Utilizing Public-Private Partnerships to Respond to Public Health Threats

A Report of Selected Findings From the
2019 APHL All-Hazards Laboratory Preparedness Survey

OCTOBER 2020

APHL ASSOCIATION OF PUBLIC HEALTH LABORATORIES®

BACKGROUND

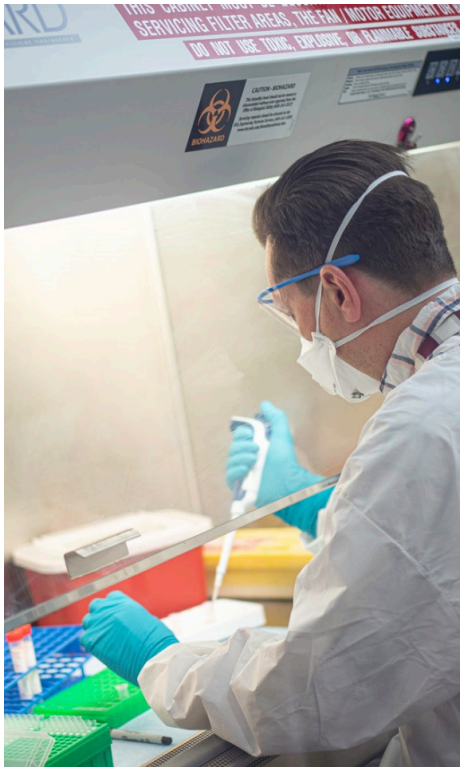
Public health and healthcare take different, yet equally important approaches to serving and protecting the nation's health. At the foundation of both approaches is laboratory testing, which is necessary for health departments to monitor disease in the population and identify novel threats, and for health care providers to make decisions to treat patients. The interdependency of the public and private sector testing has never been more important as seen with the response to severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), the virus which causes coronavirus disease (COVID-19). These two systems must work together to provide timely and accurate testing, covering a significant portion of the US population. As is the case with novel infectious threats, prompt and quality testing is critical as it shapes treatment options, epidemiological actions such as contact tracing and influences larger public health decisions including quarantine.

CORE FUNCTIONS OF PHLS

- Disease Prevention, Control and Surveillance
- Integrated Data Management
- Reference and Specialized Testing
- Environmental Health and Protection
- Food Safety
- Laboratory Improvement and Regulation
- Policy Development
- **Public Health Preparedness and Response**
- Public Health Related Research
- Training and Education
- Partnerships and Communication

In executing their eleven core functions, public health laboratories (PHLs) "engage the entire healthcare community to varying degrees in the state public health laboratory system."[1] Preparedness and response, one of these core functions, encompasses participation in key laboratory networks, planning for and ensuring surge capacity, and maintaining continuity of operations.

Many PHLs are members of various networks including the Laboratory Response Network (LRN), Food Emergency Response Network, PulseNet, Environmental Response Laboratory Network and the Global Influenza Surveillance Network, to name a few. The LRN currently has two components–Biological Threats Preparedness (LRN-B) and Chemical Threats Preparedness (LRN-C)–with a third component for radiological preparedness in development.



Via these networks, PHLs work closely with the private laboratory sector to prepare for and respond to existing and emerging public health threats. This collaboration entails maintaining contact lists, meeting on a routine basis, having knowledge of equipment and testing capabilities, providing training and other resources to ensure there is warm base poised to respond to the next threat.

Supported primarily through funding from the federal government, namely the United States (US) Centers for Disease Control and Prevention (CDC), PHLs lead the efforts to develop and maintain partnerships with a diverse group of private and other governmental laboratories within their jurisdiction. However, as Federal funding levels have decreased over the past decade, this public-private laboratory system has been strained. Its vulnerability was evident during the US response to Ebola, Zika and now, COVID-19.

Following are key data points from APHL's Annual All-Hazards Laboratory Preparedness Survey and recommendations on strengthening the US laboratory system to respond to emerging threats.

