APHL ASSOCIATION OF PUBLIC HEALTH LABORATORIES®

Public Health Laboratories: Detecting the Next Threat

A Report of the APHL 2015 All-Hazards Laboratory Preparedness Survey




Acknowledgments

APHL would like to thank the public health laboratories in all 50 states, the District of Columbia, Puerto Rico, New York City and Los Angeles County for completing the 2015 All-Hazards Laboratory Preparedness Survey.

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Executive Summary

Each year, the Association of Public Health Laboratories (APHL) surveys public health laboratories (PHLs) to assess their readiness to respond to threats and to identify challenges that affect rapid response. PHLs are at the forefront of national security, protecting the public's health by providing services to prepare for and respond to all-hazard threats—biological, chemical and radiological—as well as emerging infectious diseases and natural disasters. Over the past year, PHLs responded to several biological threats, notably Ebola Virus Disease (EVD) and chemical threats such as water contamination. The ability of a PHL to effectively respond to the threat of the day is rooted in its infrastructure—its highly skilled workforce, modern equipment, safe and secure facilities and electronic systems to quickly 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. In Fiscal Year (FY) 14, 54 PHLs reported receiving a total of $89.1 million in funds from federal agencies with $78.2 million (90%) attributed to CDC PHEP Cooperative Agreement. While these PHEP funds appear to be stable over the last decade, it doesn't reflect the true decline of more than $102+ million, given inflation, since FY04. The whittling away of CDC PHEP funds jeopardizes the ability of PHLs to be prepared to respond to the next threat, such as Zika virus.

As funds have declined, the responsibilities of PHLs have expanded greatly in the last decade, requiring highly skilled personnel capable of responding 24/7. PHLs noted that it is becoming increasingly difficult to recruit, hire and retain the highly-skilled workforce necessary to run and maintain the laboratories. Of the factors affecting PHLs ability to perform preparedness activities, competitive salaries, lack of qualified applicants and issues with hiring personnel top the list.

While having a ready, capable workforce is a critical element for PHLs, coordinating limited resources and collaborating with other partners is equally vital for an effective response. An effective public health front line defense

hinges on the ability of PHLs, clinical partners, first responders and federal agencies to respond in unison. The recent cases of Ebola provided an excellent example of a response that required the cooperation of several agencies. The value of such partnerships and collaborations was on full display when the Department of Defense (DoD), US Army Medical Research Institute of Infectious Diseases (USAMRIID) provided an assay to the CDC-managed Laboratory Response Network for Biological Threats Preparedness (LRN-B).

As members of multiple laboratory response networks, PHLs serve as hubs for testing novel pathogens and responding to emerging threats. Therefore, it is vital for PHLs to send accurate and timely test results to their stakeholders, which include hospitals, federal agencies and other sample submitters. CDC has provided several tools, namely a web based platform and support for labs to use their own systems to securely message data, but challenges in Information Technology (IT) still remain.

Over the past year, PHLs demonstrated their resiliency and their ability to rapidly change pace to protect the public's health. Successes include safely implementing a new assay to detect Ebola; leveraging membership in the LRN to respond to chemical and biological threats; strengthening biosafety by hiring new staff and reaching out to key partners; supporting the DoD by responding to the inadvertent shipping of live anthrax; and delivering training courses to thousands of clinical laboratorians.

But PHLs still face unique challenges such as inconsistent funding; limited ability to procure new technologies and ensure service contracts on aging equipment; a limited workforce pool where they are unable to attract and retain qualified applicants; and actively sustaining a robust IT infrastructure. The underpinning of these challenges is the inconsistent approach to providing much-needed resources. A sustainable funding strategy is needed to invest in PHLs and ensure their ability to detect the next threat.

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

Introduction

PHLs are at the forefront of national security, protecting the public's health by providing services to prepare for and respond to all-hazard threats—biological, chemical and radiological—as well as emerging infectious diseases and natural disasters. Over the course of the past year, US PHLs responded to several biological threats, notably Ebola and chemical threats, such as water contamination. The ability of a PHL to effectively respond to the threat of the day is rooted in its infrastructure—that is, its highly skilled workforce, modern equipment, safe and secure facilities and electronic systems to quickly send test results.

Much of the preparedness and response work in PHLs is resourced by the US CDC via the PHEP Cooperative Agreement. In fact, a key component of the PHEP Cooperative agreement is "Public Health Laboratory Testing," which is performed by the state and local PHLs of the Laboratory Response Network for Biological and Chemical Threats Preparedness (LRN-B and LRN-C). This report provides an aggregate snapshot of preparedness for PHLs in all 50 states, the District of Columbia, Puerto Rico, New York City and Los Angeles County and serves as a benchmark to document the successes and challenges of these laboratories since the inception of the CDC PHEP Cooperative Agreement Funding.

Methods

APHL collected data for the 2015 All-Hazards Laboratory Preparedness Survey in the fall of 2015. The survey covered the 12-month period from July 1, 2014–June 30, 2015, representing FY14 CDC PHEP Cooperative Agreement, Budget Period (BP) 3. PHLs reported on their capability and capacity to respond to biological, chemical and radiological threats as well as emerging infectious diseases.

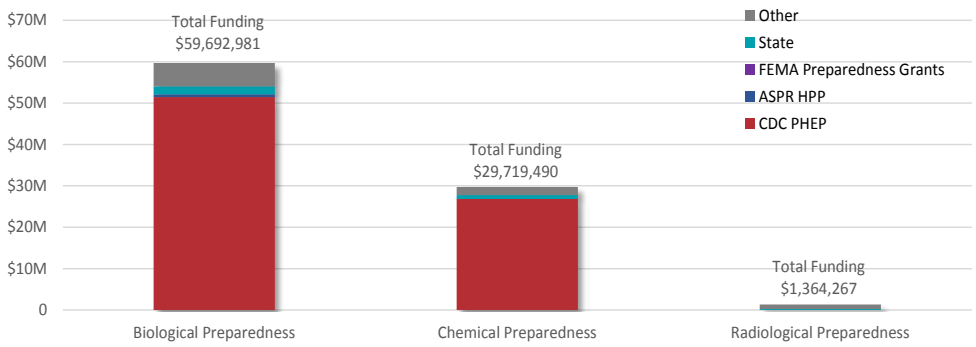
The APHL 2015 All-Hazards Laboratory Preparedness Survey was distributed to the 50 state PHLs, District of Columbia, Puerto Rico, New York City and Los Angeles County PHLs. Data were collected using Qualtrics 5, a web-based survey tool and data repository. Each survey participant received an email with a unique survey link and a copy of the survey. APHL received a 100% response rate. The 2015 APHL All-Hazards Laboratory Preparedness Survey Summary Data Report, available at APHL, presents aggregate survey assessment results for all questions.

