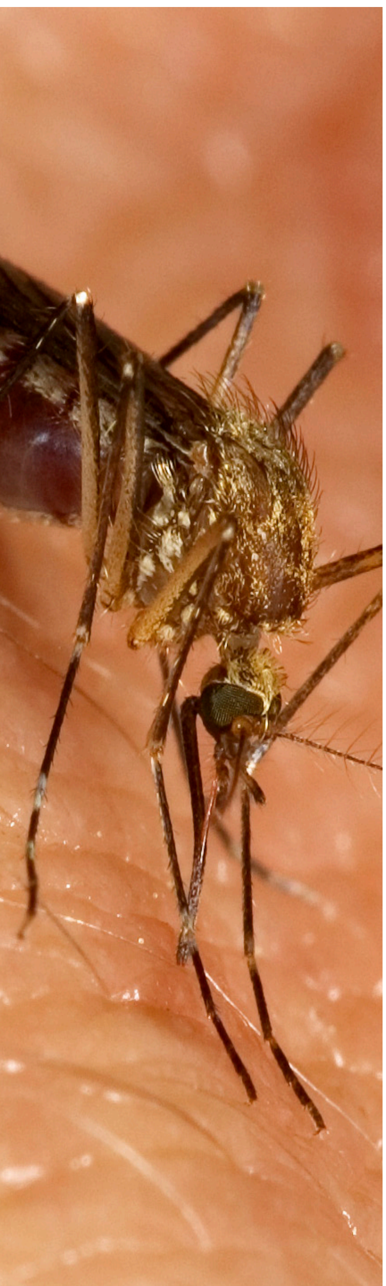
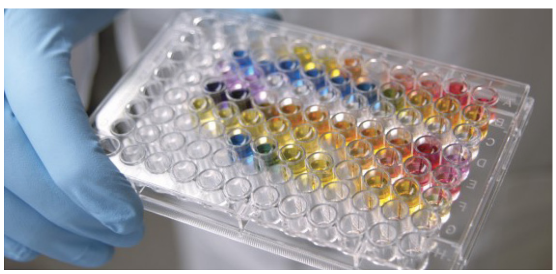
APHL ASSOCIATION OF PUBLIC HEALTH LABORATORIES®

Protecting the Public's Health: Laboratories on the Front Line to Detect the Next Threat

A Report of the APHL 2016 All-Hazards Laboratory Preparedness Survey



ACKNOWLEDGMENTS

APHL would like to thank the 48 state public health laboratories, the District of Columbia (DC), Puerto Rico, New York City and Los Angeles County public health laboratories that completed the 2016 All-Hazards Laboratory Preparedness Survey.

FUNDING

This report was 100% supported by federal funds. The total amount of funding received for the Public Health Preparedness and Response Program is $2,867,000. The total amount of funding received for the Environmental Health Program is $781,000.

This publication was supported by Cooperative Agreement #U60OE000103 funded by 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 or the Department of Health and Human Services.

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EXECUTIVE SUMMARY

The Association of Public Health Laboratories (APHL) surveys public health laboratories (PHLs) annually to assess their ability to respond to threats and to identify challenges that affect rapid response. These laboratories are paramount in protecting our nation's health from various threats, including biological, chemical and radiological, as well as emerging infectious diseases and natural disasters. Throughout the last year, PHLs across the country responded to several threats, notably the emerging threat of Zika virus and the waning effects of Ebola virus disease. These laboratories operate effectively due to their ability to have a highly skilled workforce, cutting edge diagnostic technology, modern facilities that maintain the safety of staff and integrity of specimens and electronic communication systems that provide speedy transmission of test results.

A large part of the preparedness and response work in PHLs is resourced by the US Centers for Disease Control and Prevention (CDC) via its Public Health Emergency Preparedness (PHEP) Cooperative Agreement. In Fiscal Year (FY) 15, 52 PHLs reported receiving a total of $89.7 million in funds from federal agencies with $74.7 million (83%) attributed to the CDC PHEP Cooperative Agreement. PHEP funding levels have remained stable throughout the past decade, leading to significant true-dollar declines when accounting for inflation. These reductions continue to impact PHLs abilities to prepare for the next infectious outbreak and serve their populations with everyday health needs.

Despite operating with smaller budgets, PHLs are continually tasked with expanding their responsibilities to ensure the public's safety. As in years past, PHLs expressed continued difficulty purchasing critical equipment and materials and providing necessary training opportunities to staff. The inability to hire adequate personnel also continues to hamper PHLs' ability to effectively operate, creating the potential for an ineffective response if faced with a disease outbreak or terrorist threat.

The ability of PHLs to respond effectively certainly depends on internal components such as staffing, equipment and communications systems. However, for a response to be effective, PHLs must collaborate with external partners. A thoroughly effective public health response requires a synergistic approach, relying on first responders, federal agencies and clinical partners to coalesce their efforts to identify and resolve issues. The ongoing response to Zika virus provides such an example, where cooperation and continuity of ongoing efforts is necessary to minimize the burden of disease.

This past year PHLs undertook many responsibilities necessary to protect the nation's health. Successes include validating and safely implementing a new assay to detect Zika, dengue and chikungunya viruses in a single sample; expanding access to a bioterrorism training workshop through new online formats; maintaining their Laboratory Response Network (LRN) testing demands while also responding to chemical and biological threats; and hiring new staff to strengthen biosafety and increase outreach to key partners.

Despite their many successes, PHLs still face great adversity when tackling issues encountered by limited funding: a diminished ability to rapidly expand and develop new assays and test methods; consolidation of staffing positions, which tax the personnel's ability to effectively perform; and an inability to replace aging electronic reporting systems. Further, there is a critical gap in preparedness funding and analytical capacity for radiobioassays, the testing of contaminated individuals following an accidental or intentional release of radionuclides. Without swift changes to increase funding of our nation's PHLs, efforts to effectively detect and prevent the next emergency will remain uncertain.

INTRODUCTION

Public health laboratories (PHLs) are the nation's first line of defense against a wide range of threats, protecting the public's health by preparing for and responding to emerging infectious diseases, natural disasters and all-hazard threats, whether biological, chemical or radiological. Throughout the past year, US PHLs have responded to several threats, most notably protecting pregnancies threatened by the emergence of Zika virus. The ability of these laboratories to respond to public health threats relies on their foundation: a dedicated and skilled workforce, cutting edge technology and facilities and communication systems that quickly and reliably send test results.

Much of the preparedness and response work in PHLs is resourced by the US Centers for Disease Control and Prevention (CDC) via its Public Health Emergency Preparedness (PHEP) Cooperative Agreement. One key element of PHEP is "Public Health Laboratory Testing," which is diligently performed by the state and local PHLs of the Laboratory Response Network (LRN) for Biological and Chemical Threats Preparedness (LRN-B and LRN-C). This report provides an aggregate snapshot of preparedness for state PHLs and the District of Columbia, Puerto Rico, New York City and Los Angeles County PHLs, and serves as a benchmark to document the successes and challenges of these laboratories since the inception of CDC PHEP Cooperative Agreement Funding.