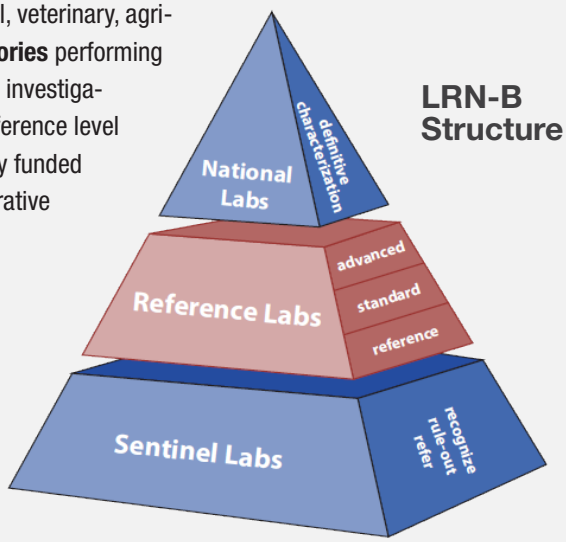
Photo: Erik Reisdorf at the Wisconsin State Laboratory of Hygiene prepares a plate for testing COVID-19 specimens. (Wisconsin State Laboratory of Hygiene)

LRN FOR BIOLOGICAL THREATS PREPAREDNESS

Established in 1999 by APHL, the CDC and the Federal Bureau of Investigation (FBI), the LRN is charged with detecting and responding to biological and chemical threats, as well as other public health emergencies, such as Zika, Ebola and global pandemics. The LRN for Biological Threats (LRN-B) operates in a tiered construct of sentinel, reference and national laboratories as an integrated network for rapid detection and response to threats.

The foundation of the LRN-B consists of thousands of **sentinel laboratories**, which perform initial screening of potential pathogens. When sentinel laboratories cannot rule-out the presence of a biological threat agent, they refer specimens and isolates to an LRN reference laboratory.

Approximately 130 state and local public health, military, environmental, veterinary, agriculture, food and international laboratories serve as **reference laboratories** performing complex analyses and providing support for law enforcement for threat investigations. State and local PHLs comprise approximately 70% of the LRN reference level laboratories. LRN-B activities in these state and local PHLs are primarily funded through the CDC Public Health Emergency Preparedness (PHEP) Cooperative Agreement.



At the apex of the pyramid are **national laboratories**, such as those at the CDC and US Department of Defense (DoD) which have additional capabilities to characterize organisms and handle extremely infectious biological agents.

Integrated into one system, these laboratories operate cohesively to identify and respond to threats, providing a vital resource to law enforcement and public health officials.

METHODS

In the fall of 2019, APHL conducted its Annual All-Hazards Laboratory Preparedness Survey of 54 PHLs, including all 50 state PHLs and PHLs in the District of Columbia, Puerto Rico, New York City and Los Angeles County, to assess capability and capacity for biological, chemical, radiological and other public health threats. The survey covered the 12-month period from July 1, 2018—June 30, 2019, representing Fiscal Year 18 (FY18) CDC PHEP Cooperative Agreement, Budget Period 1. 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. All 54 PHLs (100%) responded to this survey. The 2019 APHL All-Hazards Laboratory Preparedness Survey Summary Data[2] Report presents aggregate survey results for all questions.

Staff in the virology department at the Oregon State Public Health Laboratory prepare to handle COVID-19 specimens.
(Photo: Oregon State PHL)