Descriptive statistics were gathered for all categories:

- Demographics
- Funding and Workforce
- Planning and Response
- Biological Threats
- Chemical Threats
- Radiological Threats
- Electronic Data Messaging for the LRN

The following sections present stories and accompanying data that highlight the role of the public health laboratories and the importance of their partnerships in detecting the next threat.

Figure 1: FY14 Preparedness Funding for PHLs



Discussion of Key Findings

Funding

In FY14, 54 PHLs reporting receiving a total of $90.8 million to support preparedness activities (See Figure 1). $89.1 million of these funds came from federal agencies such as CDC, Department of Health and Human Services (HHS) Assistant Secretary for Preparedness and Response (ASPR) Hospital Preparedness Program (HPP) and the Federal Emergency Management Agency (FEMA).

PHEP funding has been relatively stable over the last decade. However, the FY14 funding level of $78.2 million represents a significant decline from FY04 when PHLs received $180.4 million (adjusted for inflation, see Figure 2). This decline of $102+ million, given inflation, over the last 10 years has contributed to the erosion of the skilled laboratory workforce; the inability of many laboratories to refresh outdated instrumentation; and the inability of PHLs to perform outreach to critical partners such as hospital laboratories and first responder communities. Moreover, today PHLs have been asked to respond to complex and various types of threats—they are expected to maintain a level of preparedness for biological and chemical terrorist attacks in addition to preparing for and responding to new and re-emerging infectious diseases such as Ebola, Chikungunya, Dengue and Zika viruses that are threatening our shores. The whittling away of CDC PHEP funds jeopardizes the ability of PHLs to be prepared to respond to emerging threats.

Figure 2: CDC PHEP Cooperative Agreement Funding, FY99-FY14 (adjusted for inflation)

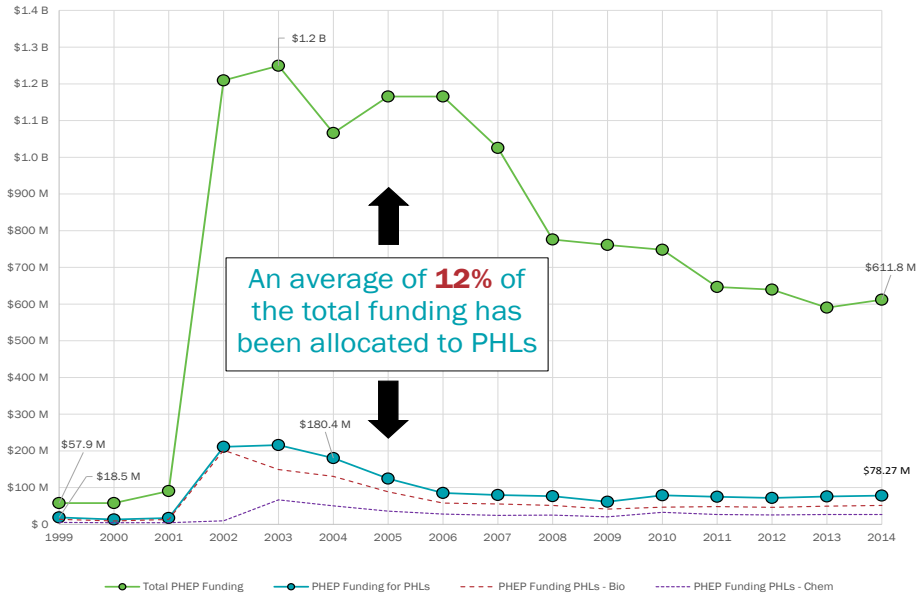
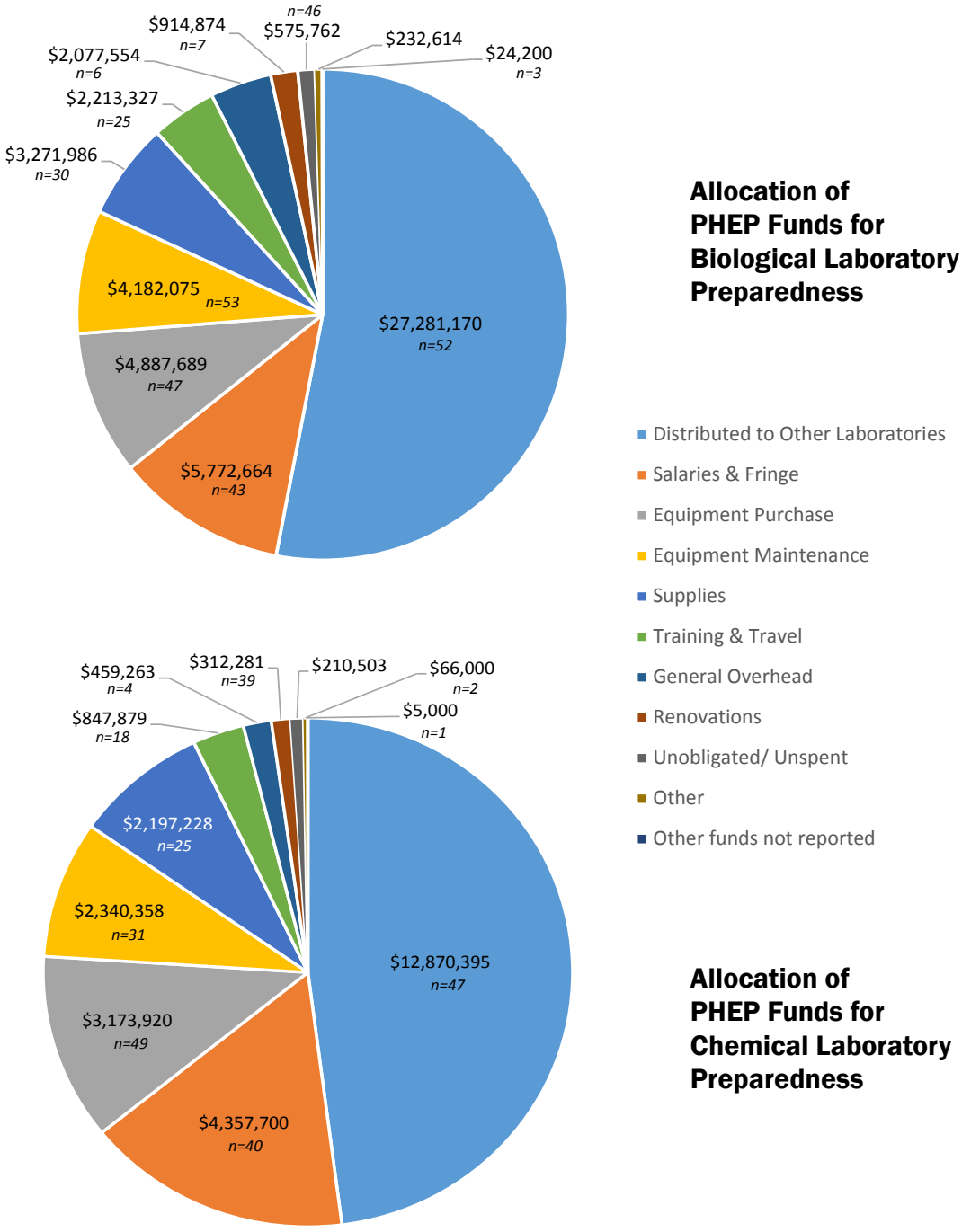