METHODS

APHL collected data for the 2016 All-Hazards Laboratory Preparedness Survey in the fall of 2016 on activities conducted during the FY15 CDC PHEP Cooperative Agreement, Budget Period 4 (July 1, 2015–June 30, 2016). The survey was distributed via email with a unique survey link and a copy of the survey; it was sent to all 50 state PHLs, as well as the District of Columbia, Puerto Rico, New York City and Los Angeles County PHLs. APHL achieved a 96% response rate.

Data were collected using Qualtrics, a web-based survey tool and data repository. Descriptive statistics were gathered for all categories:

- Demographics
- Funding and Workforce
- Planning and Response
- Biological Threats
- Chemical Threats
- Radiological Threats

PHLs reported on their capability and capacity to respond to biological, chemical and radiological threats as well as emerging infectious diseases. The following sections present stories and accompanying data that highlight the role of PHLs and the importance of their partnerships in detecting the next threat, protecting health and implementing appropriate public health interventions. Aggregate survey assessment results for all questions are available from APHL upon request.

KEY FINDINGS

Funding

In fiscal year 2015 (FY15), 52 PHLs reported receiving a total of $89.7 million in funds, primarily from federal agencies, such as CDC and the US Department of Health and Human Services (HHS) Assistant Secretary for Preparedness and Response (ASPR) Hospital Preparedness Program (HPP) (See Figure 1).

The vast majority of PHL preparedness funding—$74.7 million, or 83%—came from the CDC PHEP Cooperative Agreement, demonstrating how much PHLs rely on CDC to resource state and local laboratory preparedness activities. Although PHEP funding has been relatively stable over the last decade, the FY15 funding level of $74.7 million represents a significant decline from FY04 when PHLs received $180.4 million (adjusted for inflation). This large decline over the last 10 years has impeded the ability of PHLs to meet the changing demands of public health. Laboratories are expected to maintain preparedness initiatives for biological and chemical terrorist attacks as well as prepare for and respond to infectious diseases such as Ebola, Zika, chikungunya and dengue. As PHLs are called upon to respond to new and complex threats, their inability to maintain equipment, develop new testing procedures and perform outreach to critical partners—such as hospital laboratories and first responder communities—becomes further exposed. The continued decline of CDC PHEP funds further endangers the capability of PHLs to respond to emerging threats.

Figure 1: FY15 Preparedness Funding for PHLs by Activity and Funding Source
PHLS reported receiving $89.7 million in funding for preparedness activities; funding sources include the CDC PHEP Cooperative Agreement, HHS Assistant Secretary for Preparedness and Response (ASPR), state governments and others.

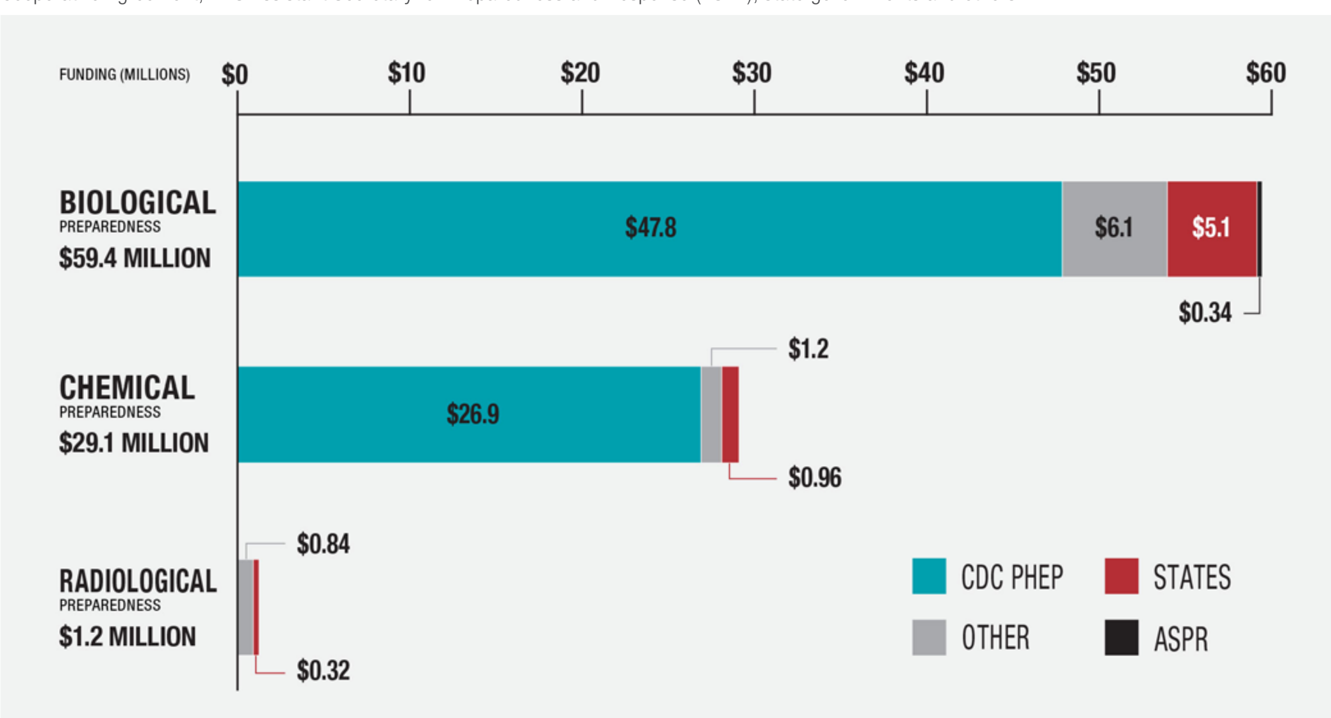
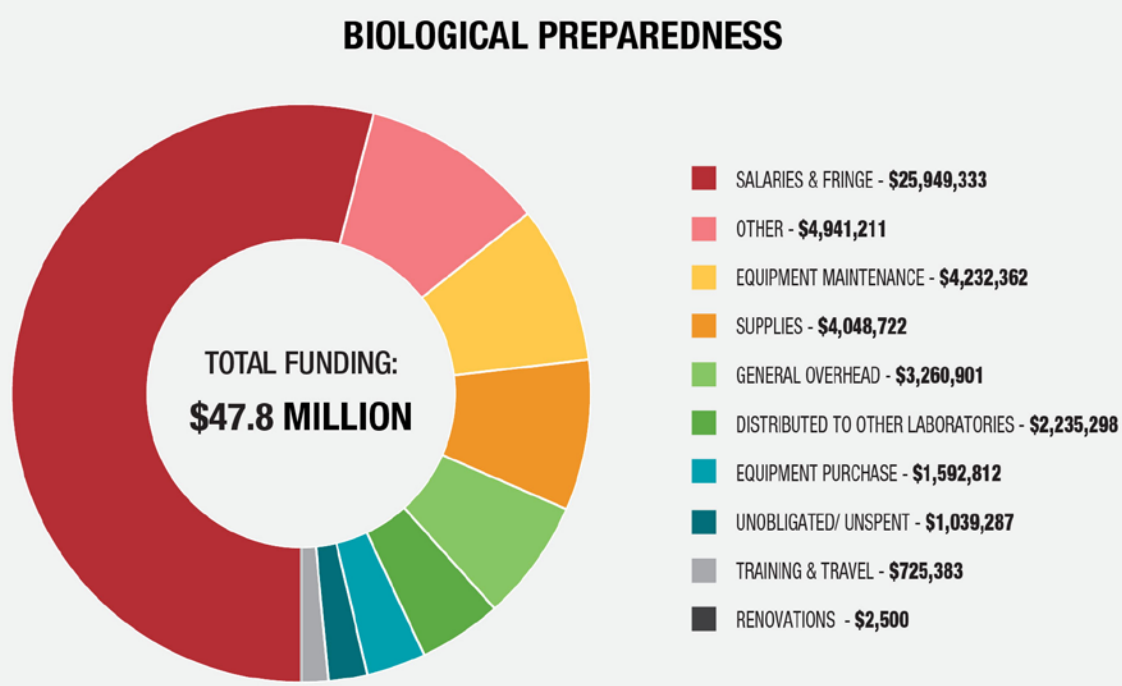
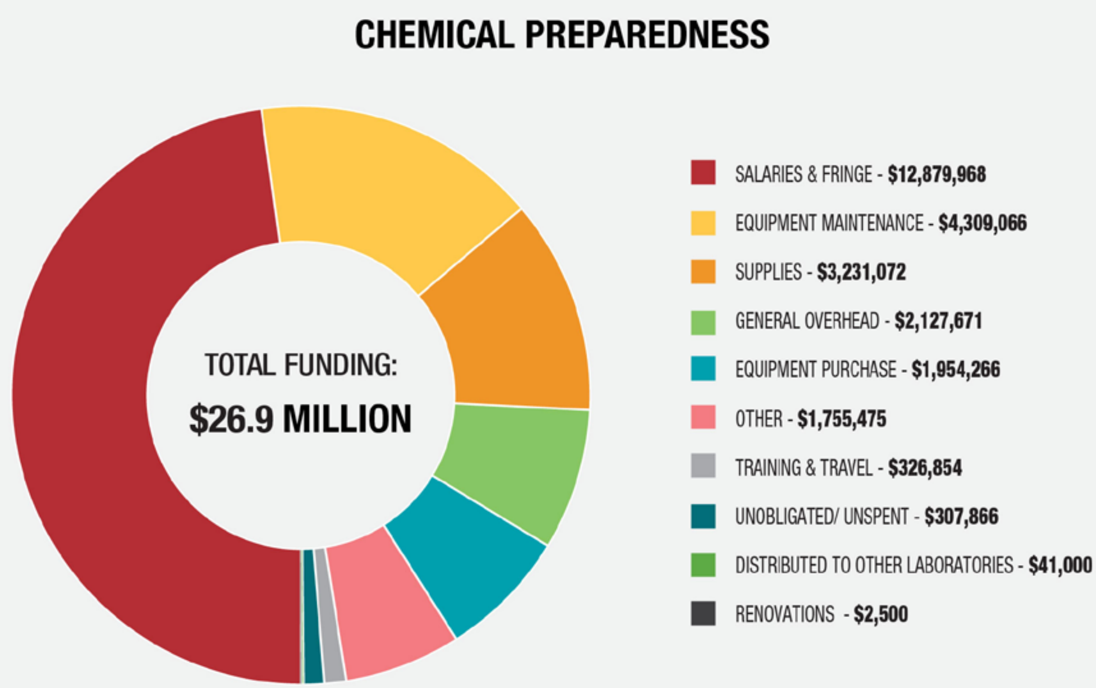