KEY FINDINGS:
STATUS OF PUBLIC-PRIVATE PARTNERSHIPS TO RESPOND TO THREATS

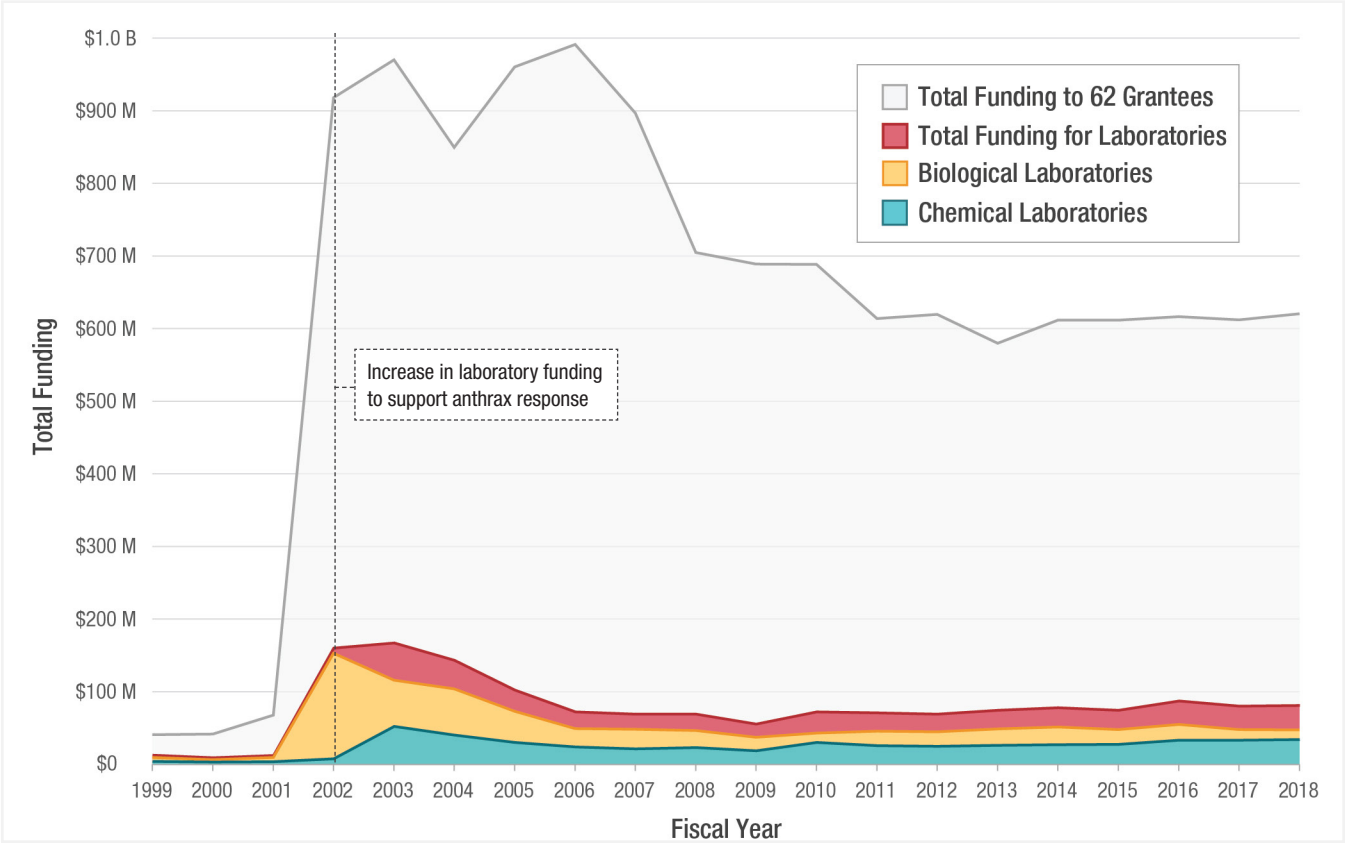
Funding

To fulfill its preparedness and response function including training and outreach to private labs (e.g. hospitals), state, local, territorial and US Affiliated Pacific Islands (US API) PHLs rely on Federal funding. When these funds decline, it greatly impacts the ability for laboratories to maintain essential infrastructure—that is—personnel, equipment, tests and communication systems to respond to emerging threats.