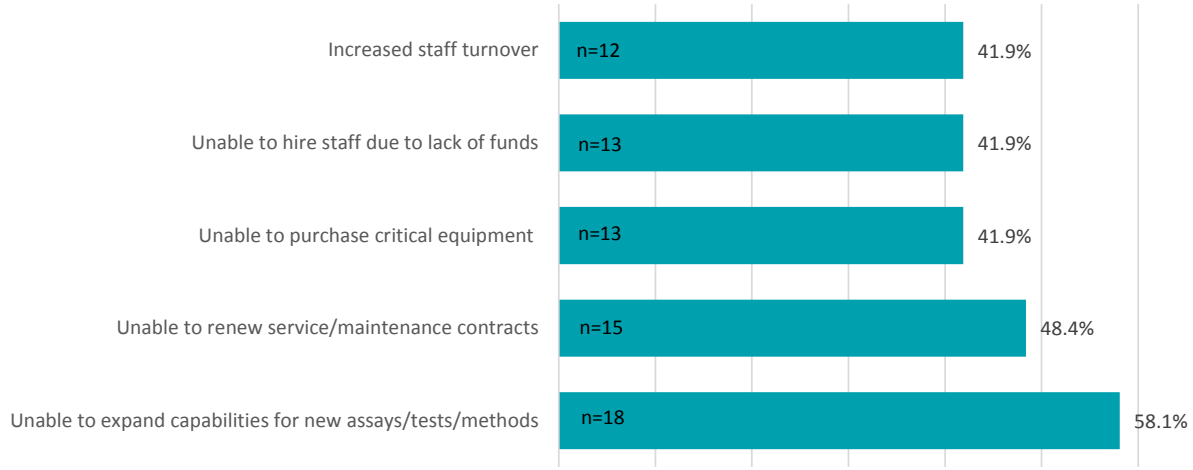
Figure 3 illustrates how PHLs allocated $78.2 million of CDC PHEP funds for biological and chemical preparedness activities.

Figure 3: Allocation of FY14 CDC PHEP Funding in PHLs (not adjusted for inflation)



31 PHLs (57%) indicated that they experienced funding cuts in FY14. In addition to the impacts listed below, other impacts include the inability of some PHLs to provide training courses and attend national meetings and training conferences.

Figure 4: Top Five Impacts of Preparedness Funding Cuts on PHLs



Funding Challenges Facing the LRN-C Infrastructure

PHLs from all 50 states, District of Columbia, Puerto Rico, New York City and Los Angeles County are members of the LRN-C, an infrastructure which remains pivotal to public health practice. But LRN-C laboratories face significant threats to their ability to maintain current infrastructure. Of labs surveyed this year, 42.6% responded that they currently have no plans to replace any LRN-C instruments, 40% have experienced reduced system support and 20% claim an inability to maintain service agreements on equipment. Problems will occur with outdated equipment, especially if service contracts lapse on equipment that is too old.

This year, 9.3% of LRN-C labs also reported a decrease in capabilities due to loss of staff (80%), the downgrade of a chemical terrorism (CT) level (20%), abandonment of a CT method (20%), inability to purchase new equipment (20%) and the loss of CT equipment (20%). Since these are the only laboratories in the country with this capability, such declines mean that our nation remains less prepared for a chemical event.

Chemical exposure concerns often continue to be secondary to infectious agents and chronic conditions by health agencies and the public. But after high-profile events such as lead-contaminated drinking water in Flint, MI and a mine waste spill into the Animas River in Colorado, more attention has been brought to environmental emergencies. At the same time, biomonitoring serves as a viable response to environmental threats and may be a helpful tool in establishing a more comprehensive model of non-infectious disease progression.

The LRN-C exists as the backbone of chemical incident response in the US. Its ability to function properly depends entirely on continued and sustained funding.

Laboratorian David Whitt from the North Carolina State Laboratory of Public Health performing a GC/MS scan on an unknown suspicious substance which analyzes samples for chemical threats using Mass Spectrometry.

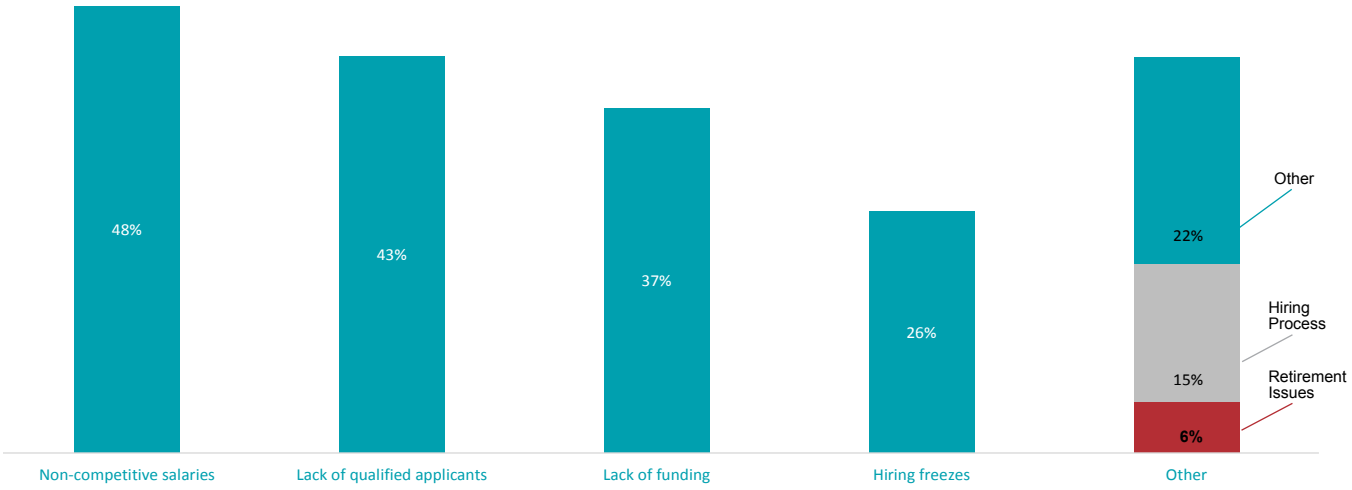
LRN-C Labs in Action

This year, LRN-C laboratories responded to incidents of possible toxic exposures (44%), chemical spills (18.5%), biomonitoring inquiries (13%) and chemical terrorism events (2%). Activities included identification of arsenic poisoning in a homicide case, testing 220 blood samples for a large epidemiological study and screening blood for lead exposure. These examples illustrate the advantage to having a sustained, at-the-ready response network for chemical concerns.