Figure 2: Allocation of FY15 CDC PHEP Funding in PHLs

Of the $89.7 million in total PHL preparedness funding for FY15, $74.7 million came directly from the CDC PHEP Cooperative Agreement. PHLs used these funds for both biological and chemical preparedness activities, with specific allocations listed below.





PHLs use their funding to support a variety of preparedness initiatives. Beyond preparing for and responding to biological and chemical threats, laboratorians must also find new and innovative ways to combat emerging infectious diseases and reduce exposure to chemical contaminants. While the demands on PHLs consistently increase, funding to support those needs continues to dwindle; 60% (31) of laboratories experienced funding cuts last year. Of the $59 million committed to biological preparedness efforts, less than $250,000 was spent on critical training for safe and effective laboratory work. In order to attend to urgent preparedness activities, largely focused on Ebola and Zika viruses, some PHLs were at a reduced capacity to handle other, more routine public health needs. These issues likely stemmed from funding cuts that left 32% (10) of laboratories unable to hire necessary staff and 39% (12) without means to participate in training courses.

Some jurisdictions, typically those with nuclear facilities, have the capability to monitor environmental radiation levels. For example, a state with a nuclear power plant tests vegetation, milk, water and other samples collected in proximity to the plant and those at more distant locations to determine whether any release of radionuclides has occurred. Additionally, a small number of states have some federal funding through the Food Emergency Response Network (FERN) to develop and maintain radiological testing capability in a wide variety of food products.

Following an intentional or accidental release of a radiological agent, there will likely be a significant demand for clinical testing of internal radiation contamination. Radiobioassay instruments are currently in development at CDC to help triage exposed individuals, but only CDC and the Department of Energy are capable of measuring internal contamination; no PHLs have that testing capability because PHEP does not fund the development of radiological testing capabilities in PHLs. Therefore, after a radiological event, the need for clinical testing will likely far exceed the testing capacity. It is critical that additional testing capacity be developed.

Figure 3: Impacts of Preparedness Funding Cuts on PHLs

Below are the five most-noted impacts that funding cuts have on PHL work. Other impacts of these funding cuts included the inability of some PHLs to provide training courses and attend national meetings and training conferences. (N=30)

Clinical laboratorians participate in a training workshop at the State Hygienic Laboratory at the University of Iowa.

Iowa Takes Hawkeye Approach in Putting PHEP Funding To Work

The State Hygienic Laboratory at the University of Iowa (IA SHL) made strong use of PHEP funding, achieving several major successes in 2016. The laboratory provided training opportunities for sentinel clinical laboratorians, renewed the select agent program and provided support for a statewide courier. The courier was responsible for a total number of 11,939 regular transports and 229 urgent transports for FY16, and continues to serve as a critical asset for the state of Iowa for preparedness and newborn screening programs.