In FY18, the Federal governmental provided 90% of PHL preparedness and response funding with the CDC PHEP Cooperative Agreement serving as the largest source of funding. In FY18, PHLs across the nation received $106 million for laboratory preparedness activities with $81.5 (76.9%) million originating from the CDC PHEP Cooperative Agreement (See **Figure 1**). Of this $81.5 million, PHLs allocated $47.6 million to support Biological Threats Preparedness programs, which included $27.9 million for staff salaries, $5.3 million for new equipment and maintenance agreements, $3.0 million for laboratory supplies, and approximately $661,000 on training and travel related expenses, such as providing in-person training workshops for clinical laboratory scientists. Only three PHLs reported receiving funding from the Department of Health and Human Services (HHS), Assistant Secretary for Preparedness and Response (ASPR) Hospital Preparedness Program (HPP) to help strengthen readiness of the national health care system. These three PHLs received a total of $236,282 HPP funding, which was used by PHLs to support personnel necessary to conduct outreach and trainings to sentinel laboratories. A challenge that plagues governmental laboratories is inconsistent, crisis driven funding. **The crisis driven approach to funding public health does little to ensure a base of highly skilled laboratory scientists, biosafety professionals, outreach staff, and equipment or tests to detect the next threat.**

Over the past decade, Federal funding for preparedness and response has not kept pace with the vast number of global threats.

Figure 1. 20 Years of CDC PHEP Cooperative Agreement Funding (Fiscal Year 1999 to 2018)



Role of Sentinel Laboratories in Preparedness and Response

Sentinel laboratories are the foundation of the LRN and they are capable of analyzing or referring samples that may contain microbial agents, biological toxins, chemical agents, chemical agent metabolites, or radiological agents of public health significance, and serve as a first-line defense for the greater public health system.[3]

There are 260,000 clinical laboratories with varying capabilities across the US. In the broadest sense, all of these laboratories are considered sentinels. PHLs designate a subset of these clinical and other laboratories as LRN-B Sentinel Laboratories. This subset of laboratories must have the appropriate certifications:

1. Clinical laboratories must have a Certificate of Compliance or Certificate of Accreditation under the US Centers for Medicare and Medicaid Services Clinical Laboratory Improvement Amendments of 1988 (CLIA).
2. Veterinary diagnostic laboratories must be accredited by the American Association of Veterinary Laboratory Diagnosticians.

In addition to these certifications and accreditations, there are other requirements for a laboratory to be considered an LRN-B Sentinel Laboratory (see right).

In FY18, 54 PHLs reported that there were 3,064 LRN-B Sentinel Laboratories in their jurisdictions. These laboratories are likely to first encounter a patient affected by a biological threat agent. As such, it is fundamental that clinical laboratory scientists are adequately trained to properly to rule-out and refer potential threat agents while maintaining their own safety. LRN-B Sentinel Laboratories perform a range of responsibilities to conduct diagnostic testing and to support the public health system.

RESPONSIBILITIES OF LRN-B SENTINEL LABORATORIES

- Work closely with local and state public health and federal laboratories to recognize potential biological threat agents and other emerging threats.
- Provide satellite facilities with directions and training as needed for sample collection and handling as well as procedures to recognize biological threat agents.
- Maintain the capability to perform testing outlined in the American Society for Microbiology Sentinel Level Clinical Microbiology Laboratory Protocols and Guidelines for Suspected Agents of Bioterrorism and Emerging Infectious Diseases.[4]
- Be familiar with reportable disease guidelines in the jurisdiction and have policies and procedures in place to refer suspicious clinical and diagnostic samples to the appropriate LRN Reference Laboratory.
- Ensure a sufficient number of personnel are trained in packaging and shipping of Category A and B infectious substances.[5]
- Have policies and procedures for the collection and referral of suspect biological threat agents or other emerging threat samples to the appropriate LRN Reference Laboratory.
- Utilize the practices outlined in the current edition of the Biosafety in Microbiological and Biomedical Laboratories[6] guidelines.
- Maintain compliance with the applicable rules and regulations of the Federal Select Agent Program.[7]