This was certainly the case in Massachusetts when the state PHL responded to two mercury spills in public locations. The first event occurred when a blood-pressure reader broke at a pediatric center, leading to the evacuation and closure of the office. The lab tested urine samples from 11 individuals (one child and ten adults, including one pregnant woman). In the second incident, another blood pressure reader broke within a school, potentially exposing eight children and three adults to mercury. In both instances, the Bureau for Environmental Health quickly set up clinics to collect urine samples for mercury testing at the state PHL. Fortunately, no individuals tested positive for mercury poisoning.

In addition to emergency response, LRN-C methods and equipment support biomonitoring studies across the country. Data from these biomonitoring studies play a critical role in assessing a population's exposure to chemicals following both unintentional and intentional chemical events by identifying the chemical agent and determining exposure levels.

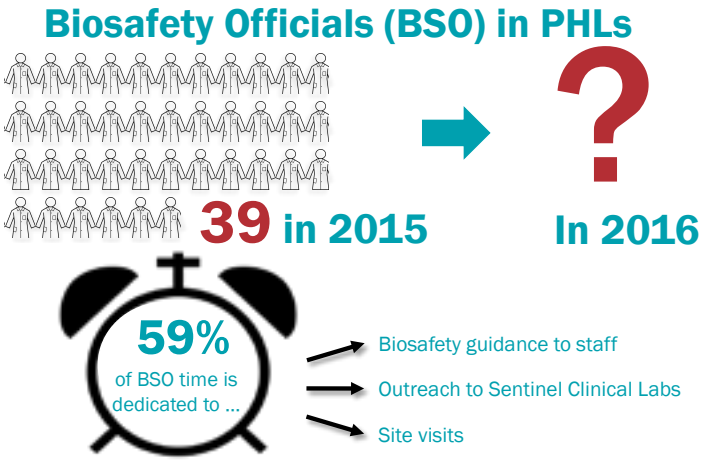
Figure 5: Top Five Factors Affecting PHLs Ability to Perform Preparedness Activities



Workforce

Laboratories are facing a number of workforce challenges. It is becoming increasingly difficult to recruit, hire and retain a highly skilled workforce necessary to run and maintain the laboratories with the varying funding sources and levels. The lack of competitive salaries, lack of qualified applicants and issues with hiring personnel top the list. Some PHLs have hiring freezes while others indicate significant delays in the recruitment and hiring process.

In the last decade, PHL directors combined critical positions to cope with these funding gaps, leading to a burdensome amount of responsibility on an already-stressed workforce. However, with supplemental Ebola funding via CDC's Epidemiology and Laboratory Capacity (ELC) Cooperative Agreement for Infectious Diseases, many PHLs were able to restore positions in biosafety and biosecurity. In 2015, 39 PHLs hired a dedicated Biological Safety Official (BSO).



There is a scarcity of experienced, credentialed scientists who are required to fill senior management roles. Across the nation, the seasoned scientific community is quickly approaching retirement age. The challenge lies in the fact that both the quantity and quality of the workforce will steadily decline without a robust pipeline of highly trained personnel. At a time when our public laboratories play such an increasingly crucial role in safety and national security, it is a risk our country cannot afford to take—a national strategy for cultivating and retaining a quality laboratory workforce is needed.

Ebola team members, Richard Feliciano, Minakshi Amin, Elizabeth Montano and David Yang, are experts in preparing packages and shipping highly infectious specimens from Ebola patients to CDC. PHL staff provide real-time on-site expertise to NYC "Ebola designated hospitals" on handling and packaging specimens to be transported to the NY PHL for Ebola testing.

NYC PHL, An Ever Ready Workforce

The New York City (NYC) PHL Director, Dr. Jennifer Rakeman-Cagno, considers the NYC PHL "every day a bit of a success story, because we accomplish what we set out to accomplish—getting good, quality results out quickly." However, she is especially proud that the NYC PHL was one of the first labs in the US to deploy the DoD EZ1 Real-time RT-PCR Assay for presumptive detection of Ebola Zaire virus. In fact, the first specimen the laboratory tested for Ebola—for a Bellevue hospital patient—was positive. The day after completing this test, the laboratory tested a specimen for a healthcare worker returning from the epidemic zone in West Africa. And the next week, the lab tested a specimen from a five year-old boy who was eventually diagnosed with a respiratory virus. "We were able to get him out of Ebola precautions and home with family quickly," said Rakeman-Cagno. The laboratorians who tested these Ebola specimens safely with no self or community exposures demonstrates the high level of expertise and training that goes into such a response. The training and skill the laboratorians need to do such testing takes time and cannot be done with "just-in-time" training without additional risk to the staff and community. "We needed to be able to do specimen pick-up and testing any time, day or night, if one of those people showed symptoms," said Rakeman-Cagno

Still there are challenges. As with PHLs in general, Rakeman-Cagno faces challenges recruiting and retaining a highly qualified staff. NYC has a high cost of living and there is, she says, "lots of competition" from clinical and research laboratories that offer higher salaries. The PHL has around 130 employees, down from over 400 when the laboratory first moved into its current building 50 odd years ago. Said Rakeman-Cagno, "Our staff is awesome. People really pull together and make happen what they need to make happen. They are dedicated."

Partnerships and Outreach

While having a ready and capable workforce is a critical element for PHLs, coordinating those limited resources and collaborating with other partners is equally vital for an effective response. PHLs communicate and collaborate with other state and local laboratories, sentinel clinical laboratories, hospitals, first responders and law enforcement, and other government agencies. Figure 6 depicts the diversity of PHL partners. This partnership is vital in any response effort. PHLs are woven into the very fabric of our nation's surveillance and response networks—these labs are members of the LRN-B, LRN-C, the Environmental Response Laboratory Network (ERLN), which covers chemical threats including Chemical Warfare Agents (CWAs), the Water Laboratory Alliance (WLA), the Food Emergency Response Network (FERN), the National Animal Health Laboratory Network (NAHLN) and other foodborne surveillance networks such as PulseNet (see figure 7).