With CDC PHEP funding, IA SHL was also able to host a multitude of training opportunities, providing a biological threat wet workshop, a packaging and shipping workshop and a bioterrorism “train-the-trainer” workshop within their Center for Advancement of Laboratory Science. The laboratory also participated in an unannounced inspection of the CDC Division of Select Agents and Toxins (DSAT) program in December 2015 and maintained their registration in the Federal Select Agent Program.

CDC PHEP funding enabled IA SHL to protect its residents – even its youngest – by ensuring the timely transport of newborn screening samples and training of laboratorians across the state.

Planning Ahead: Surge Capacity and Continuity of Operations

It can be difficult to predict how taxing a potential outbreak will be on laboratory personnel and infrastructure. 92% percent (48) of PHLs indicated that infectious disease testing was critical for the laboratory to respond to, even when facing a facility shutdown and only having a small portion of staff to work. All but one laboratory indicated having a plan to receive samples from sentinel laboratories during non-business hours. Over 94% (49) of PHLs have found it prudent to have a plan in place to handle a significant surge in testing volume for up to eight weeks, but many of them have not exercised these plans.

Continuity of Operations Plans (COOPs) are critical in ensuring PHLs are able to perform all essential functions during a wide range of emergencies. Over 94% (49) of PHLs have established a COOP consistent with National Incident Management Systems guidelines at either the state, department or laboratory specific level. In order to maintain functionality of COOP, 56% (29) of PHLs evaluated their plans with either a real event or exercise, an important practice when considering that 33% (17) of PHLs had to activate their laboratory COOP in 2016. Realizing the importance of having a COOP, the remaining 6% (3) of laboratories that do not already have such a plan are in the process of developing one.

Attendees at a workshop for biosafety officers and officials at the Hawaii State Laboratories Division; Pearl City, October, 2016.

Laulima: Working Together to Keep Paradise Safe from Diseases

Laulima, a Hawaiian word meaning “many hands working together,” is a key principle within Hawaiian culture. Hawaii sits right in the middle of Earth’s largest ocean, providing laboratory consultation and testing support to a fragile network of US-affiliated jurisdictions.

The partnership between Hawaii State Laboratories Division and the Pacific Island Health Officers’ Association (PIHOA), which was facilitated by APHL and CDC, began in response to the Influenza A H1N1 pandemic. Since then, Hawaii has assisted three US territories (Guam, Northern Mariana Islands and American Samoa) and three Compact of Free Association nations (The Republic of Palau, Republic of the Marshall Islands and Federated States of Micronesia) in activities ranging from outbreak support (measles, mumps, chikungunya and dengue), training (quality systems, Trioplex PCR, packing and shipping, and biosafety) and consultation (peer-to-peer lab visits, testing algorithms and results interpretation).

The importance of this cooperative network has been abundantly clear during the ongoing Zika response. With periodic dengue and chikungunya activity always a possibility in this region, testing strategy and interpretation of results is challenging. Hawaii has worked with its island neighbors to overcome these obstacles and help keep visitors and residents safe from public health threats.

Laboratory Partnerships and Outreach

Maintaining active partnerships is key to preparing for public health emergencies. As public health issues do not recognize borders, PHLs at the northern and southern border maintained cross-border contacts with Canada and Mexico. Over 92% (48) of laboratories indicated membership in FERN, which integrates food-testing laboratories at all levels of government to increase sample analysis capacity in the event of a foodborne outbreak or large food-related emergency. Other collaborations went beyond common agency relationships, with some laboratories connecting with airports, their state Departments of Transportation and even Air Force base response teams to handle public health issues (Figure 4).

Many PHLs have found outside relationships helpful as an advisory mechanism. 42% of laboratories (22) had a Laboratory Advisory Council, the members of which come from the wider clinical laboratory community. Another 14% of PHLs (7) indicated that they were developing a Laboratory Advisory Council to seek external feedback on laboratory practices and outreach needs. These advisory councils play an important role in building partnerships and communicating about a range of issues, such as improving collaboration and communication (91%, 20) and new laboratory tests and technologies (86%, 19).

PHLs often rely on partnerships with other states when facing unforeseen issues. For example, after a national recall of a molecular testing system used to detect cystic fibrosis gene mutations in newborns, the North Carolina State Laboratory of Public Health contracted with the Wisconsin State Laboratory of Hygiene to handle testing duties while their equipment was replaced. The assistance from the Wisconsin laboratory was imperative in determining if newborns had an elevated risk for cystic fibrosis and it ensured that testing was not delayed.

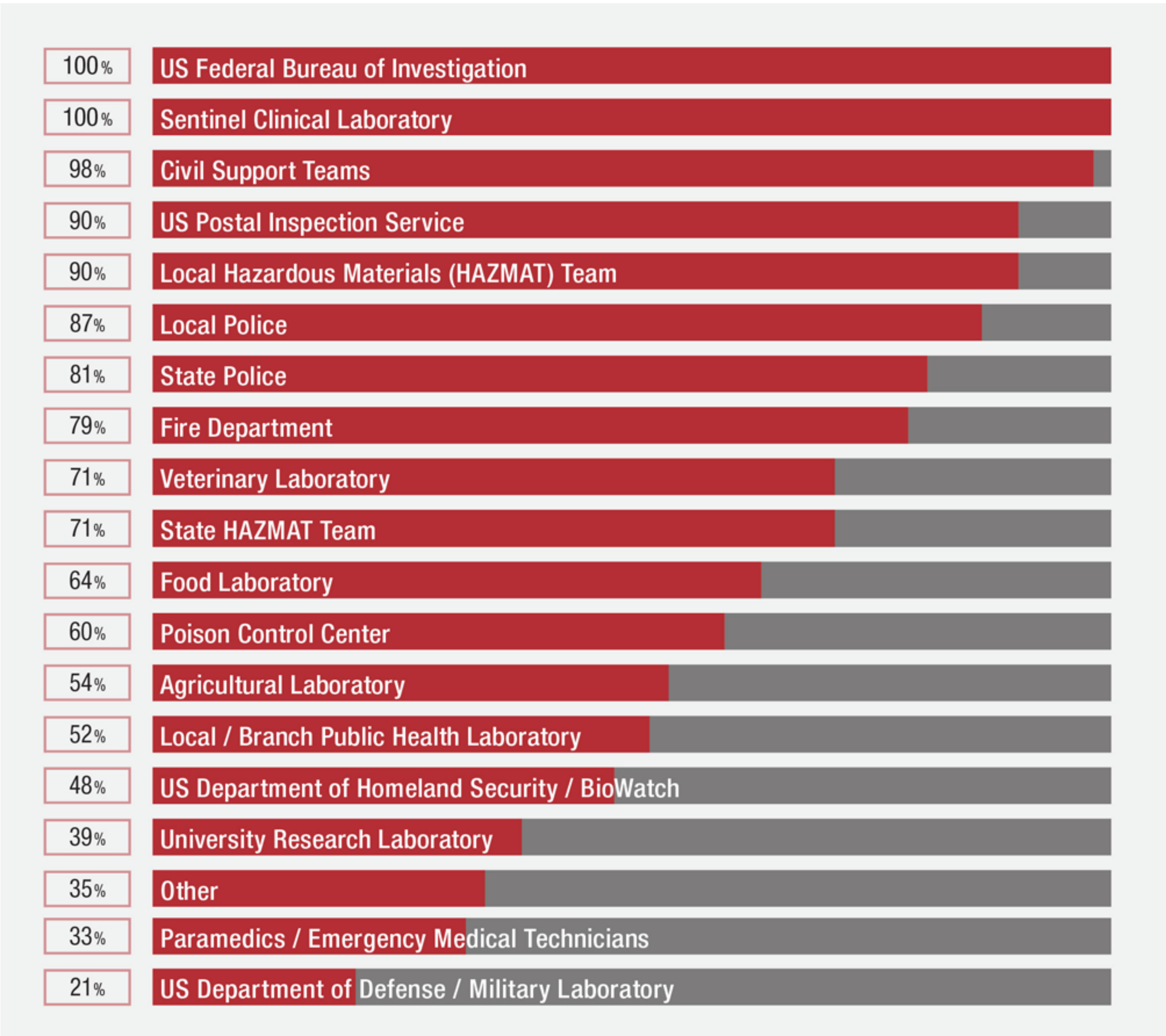
North Carolina State Laboratory of Public Health Engages Sentinel Clinical Laboratories