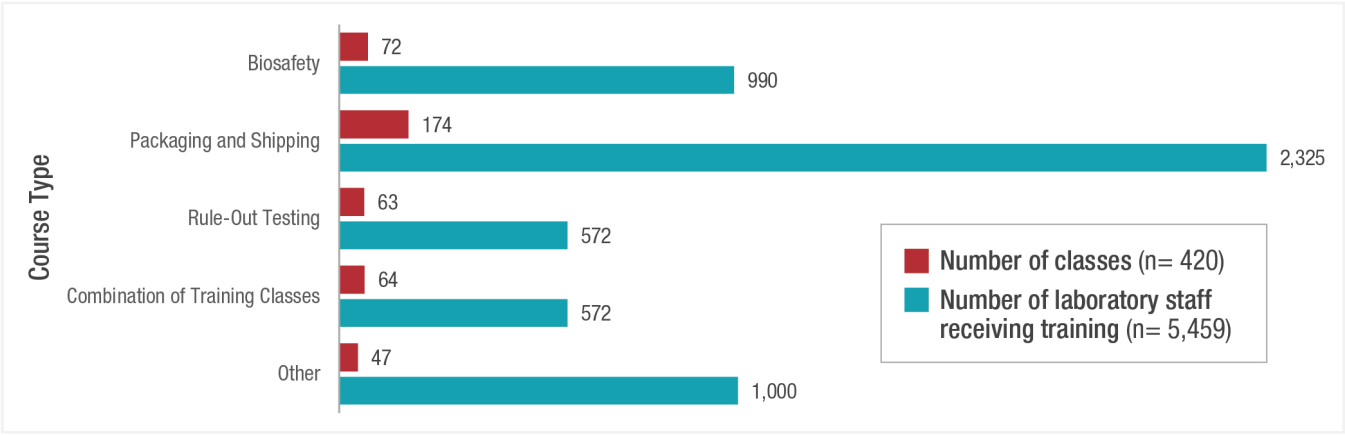
For a more detailed overview of sentinel laboratories, view the Definition of Sentinel Clinical Laboratories.

Clinical laboratory scientists participate in a workshop at the New Hampshire PHL. (Photo: New Hampshire PHL)

Role of Public Health Laboratories in Supporting Sentinel Laboratories

PHLs provide extensive outreach and training to help ensure that laboratories which serve as sentinels are capable of meeting the responsibilities to safely handle specimens that may contain biological threat agents, rule-out such threats and refer specimens for further testing. In FY18, 44 PHLs (81.5%) provided a total of 420 training classes, reaching 5,459 laboratory scientists (**Figure 2**).

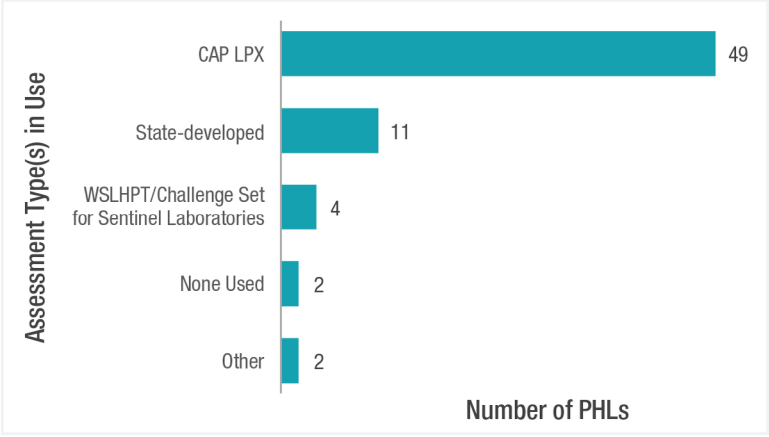
Figure 2. PHL Training of Sentinel Clinical Laboratory Scientists



In addition to providing training courses, PHLs support and engage sentinel laboratories by providing the following:

- **Transportation of Samples:** 52 PHLs (96.3%) have a method in place to ensure the timely transport of a suspicious specimen to a LRN Reference Laboratory, even during non-business hours. This helps facilitate the quick identification of pathogens and therefore treatment of patients.
- **Simulated Exercises:** PHLs routinely conduct exercises and utilize real events to evaluate laboratory response time. 50 PHLs (92.6%) utilized simulated exercises and other methods to ensure that testing partners are able to quickly respond during times of need.
- **Rapid Communications:** Rapid communication methods including blast emails and Health Alert Network messages are commonly used by PHLs to communicate with sentinel laboratories and other partners on topics such as routine updates and for distributing urgent information on outbreaks. 52 PHLs (96.3%) utilized such communication methods to assure important information reached all partners.
- **Competency Assessments:** In addition to formal proficiency testing programs, sentinel laboratories also participate in other competency assessments that are sponsored or recommended by PHLs. PHLs use the results of these assessments to collaborate with sentinel laboratories on areas for improvement. These assessments also allow PHLs to identify challenges in following notification procedures and with proper packaging and shipping techniques. APHL, CDC and College of American Pathologists (CAP) Laboratory Preparedness Exercise (LPX) is widely administered throughout the US, with 49 PHLs (90.7%) using the assessment to evaluate the competency of sentinel laboratories to rule-out and refer biological threat agents. Some PHLs also use other assessments, with 11 (20.4%) utilizing individual state developed tests and five (9.3%) using the Wisconsin State Laboratory of Hygiene (WSLH) Proficiency Testing (PT). In total, 52 PHLs (96%) utilized assessments to determine the competency of sentinel laboratories in their jurisdiction (**Figure 3**).

Figure 3. Number of PHLs Utilizing Assessments to Evaluate Competency of Sentinel Laboratories



RECOMMENDATIONS FOR STRENGTHENING PUBLIC-PRIVATE LABORATORY PARTNERSHIPS

Public and private laboratories must continue to work together to provide timely responses to existing and emerging threats. The following are key issues and recommendations to strengthen the US laboratory system to respond to novel threats such as COVID-19:

1. Disparate Laboratory Systems and Fluctuating Federal Funding

Issue

The LRN has a successful model for response where private laboratories, governmental state, local, territorial PHLs and federal labs integrate to meet the demands for threat agent testing. This model needs to be supported and expanded to a national laboratory system where all laboratories are prepared to respond to emerging threats.

As CDC PHEP Cooperative Agreement funds declined over the years, and the Ebola Supplemental funds ended in May 2019, as well as little to no funding for laboratories via the ASPR HPP Cooperative Agreement, PHLs have struggled to maintain full-time positions such as a Laboratory Outreach Coordinator and Biosafety Officer (BSO) or Biosafety Outreach Officer. PHLs have also encountered difficulty in traveling clinical laboratory staff for much needed in-person training. Laboratory science and training can not be sustained solely through virtual means. Only 31 PHLs (57%) have personnel whose position is dedicated to outreach to clinical laboratories. In fact, in FY18 20 PHLs (37%) were unable to physically visit at least one clinical laboratory.

In addition to staffing issues, both public and private laboratories are in urgent need of improvements to their laboratory information management systems (LIMS). These systems need to be modernized and allow for secure and timely transmission of electronic test orders and results (ETOR).

Recommendations

- Utilize the LRN model as a guide for a broader national laboratory system for diagnostic testing and public health surveillance.
- Increase federal funding for laboratory preparedness and response, ensuring adequate resources are provided via the CDC PHEP and HHS/ASPR HPP Cooperative Agreements.
- Dedicate federal funding for public health emergency response.
- Expand the number of laboratory outreach staff in PHLs.
- Support the CDC Data Modernization Initiative to provide better data, which drives public health decisions and, ultimately, health outcomes.

2. Laboratory Safety is not Prioritized

Issue

BSOs are charged with providing guidance on biosafety to staff at PHLs and clinical laboratories. They continue to experience various challenges, such as managing heavy workloads and coordinating trainings for a large number of laboratories. Having a dedicated BSO position ensures that more laboratories receive training on conducting biological risk assessments, use of personal protective equipment and certification in packaging and shipping of infectious substances. In FY18, only a total of 30 PHLs (55.6%) had a full-time BSO on staff, with a lack of funding indicated as the primary factor.