Figure 6: PHL Partnerships and Outreach

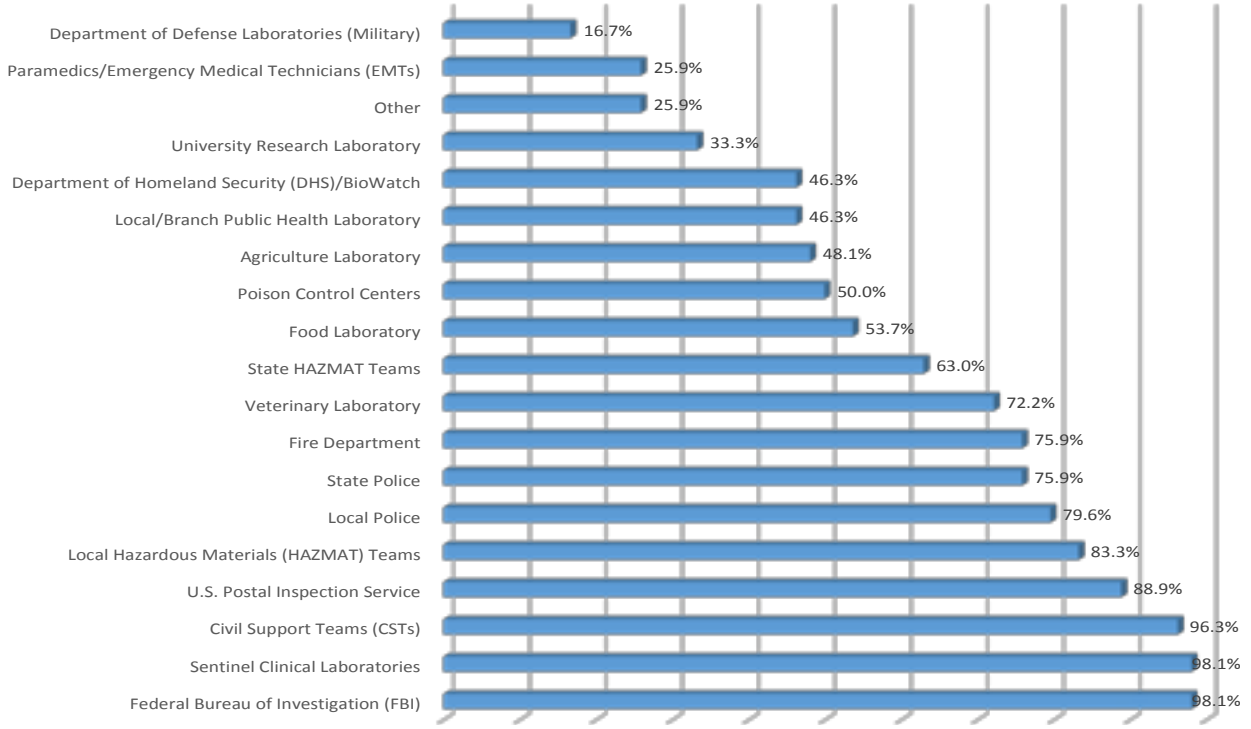
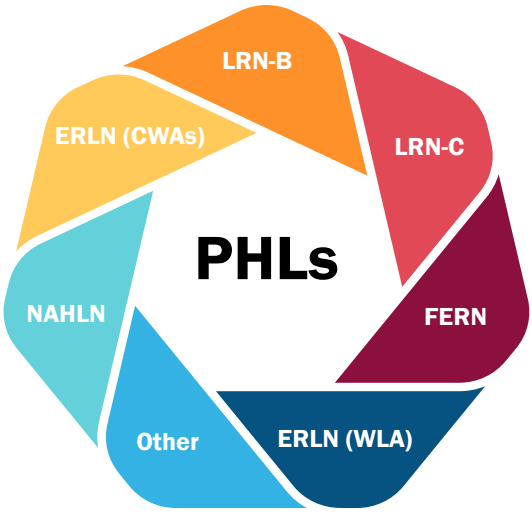


Figure 7: PHL Laboratory Response Networks



North Carolina Partners with Law Enforcement to Detect Designer Drug

When a laboratory agrees to serve as a back-up for another lab, it rarely expects to be called upon. This was not the case when the North Carolina State Laboratory of Public Health agreed to provide emergency response back-up for South Carolina's Department of Health and Environmental Control, Bureau of Laboratories during scheduled maintenance. In February 2015, a suspicious package with an unknown but potentially hazardous substance led the FBI to investigate. The suspicious substance was ruled out as a biological threat and, upon request of the North Carolina Chemical Terrorism and Threat Coordinator, submitted for chemical identification via the routine all-hazards approach used by North Carolina's Preparedness Unit.

Chemical testing was performed on an instrument common to the LRN-C, a Gas Chromatograph/Mass Spectrophotometer (GC/MS). Analysis revealed the substance to be Methoxetamine, a designer drug similar in its effects to Ecstasy. The South Carolina Bureau of Laboratories and the FBI were notified of the results and the sample was taken into evidence for an ongoing criminal investigation. Through the cooperative all-hazards approach of North Carolina's chemical and biological threat departments, a definitive identification of an illegal substance was obtained. This incident has also led to several consultations with federal law enforcement on the capabilities of the LRN-C, both locally and as a national network.

This past year, PHLs in the LRN-B responded to the DoD's inadvertent shipping of live anthrax by providing testing support and communications to ensure safety of the facilities and laboratorians who worked with these samples. In addition to the safety implications of such an incident, a major shipper refused to transport select agents resulting in a nationwide gap to quickly transfer these agents to CDC.

In addition to supporting federal partners such as FBI and DoD, PHLs also provide guidance and assistance to clinical labs. In 2014, the largest outbreak of Ebola devastated the West African countries of Sierra Leone, Liberia and Guinea. Thousands of people died in these countries and healthcare systems continue to struggle to respond to this epidemic. In the US, a few cases posed great challenges and revealed gaps in the connections between the public health and healthcare systems. Many clinical laboratories were unprepared to perform routine tests of patients under investigation and the response revealed further gaps such as:

- Inability of some clinical laboratories to safely and correctly package and ship specimens to PHLs
- Inadequate biosafety programs in most clinical laboratories
- Lack of timely guidance for clinical laboratories to perform routine diagnostic tests on patients under investigation
- Limited connectivity between private clinical laboratories and the public health system

In response to these gaps, the US Congress awarded funding to procure new technologies, strengthen biosafety and biosecurity, and train the workforce. PHLs are utilizing these funds to strengthen their systems and rebuild strong partnerships with clinical laboratories.

Erin Swaney (seated) demonstrates Ebola Zaire virus sample inactivation to Mark Mergen (hidden), Garrick Gillispie (left) and Wanda Songy (right) at the Texas DSHS Laboratory Services Section.

Texas: Leveraging the LRN-B to Respond to Ebola and Other Threats

In spring 2014, world news turned its focus towards West Africa where an outbreak of Ebola was adversely affecting thousands of people. In the US, the CDC was developing plans and strategies for preventing a domestic Ebola outbreak. A rapid test, polymerase chain reaction (PCR), which had been developed by the DoD and used in the African countries affected by the Ebola outbreak gained emergency use authorization (EUA) from the US Food and Drug Administration (FDA) and made its way into the CDC LRN for distribution to selected PHLs (see Figure 8).