Efficient communication between health departments and sentinel clinical laboratories is imperative in mounting a strong response to a potential public health emergency. To ensure connectivity with their sentinel clinical laboratories and health departments, the North Carolina State Laboratory of Public Health (NC SLPH) used CDC PHEP resources to engage clinical laboratories and strengthen the overall system to prepare for and respond to threats.

In June 2016, NC SLPH conducted a Notification and Communication drill to determine the speed at which their sentinel clinical laboratories could respond to an urgent request for information during an emergency. The drill was coupled with a request by ASM and CDC to distribute a survey to all sentinel labs in North Carolina. Eighty-three North Carolina sentinel laboratories in the database were sent the exercise notification and survey with instructions to acknowledge receipt of the notification message as soon as possible via email or fax. All but two sentinel clinical laboratories responded within 24 hours; 50% responded within 70 minutes and 90% within seven hours.

Figure 4: **PHL Emergency Preparedness and Response Partners**

All PHLs surveyed (n=52) had collaborated in some way with an outside partner during the course of their emergency preparedness and response activities. Below are the percentages of PHLs that partnered with various federal, state and local agencies during FY15.



Laboratory personnel train CST members on proper use of personal protective equipment.

New Mexico Partners with Civil Support Team to Simulate Response Scenario

Throughout the past year LRN-B staff from the New Mexico Department of Health (NMDH) trained the 64th Civil Support Team (CST) members to process respiratory samples in a scenario where the Laboratory Information Management System and all communication networks are inoperable and all reports must be manually recorded. Staff learned the lengthy process of handling the samples: electronically recording sample information, preparing samples for extraction in biological safety cabinets, downloading and recording real-time reverse transcriptase polymerase chain reaction assay results and interpreting the data.

A full-scale exercise was conducted in April 2016. CST members and LRN-B staff processed 500 samples in just under nine hours over two days. Errors in the paperwork were intentionally inserted, so LRN-B staff performed a quality check; overall accuracy was 99.8%. This exercise highlighted the strengths of the collaboration, but also addressed gaps in the protocol, which have since been reconciled. NMDH plans to continue training CST members, repeating the exercise with additional communication components, such as using radios to relay results from the laboratory in Albuquerque to the state epidemiologist in Santa Fe.

Training events like these are crucial to ensure that response personnel are prepared to act when a real emergency occurs. PHEP funding directly supports these initiatives, protecting the public's health when the unexpected happens and quick action is needed.

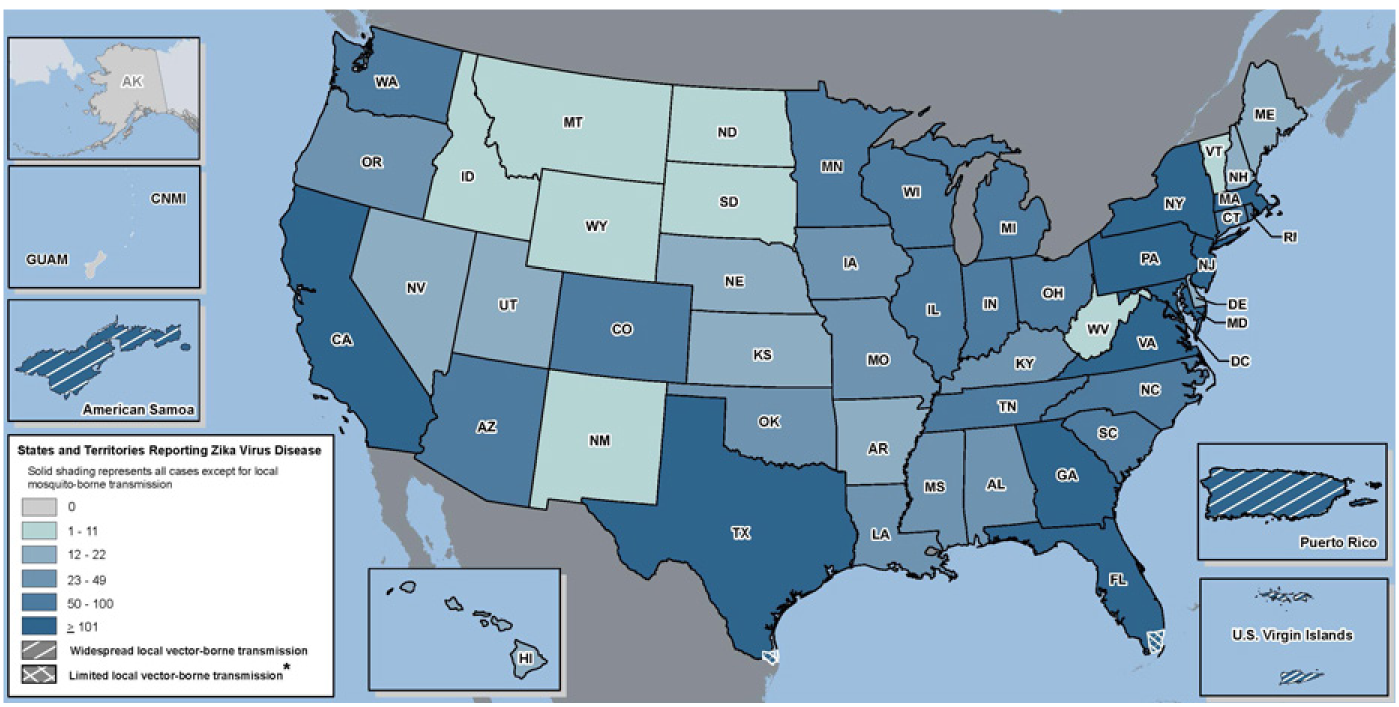
Zika Response

Laboratories continue to face significant challenges associated with last year's emergence of the Zika virus. Although a relatively harmless disease to otherwise-healthy adults, the risk for pregnant women of significant fetal developmental issues put Zika at the forefront of public health preparedness and response priorities. Despite being a rare disease in the US, the fact that Zika can spread by both mosquitoes and sexual contact provides a unique challenge to public health officials.