Recommendations:

- Integrate biosafety and broader safety under the quality systems umbrella in laboratories.
- Fund at least one dedicated BSO position and a second biosafety outreach officer position in PHLs.
- Leadership at clinical and other laboratories should ensure that there is dedicated personnel for biosafety.
- Public and private laboratories should collaborate to develop and deliver more training resources for biosafety (e.g. risk assessments).

3. Lack of Laboratory Advisory Councils

Issue

Due to a lack of funding, many PHLs have not implemented a Laboratory Advisory Council where they engage members of the clinical laboratory community. In FY18, only 19 PHLs (35.2%) had established such a group, covering topics including recommendations to improve collaboration and communication, addressing new tests or technologies, and laboratory system improvements.

Recommendation:

PHLs should form and convene an Advisory Council, at least annually, to shape testing strategies, training programs, safety and quality across the laboratory system. These councils must be representative of the jurisdiction and include representatives from the healthcare community.

4. Lack of Formal Recognition of LRN-B Sentinel Laboratories

Issue

Private laboratories are vital to the laboratory system to prepare for, respond to and recover from all-hazard threats. In FY18, only eight (14.8%) PHLs awarded either a state developed or LRN Joint Leadership Committee approved certificate of recognition to sentinel laboratories within their jurisdiction. Formal acknowledgment of these laboratories can foster more participation in training programs, strengthen communications and demonstrate the importance of private laboratories within the broader public health system.

Recommendation:

PHLs should issue certificates of recognition to sentinel laboratories that are actively engaged in the LRN-B.

5. Lack of Formal Agreements for Response

Issue

Entering into contracts or other formal agreements is a complex process made even more complicated with unsteady funding. However, initiating discussions prior to a major event and understanding the capacity, capability, workflow and other needs, would be valuable to strengthening the laboratory system. This approach would be valuable especially in scenarios where laboratory surge capacity is challenging. In FY18, 39 PHLs (72.2%) had formal agreements in place with other laboratories, such as agricultural or local PHLs within the state, to support surge capacity needs.

Recommendation:

As part of their Continuity of Operations Plan, PHLs should consider formalizing agreements for testing with a broader group of laboratories including private entities.

CONCLUSION

Laboratories are critical in responding to threats, providing the capability and capacity necessary to support testing which drives treatment and public health interventions. Developing and maintaining a laboratory system capable of responding to these threats requires strong partnership between private and public sectors and sustained funding. The majority of funding in place to support these efforts is provided from the US federal government through various CDC and HHS/ASPR Cooperative Agreements, which have declined or remained flat over recent years. Sustained funding is a critical need for laboratory preparedness and response.

PHLs can strengthen private partnerships through well-rounded outreach programs. Utilizing Laboratory Advisory Councils to gain input from private and other laboratories on key issues affecting them provides a vital opportunity to improve collaboration and discuss laboratory system improvements. Utilization of competency assessments allows PHLs to identify and address laboratory scientist challenges with certain testing methods. Further, official recognition of sentinel laboratories provides acknowledgment and demonstrates value for the public-private collaborative, ensuring a robust network is in place to respond to major threats.

A robust public health system is critical to respond to the plethora of threats—from climate change to infectious diseases. With the re-emergence of Ebola, Zika and new threats such as SARS-CoV-2, timely and accurate laboratory testing is the linchpin to an effective response. The public health system, comprised of private and public partners, must be in sync, working together to prioritize laboratory preparedness and response.

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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.

Acknowledgments

APHL would like to thank the 54 public health laboratories that completed the 2019 All-Hazards Laboratory Preparedness Survey.

Cover Photo: Clinical laboratory staff participate in a training hosted by the Oregon State Public Health Laboratory. (Photo: Oregon PHL)

This report was 100% funded with federal funds from a federal program of $1,404,465. This publication was supported by Cooperative Agreement #NU60OE000103 from CDC. Its contents are solely the responsibility of the authors and do not necessarily represent the official views of CDC.

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