The Texas Department of State Health Services (DSHS) Laboratory was a member of the CDC LRN and already had staff trained to handle specimens using Biosafety Level 3 (BSL-3) practices. The LRN provided training, infrastructure and resources needed for the DSHS Biothreat Team to test for infectious agents that cause serious and lethal diseases. Prior to the arrival of the Ebola testing kit, the DSHS Biothreat Team had been testing samples for ricin, anthrax, and other organisms that can be both naturally acquired or be part of a public health threat.

Because of LRN support, the DSHS Laboratory was ready to perform testing for Ebola within three weeks of the EUA announcement. When the call came in late September of a suspected Ebola case at a Dallas hospital, the DSHS Biothreat Team was ready to receive the sample and begin testing immediately. Within a few hours of the specimens arriving simultaneously at the DSHS Laboratory and the CDC, a positive PCR result was received and the first case of Ebola was diagnosed on US soil. The DSHS Laboratory eventually received more specimens for testing, two of which would be the second and third cases of Ebola.

The CDC PHEP Cooperative Agreement provided the funding to not only build these types of capabilities but also maintain them. The Texas network of LRN laboratories was built using this funding and has allowed the state to maintain ten LRN-B laboratories located in large metropolitan areas, which can be used to respond to threats and other public health emergencies, such as the 2009 H1N1 pandemic, emergence of Middle East Respiratory Syndrome Coronavirus (MERS-CoV), Ebola and now Zika.

William Dorman, USAMRIID, accepts the LRN Award for Excellence in Partnership, 2014 Ebola Response, from APHL's President, Judith C. Lovchik, PhD, D(ABMM)

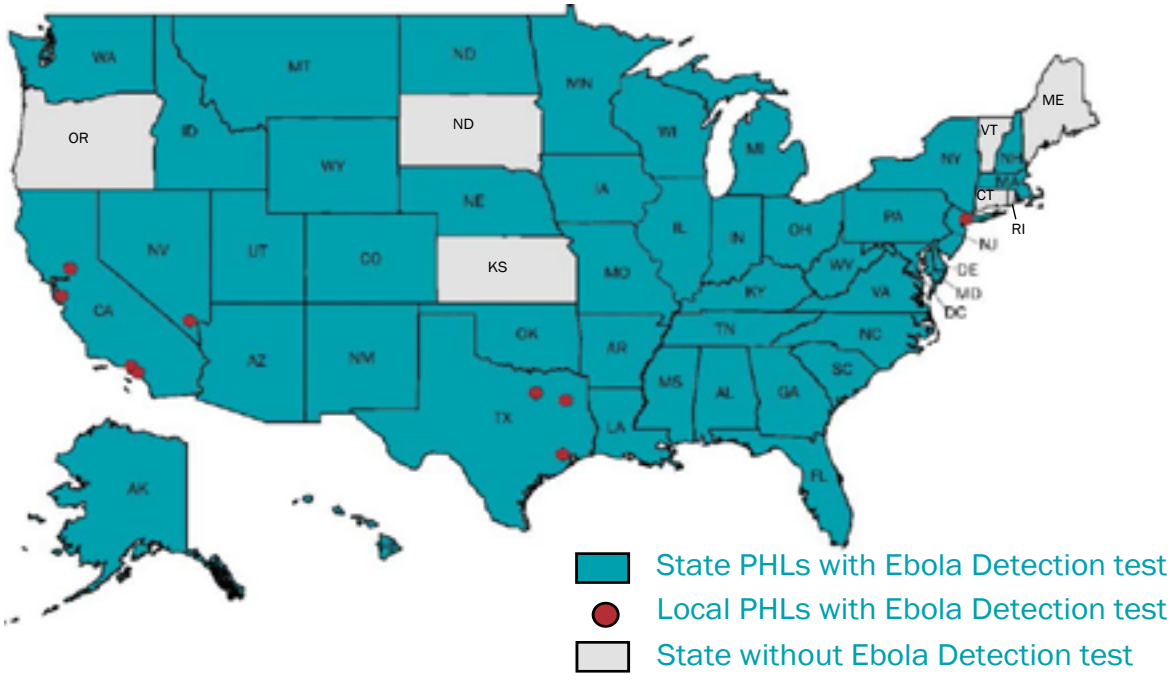
As seen in Texas and other states, PHLs rely on their partners such as clinical laboratories for the timely submission of samples:

- 100% CDC PHEP-funded PHLs maintained a database of sentinel clinical labs in their jurisdiction. Nationwide, information for over 4,000 sentinel clinical labs is housed in these databases which allows for timely communications.
- 90% PHLs use a standard national definition to identify sentinel clinical labs.
- 95% PHLs assess competency of sentinel clinical labs.
- 40% PHLs award a certificate of recognition to sentinel clinical labs.
- On an ongoing basis, PHLs conduct preparedness training and outreach activities to engage sentinel clinical labs, first responders and other partners within their jurisdictions.
- 82% PHLs sponsored training which included rule-out testing, packaging and shipping and 63 biosafety courses to 410 sentinel clinical labs and 1660 laboratorians.

In light of new technologies and emerging threats, it is important for PHLs to enhance partnerships with clinical laboratories which can benefit from training, biosafety guidance, risk assessments and knowledge of capabilities at other laboratory facilities.

PHLs can stay ahead of the next threat by reaching out to sample submitters and other partners to maintain and strengthen relationships.

Figure 8: PHL Ebola Testing Capabilities Across the US



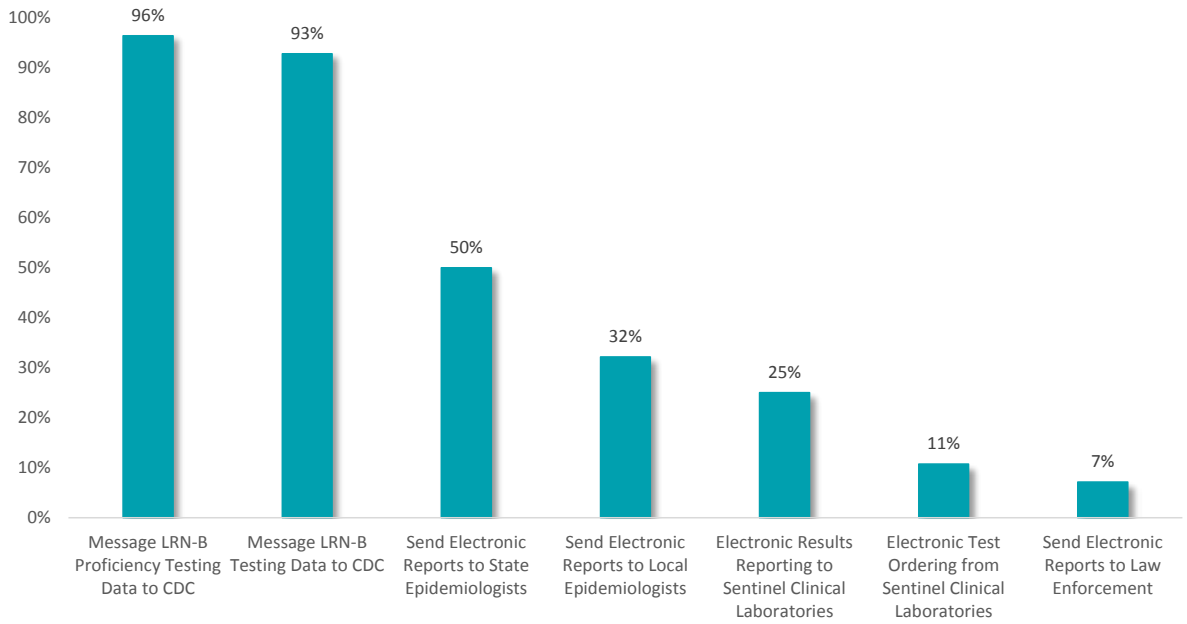
Electronic Data Exchange – Why Timely Results Matter