With the confirmation of domestic local transmission within the US last year, PHLs were inundated with testing requests, requiring them to increase testing capacity and validate new detection methods. One such example comes from the Florida Department of Health Bureau of Public Health Laboratories, which detected its first case of travel-associated Zika infection in January 2016. Over the next six months, Florida tested over 1,700 people and confirmed infections in 203 non-pregnant individuals and 43 pregnant women. The Massachusetts State PHL faced similar testing surges: by June 2016 over 1,400 specimens had been tested, including samples from three neighboring state laboratories which were unable to meet their own testing demands.

Figure 5: Zika Cases in the US

US Zika cases reported in US as of March 2017 (CDC)



Members from the Bureau of Public Health Laboratories in Tampa, Florida are working hard to ensure the public is protected from Zika virus.

Florida Health Department Progresses on Zika Diagnostic Methods

The Florida Department of Health, Bureau of Public Health Laboratories (FL PHL) made great strides in the ongoing fight against Zika virus. This year alone, FL PHL was able to both validate and implement three separate Zika virus assays: a laboratory-developed rRT-PCR Zika test based on data from a CDC publication; the CDC Trioplex rRT-PCR assay for the simultaneous detection of Zika, dengue and chikungunya viruses; and the Zika MAC-ELISA serological test.

The FL PHL prepared for the current Zika public health emergency by implementing the rRT-PCR and MAC-ELISA assays in 2015, eventually ramping up their use in 2016. Within six months of Florida's first travel-associated Zika infections, which occurred in January 2016, FL PHL had tested 1,706 people for Zika, leading to 203 confirmed cases in non-pregnant individuals and 43 in pregnant women. Local transmission occurred shortly after, with the first cases detected in July 2016. As Florida saw local transmission, the demand for testing quickly outpaced the testing capacity of the laboratory. CDC laboratories provided surge capacity testing support to Florida to ensure ample coverage for Zika testing.

Knowing that Zika infection could occur through various specimen types, the laboratories evaluated other means of transmission, including urine, saliva and semen for detection of the virus, publishing some of these findings in the May 2016 MMWR article Interim Guidance for Zika Virus Testing of Urine–United States, 2016. By being prepared with previously implemented laboratory assays, surge staffing and testing plans, the laboratories have been able to respond to this continuing public health emergency.

Virginia Narrows Focus to Fight Zika

In response to the Zika virus outbreak in South and Central America, CDC released a memorandum in January 2016 recommending that US PHLs increase their focus on diagnostic testing for Zika, chikungunya and dengue viruses. Although the Virginia Division of Consolidated Laboratory Services (DCLS) had been performing MAC-ELISA serological testing for chikungunya since October 2014, like all other state PHLs in the US, DCLS did not have the capability to test for Zika and dengue. They quickly recognized the public health impact Zika could have on their state, so they developed plans to rapidly enhance the arbovirus* testing capabilities of the Commonwealth of Virginia.

To put their plans into action, DCLS needed to address the major gaps in their testing capabilities. The first step was validating and implementing molecular testing for Zika, dengue and chikungunya and serological testing for Zika and dengue. DCLS first completed validation of the CDC-developed chikungunya rRT-PCR assay and the dengue DENV-1-4 rRT-PCR assay. Next, DCLS received the Zika rRT-PCR and MAC-ELISA protocols from CDC and immediately began to prepare validation proposals for laboratory management approval. During this time, risk assessments were performed for both serological and molecular testing of Zika and changes in testing workflow and testing areas were made to address gaps in biosafety for chikungunya testing. As a result, testing was relocated to containment facilities, critical instrumentation was relocated and staff were trained to work in the biosafety level 3 containment laboratories. Throughout this process, additional staff were trained on the new protocols to increase the laboratory's overall testing capacity.

In early 2016, the Laboratory Response Network (LRN) deployed the FDA-approved Emergency Use Authorization (EUA) protocols for the Zika MAC-ELISA and Trioplex rRT-PCR assays. DCLS promptly drafted validation proposals for the new Zika assays and received approval from the LRN to commence testing in April; validation testing of dengue with MAC-ELISA assays soon followed. Since the implementation of the Zika EUA serological and molecular protocols in April 2016, DCLS has received over 1,700 specimens from patients approved for Zika testing.

Funding from PHEP and the CDC's Epidemiology and Laboratory Capacity for Infectious Diseases (ELC) Program allowed DCLS to have a sufficient personnel, supplies and reagents on-hand when testing commenced, and provided for the purchase of additional materials. Proper funding, combined with major in-person and digital communication efforts to keep all involved parties up-to-date resulted in a well-coordinated and timely response to the Zika public health emergency.

* Arbovirus refers to any virus transmitted by arthropod vectors

PHLs have worked tirelessly to validate and implement the three different Zika virus assays: a real-time reverse transcriptase polymerase chain reaction (rRT-PCR) laboratory-developed Zika-specific test based on data from a CDC publication; the CDC Trioplex rRT-PCR assay for simultaneous detection of Zika, dengue and chikungunya viruses; and the Zika IgM antibody capture enzyme linked immunosorbent assay (MAC-ELISA) serological test. Once validated, states started putting these tests to use. For example, the PHL in Texas, where high rates of localized transmission and a correspondingly high volume of Zika testing are expected, has implemented both PCR and ELISA testing methods to help meet testing demands. As a whole, 96% (50) of PHLs have successfully implemented at least one molecular assay for the detection of Zika while just under 85% (44) had implemented serological assays. Combined, these efforts help streamline reporting, providing faster knowledge of health status and a quicker linkage to care for patients.

LRN-C & PHEP: STORIES FROM THE FIELD

The LRN-C is a network of state and local PHLs that respond to chemical threats and other public health emergencies, providing local laboratory diagnostics and surge capacity to the CDC. The CDC PHEP Cooperative Agreement is a critical source of funding, supporting guidance and technical assistance for state, local, tribal and territorial public health departments to strengthen their public health preparedness capabilities. Since 9/11, the PHEP program has saved lives by building and maintaining a nationwide public health emergency management system that enables communities to rapidly respond to public health threats.

New York

In late 2014, the Village Board of Hoosick Falls, NY, at the request of a local resident, began sampling and testing water for perfluorooctanoic acid (PFOA).

