergency response chemists determined that the substance was a mixture of fungicides. The results were reported to different local and state agencies the following day, allowing for a safe conclusion to an otherwise potential threat.

TRAINING AND OUTREACH

With the advent of culture-independent and field screening technologies, it is becoming difficult to determine a source of infection or contamination. PHLs engage with traditional partners such as clinical laboratories (e.g. hospitals) as well as non-traditional partners such as firefighters, police and other law enforcement so they are well-positioned to respond to the next threat (see Public Health Laboratory Collaborations table below).

Thirty PHLs (57%) indicated having a position dedicated to clinical laboratory outreach. Of these laboratories, 26 conducted trainings, 20 performed outreach on reporting requirements and referral for laboratory testing, and 16 engaged in chemical threat response outreach. Public health laboratories hosted 439 classes and training courses in FY16, providing trainings for almost 5,500 laboratory professionals in performing risk assessments, packing and shipping of hazardous materials and important protocol updates.

While PHLs continue to provide training and/or ensure access to relevant training materials, there are many limitations to ensuring laboratorians and the public are safe from an emerging public health threat. With the end of CDC ELC Ebola Biosafety Supplemental funds and reduction in other federal funding, many states are struggling to determine how to expand outreach to clinical partners.

In FY16, PHLs offered many biosafety training courses but only secured an average participation of 44.5% of sentinel clinical laboratories in their state or jurisdiction. While 50 (94%) states issued proficiency tests or exercises to assess the competency of sentinel clinical laboratories, participation is not mandatory. PHLs use the results of these assessments to modify training courses, target communications and also identify areas for ongoing support. Of note, only four (8%) PHLs use the results of these assessments to impact the renewal status of sentinel clinical laboratories.



The Minnesota Department of Health conducts a HAZMAT training.
Photo: MN DOH

Public Health Laboratory Collaborations

Partner	Number of PHLs
Sentinel Clinical Laboratory	53
Civil Support Teams (CSTs)	53
Epidemiologists	52
Federal Bureau of Investigation (FBI)	52
U.S. Postal Inspection Service	48
State or Local Law Enforcement	48
Local Hazardous Materials (HAZMAT) Teams	45
Physician/Medical Providers	43
Veterinary Laboratory	39
Fire Department	38
State HAZMAT Teams	36
Food Laboratory	33
Poison Control Centers	29
Agriculture Laboratory	29
Local/Branch Public Health Laboratory	24
Department of Homeland Security (DHS)/BioWatch	24
University Research Laboratory	24
Paramedics/Emergency Medical Technicians (EMTs)	20
Department of Defense Laboratories (Military)	14
Other	13

Strengthening State and Federal First Responders in Alabama

The Alabama Bureau of Clinical Laboratories (BCL) LRN-B and LRN-C labs conduct a full-scale exercise each year with the 46th Weapons of Mass Destruction (WMD) CST in order to test existing sample processing capability. In summer 2016, BCL and CST participated in an Analytical Laboratory System Challenge conducted by a Field Identification Biological Warfare Agents (FIBWA) team from the US Army Medical Research Institute of Infectious Diseases. It was decided after multiple planning calls that BCL would be the ideal location to stage the challenge and, in an effort to maximize the exercise, the 44th WMD CST based in Florida would also participate.

BCL's conference room was used as the command center and routine laboratory security measures were adjusted to allow the CSTs to drill their 48-hour work rotation. The FIBWA team hosted briefings throughout the two-day challenge for scenario updates and to distribute challenge samples, which had been shipped directly to BCL. Because the challenge was more detailed than usual, both groups were able to identify and use each other's strengths to accomplish efficient testing. It also generated discussions on a new testing algorithm and identified the need to train with the preparedness staff at Maxwell Air Force Base. As a result, BCL, the 44th CST and the FBI WMD coordinator hosted a training for the Maxwell Air Force Base Emergency Management, Fire Department and Bioenvironmental groups that included collection and submission of samples, best practices and common mistakes, and testing analysis by the CST and BCL.