As members of multiple laboratory response networks, PHLs serve as the hub for testing novel pathogens and responding to emerging threats. As such, it is vital for PHLs to send accurate and timely data to their stakeholders which include hospitals, federal agencies and other sample submitters. It is no secret PHLs have multiple systems to send data to the same partners. Several efforts are underway to improve the electronic data exchange of test results. Patient privacy, security and ease of use top the requirements for such systems. PHLs which comprise the LRN either use the LRN Results Messenger (RM), a web based platform or their own Laboratory Information Management System (LIMS) to send data to key partners.

LRN-RM allows member laboratories to instantly manage and share standard LRN-related laboratory data. LRN-RM represents the first iteration in an incremental approach to providing full standards-based electronic data exchange for this vital laboratory network. However, the nature of the application requires laboratorians to enter their data into LRN-RM and their laboratory's LIMS, a time-consuming double-entry process that could take up critical time in an emergency.

In 2010, CDC and APHL launched the LIMS integration (LIMSi) project which is capable of communicating biothreat test data directly from a laboratories internal LIMS to CDC. By sending test results directly to the CDC, there is no need for double data entry into LIMS and LRN-RM, a system configured only to report results to CDC. 28 PHLs (52%) currently utilize their own LIMS to send data to CDC and other partners. Figure 9 illustrates how these 28 PHLs utilize LIMSi.

Figure 9: Utilization of LIMS Integration for LRN-B Data Exchange



Rapid Data Exchange in the LRN: The New York State Experience

In 2012, the New York State Department of Health–Wadsworth Center completed implementation of the LIMSi project. This has significantly reduced the input time required by laboratorians, especially during surge events like the 2014 Ebola outbreak. A useful additional feature is instrument interfacing, or the ability to automatically import test results from instruments into LIMS. While final result interpretation is still the responsibility of a technician, the laboratorian does not have to transfer data sets multiple times between systems. Sample reports can also be generated through LIMS integration and are available electronically from submitting laboratories (e.g., sentinel clinical labs), allowing immediate retrieval of test results when they are released. If specimens need to be referred to another laboratory such as the CDC, the referral laboratory typically provides an electronic report to the intermediate laboratory. To ensure that the original submitting laboratory receives the referral results, LIMS integration has the capability to make electronic files reportable and available to submitting laboratories.

Despite LIMS integration success stories like the Wadsworth Center, laboratories have encountered issues maintaining and expanding their LIMS integration capabilities. Since 2010, CDC and APHL have granted over $2.2 million to laboratories for initial implementation. Upon implementation, it is the responsibility of the laboratory to maintain the system, a task often neglected due to overextended IT staff and lack of additional funding. Unsustained LIMS integration capabilities are problematic during an outbreak, increasing the turnaround time for results reporting and expanding the margin of error in results reporting.

Conclusion

PHLs are on the front lines of identifying the next threat, whether it is water contamination as seen in Flint, MI or emerging infectious diseases such as Ebola and Zika viruses. But PHLs still face challenges such as inconsistent funding; limited ability to procure new technologies and ensure service contracts on aging equipment; a limited workforce pool where they are unable to attract and retain qualified applicants; and actively sustaining a robust IT infrastructure. It is unrealistic to expect PHLs to function according to a “just in time” model of operation. An Ebola response event is not the time to train a laboratory workforce. This workforce must be in place and ready to respond as demonstrated by the Texas LRN, the New York City PHL and other PHLs across the nation.

Ultimately, public health laboratorians remain unsung heroes as one of the nation’s vital resources in facing a public health threat. Often behind the scenes and underpaid, they carry out an important role of providing timely and accurate testing and outreach, thus contributing to an effective response.

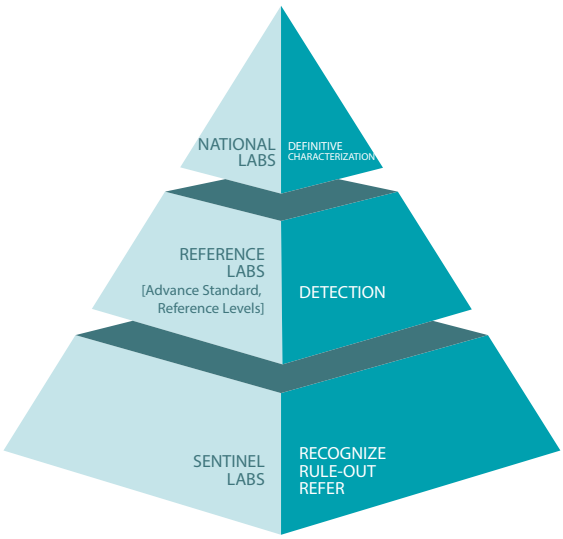
The viability of these laboratorians and laboratories is constantly threatened by diminishing resources. Simply put: inconsistent funding jeopardizes the ability of laboratories to prepare for, respond to and recover from public health threats. A sustainable funding strategy is needed to invest in PHLs and their ability to detect the next threat.

Appendix 1: Laboratory Response Network

Mission of the LRN

The 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), and, in 2014, the MERS coronavirus (MERS-CoV) and Ebola virus. 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 Structure for Responding to Biological Threats

The Laboratory Response Network for Biological Threats Preparedness (LRN-B)

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 sentinel clinical labs cannot rule out the presence of a threat agent, they refer specimens and isolates to an LRN Reference Laboratory. The LRN Reference category is further categorized into Advanced, Standard, and Reference laboratories. At a minimum, an LRN-B Reference laboratory must be able to perform polymerase chain reaction (PCR) for at least biological threat agent tested in the LRN. Standard laboratories must be able to perform multiple-agent screening on high-risk environmental samples, as well as other biological threat agents defined by the LRN. Finally, Advanced laboratories are required to meet the standard level requirements, as well as maintain Select Agent certification, and, if requested, support CDC with assay development, evaluation of new technologies, proficiency testing remediation, and high throughput surge capacity.