The Incident

High levels of PFOA were identified in the water of Hoosick Falls, NY in 2014.

The Response

Using a PHEP-funded LRN-C lab, staff were able to develop an efficient, high-throughput method to test residents' blood samples for PFOA.

The Outcome

New York's testing method can be deployed to support other states as they mobilize their resources for similar incidents.

PFOA is a chemical used to make household products resistant to heat, water, oil and stains. Exposure most often occurs through contaminated food or drinking water. Effects of PFOA on human health are largely unknown but may be associated with delayed growth and development, reproductive issues and liver damage. At the time of the Hoosick Falls contamination, the US Environmental Protection Agency (EPA) had set PFOA's health advisory level at 400 parts per trillion, but it has since been lowered to a lifetime level of 70 parts per trillion. Tests found Hoosick's levels of PFOA ranged from 180 to 540 parts per trillion.

Luckily, the New York State Department of Health (NYSDH) maintains a laboratory and epidemiologic surveillance system capable of rapid detection and identification of public health threats, due in part to the LRN-C infrastructure provided by PHEP.

LRN-C staff developed a high throughput method to measure serum levels of PFOA to assess the exposure of residents. Existing PHEP funds for LRN-C infrastructure, such as additional analytical instrumentation and trained staff that can help accommodate surges in testing, were used to quickly take on this challenge. The efficient, high-throughput method was particularly important given that over 3,000 residents submitted blood for testing.

"Without the infrastructure provided by CDC we could not have taken on this task as quickly or effectively as we did," said Dr. Kenneth Aldous, director of the NYSDH's Division of Environmental Health Sciences.

Because similar situations may be unfolding in other states, New York's LRN-C lab has been contacted by other state public health departments to assist in their environmental and biological testing.

CDPHE technician Jean Aldrich draws a sample in a consolidated ditch test.

Colorado

On August 5, 2015, while workers from Gold King Mine were conducting a study of the mine's drainage system, pressurized water was accidentally released into Cement Creek, a tributary of the Animas River, impacting the drinking water supply of 220,000 individuals in Durango and Silverton, CO. The toxic waste water from the mining operation contained various metals, which are found in the environment both naturally and through pollution such as manufacturing waste, fossil fuel emissions and vehicle combustion. In small amounts, many metals are essential to human life, but in larger doses they can become toxic.

Within two days of the spill, the Colorado Department of Public Health and Environment Laboratory Services Division (CDPHE LSD)—a Level 2 laboratory of the LRN-C—had their Chemical Threat (CT) staff on-site to analyze water and environmental samples. The CT team consisted of five full-time LRN-C staff members who, over the next two weeks, collected and analyzed 146 samples of surface, well, drinking and irrigation water, river sediment and fish from Cement Creek and the Animas River. The samples were analyzed within 24-36 hours after collection for total and dissolved metals using state-of-the-art, specialized instruments for detecting and measuring toxic metals in human clinical samples.

The data were used by public health officials to make health-related decisions about the quality and safety of drinking water, fish consumption advisories, recreational water use, agricultural and livestock irrigation and river sediment from Cement Creek and the Animas River.

The speed and accuracy of CDPHE LSD's response would not have been possible without the LRN-C infrastructure already in place, which requires ongoing PHEP support and funding to maintain.

The Incident

On August 5, 2016 toxic waste water was spilled from a mine into Cement Creek, a tributary of the Animas River.

The Response

CDPHE LSD staff tested over 140 water, soil and fish samples for heavy metals.

The Outcome

Data produced by CDPHE was used to make decisions on quality and safety of using/consuming materials from the area.

PUBLIC HEALTH EMERGENCY RESPONSE FUND URGENTLY NEEDED

The importance of immediately accessible, comprehensive response funding cannot be overstated. As demonstrated by several recent public health events, state and local health departments—and especially their laboratories—cannot count on the ready availability of emergency appropriations: it took more than 60 days for Congress to appropriate supplemental funding for H1N1 after CDC activated their Emergency Operations Center, about 160 days for Ebola and roughly 220 days for Zika.

This concern, among others, has driven bipartisan interest in the establishment of a permanent, federal public health emergency fund. Providing immediately accessible money would bridge the gap between the onset of a public health crisis and appropriation of supplemental federal funding.

The concept of setting aside public health monies that can be accessed without special Congressional action is nothing new. In fact, the US Congress created the Public Health Emergency Fund (PHEF) in 1983. The challenge with using PHEF as a funding stop-gap is that it has not been consistently or sufficiently funded; in some years it received minimal funding and in others, none. Efforts were made in 2016 to fund PHEF or to create a new fund that addressed PHEF's shortcomings: the Public Health Emergency Preparedness Act (HR 4525), the Public Health Emergency Response and Accountability Act (S 3280) and the Centers for Disease Control and Prevention Emergency Response Act of 2016 (S 3302). None of the three made it out of committee.

Despite a lack of traction in Congress, professional interest in creating an emergency response fund remains. Without a source of comprehensive funding for all potential threats, the health of the American public cannot be adequately protected.

CONCLUSION

The work of PHLs is essential to identifying the next threat to public health, while simultaneously protecting the public from existing issues. Adequate staffing and training is imperative to maintaining response capabilities and testing capacity; expanding acess to online training workshops can ensure more of the public health workforce is prepared to protect both themselves and the public. Collaboration is also a key component of successful public health responses; efficient communication systems and protocols allow PHLs to tap into the wider network of state, local and federal laboratories which contribute knowledge and resources to ensure timely and effective action.

Emerging infectious diseases such as Zika task PHLs with identifying new methods of prevention and working with researchers to develop a cure. PHLs worked diligently this past year to successfully validate and implement a new assay to detect Zika, dengue and chikungunya viruses in a single sample, a method by which laboratories can minimize expenditures and quickly identify the culprit pathogen.

PHLs also respond to chemical contaminations, identifying sources of exposure by analyzing drinking water, food and consumer products. Some PHLs have developed high-throughput methods, increasing the national testing capacity. These activities enable PHLs to contribute important scientific information that is used on the local, state and federal level to make health-related decisions and respond to community concerns.

While a small number of PHLs have the capability to monitor environmental media and food products for radionuclides, there is limited capacity for testing the high number of samples that may be required following a radiological or nuclear event. An even more critical gap in radiological testing capacity, there are currently no PHLs with the capability of testing human clinical samples for internal radiation contamination and it is expected that CDC and the DOE, the only two laboratories with this analytical capability, would be unable to meet testing demand following a large-scale radiological event.

Public health laboratorians remain dedicated to their jobs year-round, not only protecting their local communities but also those across the globe. While much of their work goes unnoticed, their fundamental commitment to protecting the public's health safeguards against emerging threats, while rigorously eliminating others. As funding reductions constantly threaten both their jobs and the physical resources necessary to operate, a sustainable funding strategy is needed to invest in PHLs and their ability to detect emerging threats. Without timely changes, the ability of laboratories to prepare for, respond to and recover from public health threats will remain challenged.