CONCLUSIONS

Following the tragic events of September 11, 2001 and the subsequent anthrax attacks, Congress determined that the public health infrastructure for emergency preparedness and response was lacking and needed a significant infusion of funds to be able to respond to all-hazards public health emergencies. As noted earlier, the PHEP Cooperative Agreement, administered by CDC, is the primary resource utilized by state and local health departments to prepare for and respond to all-hazard public health threats. Using PHEP as its primary funding source, state and large local PHLs have made great strides in preparedness since first receiving CDC PHEP Cooperative Agreement funding. These successes encompass:

- Maintaining a warm base – that is, highly trained personnel; dedicated equipment and supplies; electronic systems for notification and data exchange; safe and secure facilities – to respond to all threats
- Utilizing existing systems (e.g., LRN) to respond to multiple threats, including acts of terrorism, emerging infectious diseases, chemical incidents such as oil spills and other events, and natural disasters (e.g. hurricanes)
- Providing training and outreach to partners such as clinical laboratories, first responders and other local PHLs
- Testing the system by implementing formal exercises and drills to assess gaps in planning and capacity and capability
- Maintaining and strengthening diverse partnerships to ensure an effective response

The combination of these efforts has resulted in a stronger public health system and a nation with enhanced preparedness and response capacity and capability. However, despite these improvements, notable gaps in laboratory preparedness remain. These include complacency, funding gaps, workforce shortages, lack of standardized platforms to exchange data electronically and lack of a national strategy to address gaps in laboratory capacity for radiological and nuclear preparedness.

APHL continues to call attention to the gaps in capacity and capability for the detection of radiological and nuclear threats as well as the need for enhanced capability to detect chemical threats in environmental matrices. APHL recommends a sustained funding approach to support state, local and territorial PHL systems.

REFERENCES

1. New York State Department of Health. (2017, April). Emergency Preparedness and Bioterrorism Coordinator. Retrieved from https://www.health.ny.gov/prevention/public_health_works/careers/emergency_preparedness_and_bioterrorism_coordinator.htm
2. Association of Public Health Laboratories (2018, February). Laboratory Network Response-Chemical (LRN-C) Level 3 Resource Handbook. Silver Spring, MD: Association of Public Health Laboratories.
3. Association of Public Health Laboratories (2015). Competencies Based Position Description for Biosafety Officials. Silver Spring, MD: Association of Public Health Laboratories. Available at https://www.aphl.org/MRC/Documents/BS_2015_APHL-Competencies-Based-Biosafety-Official-Position-Description.docx (login required)
4. Association of Public Health Laboratories (2002). Who will run America's public health labs? Educating future laboratory directors. Silver Spring, MD: Association of Public Health Laboratories. Available at http://www.aphl.org/AboutAPHL/publications/Documents/Who_Will_Run_Americas_PHL_2002.pdf
5. Department of Homeland Security (2018, April). Detecting Bioterrorist Attacks. Retrieved from <https://www.dhs.gov/biowatch-program>

Association of Public Health Laboratories

The Association of Public Health Laboratories (APHL) works to strengthen laboratory systems serving the public's health in the US and globally. APHL's member laboratories protect the public's health by monitoring and detecting infectious and foodborne diseases, environmental contaminants, terrorist agents, genetic disorders in newborns and other diverse health threats.

This project was 100% funded with federal funds from a federal program of \$1,768,631. This publication was supported by Cooperative Agreement #NU600E000103 from the US Centers for Disease Control and Prevention (CDC). Its contents are solely the responsibility of the authors and do not necessarily represent the official views of CDC.



8515 Georgia Avenue, Suite 700
Silver Spring, MD 20910
Phone: 240.485.2745
Fax: 240.485.2700
www.aphl.org

© Copyright 2018, Association of Public Health Laboratories. All Rights Reserved.