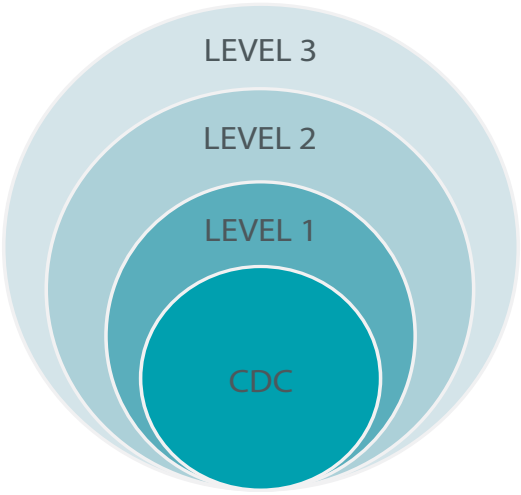
Initially, there were just 17 LRN reference labs. Today, more than 140 state, local and federal facilities provide reference testing, producing high-confidence test results that are the basis for threat analysis and intervention by both public health and law enforcement authorities. State and local public health labs comprise approximately 70% of the 140

LRN-B member laboratories. At the apex of the pyramid are national labs such as those at the CDC and the DoD. 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 Laboratory Response Network for Chemical Threats Preparedness (LRN-C)

In addition to detecting biological threats and emerging infectious diseases, there are two other core areas of LRN: chemical and radiological threats.

The LRN-C, established in 1999, originally comprised CDC laboratories and four public health laboratories. Now 64 laboratories qualify to package and ship clinical specimens for chemical threat analysis (Level 3), 43 of which can test for exposure to toxic chemical threat agents (Level 2), and 11 of which (10 state public health laboratories and CDC) can test for exposure to additional threats, such as mustard agents, nerve agents and industrial chemicals (Level 1). The Level 1 laboratories can provide 24/7 analytical analyses in a large-scale event.



The LRN Structure for Responding to Chemical Threats

The initial focus of the LRN-C was to develop methods for detecting human exposure to chemical weapons. Today, the methods include a variety of different chemical threats that pose a public health risk, including a variety of toxins and poisons. Using quantitative mass spectrometry to detect chemical agents or their metabolites in urine or blood, LRN-C methods identify those individuals who have been exposed but do not display symptoms or injuries immediately following the incident. This is because in an overt incident, the agent will most likely be known based on symptoms and injuries. For those with obvious symptoms or injuries, detecting exposure or the extent of exposure to the agent is probably not necessary. LRN-C also helps alleviate the concerns of individuals worried about exposure.

Currently, the LRN for Radiological Threats Preparedness (LRN-R) consists solely of CDC. Once funded, the broader network will be structured similarly to the LRN-C, with some laboratories having more advanced capabilities, others with more limited capability and still others with the capacity for packaging and shipping specimens to a laboratory with higher functionality.

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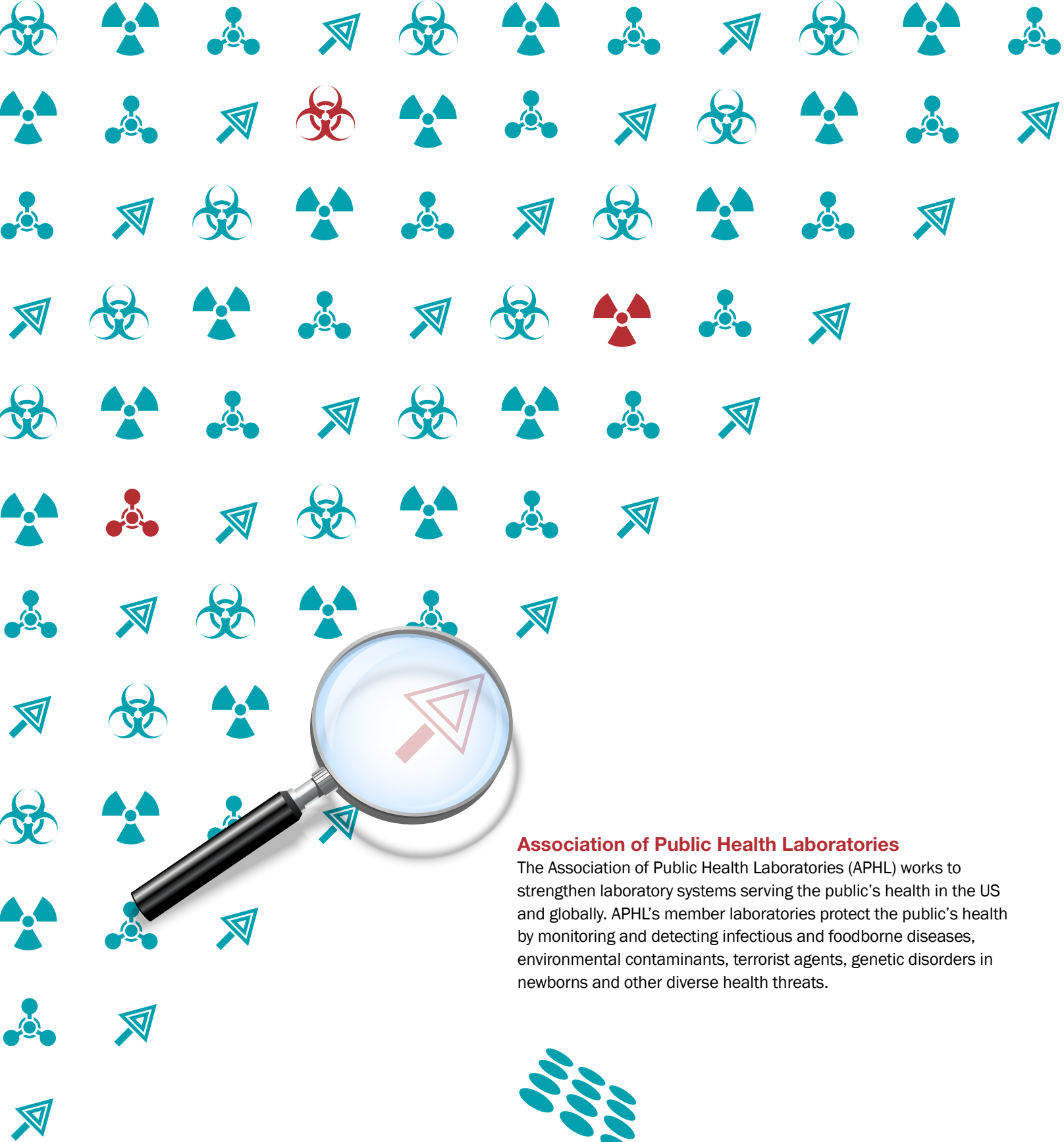

Association of Public Health Laboratories

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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