APPENDIX: LABORATORY RESPONSE NETWORK

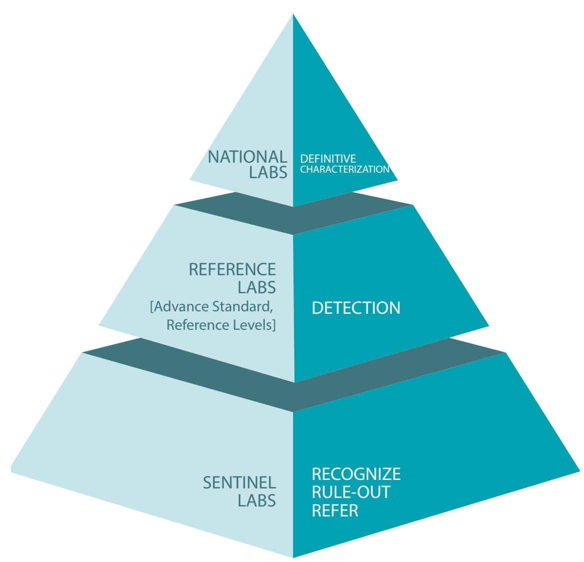
The Laboratory Response Network (LRN) is a national security asset that, with its partners, will develop, maintain and strengthen an integrated domestic and international network of laboratories to respond quickly to biological, chemical and radiological threats and other high-priority public health emergency needs through training, rapid testing, timely notification and secure messaging of laboratory results.

When the LRN was first established, the primary focus was to prepare for and respond to potential bioterrorism events. In fact, the preparation efforts of the network enabled the US to have a rapid and extensive response to the 2001 anthrax attacks. Lessons learned from this response were used by APHL and CDC to strengthen outreach to clinical laboratories and first responders and to develop tools to assist laboratories in planning for surge capacity. Over the years, the LRN mission has expanded to include response to chemical threats and other public health emergencies, such as severe acute respiratory syndrome (SARS), monkeypox, influenza A virus subtype H5N1 (avian influenza), influenza A virus subtype H1N1 (2009 pandemic influenza), the MERS coronavirus (MERS-CoV), Ebola virus and Zika virus.

LRN-B: Biological Threats Preparedness

Today's vision for the LRN-B is a laboratory system for rapid, high-confidence results to inform critical public health decisions about biological threats.

The LRN-B is organized as a three-tiered pyramid. At the base are thousands of sentinel clinical labs which perform initial screening of potential biological threat agents. When these sentinel labs cannot rule out the presence of an agent, they refer specimens and isolates to an LRN reference laboratory. Initially, there were just 17 LRN reference labs. Today, more than 125 state, local and federal facilities provide reference testing, producing high-confidence test results that are the basis for threat analysis and intervention by both public health and law enforcement authorities. State and local public health labs comprise approximately 70% of the 126 LRN-B member laboratories. At the apex of the pyramid are national labs such as those at the CDC and the US Department of Defense. National labs primarily provide specimen characterizations that pose challenges beyond the capabilities of reference labs, and they provide support for other LRN members during a serious outbreak or terrorist event. The most dangerous or perplexing pathogens are handled in the BSL-4 labs at CDC and the US Army Medical Research Institute of Infectious Diseases.

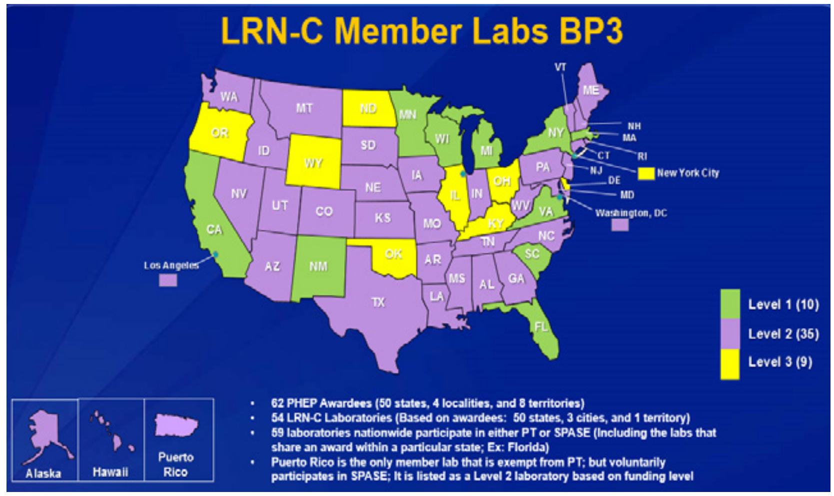


The LRN structure for responding to biological threats

LRN-C: Chemical Threats Preparedness

The LRN-C is a network of highly trained, well-equipped public health laboratories able to respond to chemical threats resulting from intentional and or accidental chemical releases. These laboratories have advanced analytical capabilities and processes for mounting rapid responses, contributing to the national capacity for identifying chemical exposure and/or environmental contamination.

The LRN-C structure denotes levels of capability, with 1 being the highest. Level 1 is responsible for conducting all activities required of Levels 2 and 3, while Level 2 is also required to conduct Level 3 activities.

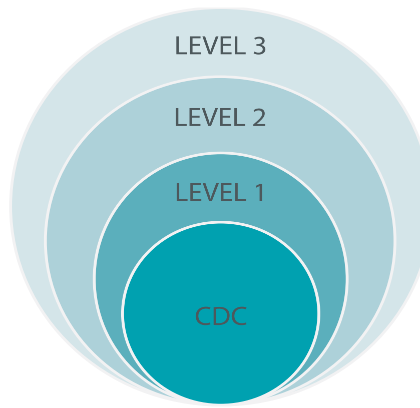


There were 54 LRN-C member labs in budget period three, including all 50 states, three cities and one territory.

Level 3 activities include providing outreach to the clinical community regarding the signs and symptoms of high-risk chemical exposures and maintaining the capability to collect, package and transport the appropriate clinical specimens to identify and measure exposure.

Level 2 laboratories maintain the staff, equipment, reagents and analytical capabilities to respond to human exposure to toxic metals--such as mercury, arsenic and lead--selected industrial chemicals, plant toxins and metabolites of nerve agents.

Level 1 laboratories have advanced analytical capabilities to identify and measure additional threat agents using a high-throughput testing platform providing surge capacity to CDC and other state public health laboratories. Ten public health laboratories qualify for Level 1 status.



The LRN structure for responding to chemical threats

Recognizing the value of this technical resource, many states have enlisted the LRN-C laboratories to assist with challenging public health issues such as harmful algal blooms, emerging contaminants and opioid addiction.

LRN-R: Radiological Threats Preparedness

Currently, there is limited capability and capacity for measuring radionuclides in clinical sample matrices. A new LRN network for radiological threats has been conceptualized by CDC but does not currently have funding for implementation in the states.

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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.

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