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An Introduction to Public Health Laboratories

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From tracking a meningitis outbreak to testing drinking water to training laboratory professionals on how to identify anthrax, public health laboratories (PHLs) operate where scientific inquiry meets on-the-ground community impact. PHLs provide diagnostic testing, disease surveillance, applied research, laboratory training, and more. Without the critical information generated by these scientists, many of the more familiar activities that characterize the practice of public health could not take place. Laboratory science and practice is a common denominator for fulfillment of fundamental public health services, including monitoring health status to identify and solve community health problems and diagnosing and evaluating diseases and environmental hazards that threaten the health of populations.[1–8] For example, laboratory services have been integral to public health efforts to prevent and control vector-borne illnesses such as West Nile virus, diarrheal diseases initiated by food- and water-borne organisms like Salmonella, conditions caused by exposure to environmental toxicants, highly infectious illnesses such as severe acute respiratory syndrome, and illness that is the result of biological terrorism.[2] When health risks emerge or re-emerge, laboratories in public health analyze the threat, provide the answers needed to mount an effective response, and act to protect the public.[3]

> "We're emergency responders from the lab perspective."
>
> Peter Shult, Director, Communicable Disease Division and Emergency Laboratory Response, Wisconsin State Laboratory of Hygiene[4]

Thus, PHLs must concern themselves not only with high-quality performance of complex laboratory procedures, but also their roles as part of a larger regional, national, and even global public safety network. Achieving uniformity of data and prompt, integrated reporting is both more possible and more difficult than ever before. Today's laboratories on all levels must have multidisciplinary capabilities in addition to good, up-to-date science: Knowledge of informatics, the skills to negotiate budgets and policy, understanding of communications among laboratories and with the public, the ability to train others and to anticipate workforce and resource needs, practical experience in emergency procedures, grounding in standards and performance measurement—the list can go on.

This chapter will look at the growth of PHLs, their mission, and what makes them unique, including their core functions and how they interact with the greater network of public health organization and agencies to carry out these functions. Finally, it will project future directions and challenges and offer some insight on how PHLs might meet them.

A Brief History of US Public Health Laboratories

More than a century ago, as the United States shifted from a mostly rural society to a modern, urban-centered one, PHLs emerged in concert with public health departments.[5] Both were working toward a common goal: to identify the causes behind—and stem the spread of—the many diseases ravaging a growing nation. In the late 19th century, urbanization and population growth were causing health problems unlike any the United States had seen before. Cities dumping untreated sewage into rivers and streams caused typhoid fever to run rampant. It was not uncommon for young children to die from diseases we today consider obscure, nonexistent, or treatable, such as measles, mumps, diphtheria, whooping cough, and scarlet fever. At the turn of the century, tuberculosis alone killed 194 of every 100,000 residents.[6]

To tackle their dire hygiene and sanitation issues, regional and municipal governments adopted formal health boards and implemented public health policies to protect their residents. The budding area of laboratory-based investigation played an important role in their solutions. Building upon the work of Louis Pasteur and Robert Koch, researchers applied the germ theory of disease and discovered causative agents for leprosy, typhoid fever, tuberculosis, cholera, and diphtheria—all common diseases for the time. In the world of science, applied research now focused on addressing pressing real-world problems.[5] State and federal government created facilities to conduct this research. One of the first, the Marine Hospital on Staten Island in New York, moved to the Washington, DC, area in 1888 to become the precursor to the National Institutes of Health (NIH). PHLs soon opened their doors at the state level, starting in Rhode Island, Kansas, and Michigan, and growing across the nation.[6]

Food safety and the elimination of water-borne disease were the first targets of the early PHLs. Over the next years, technological advances made tackling infectious diseases more possible and more critical. World Wars I and II presented the public health threat of sexually transmitted diseases, also leading laboratories to make advances in handling and planning for crisis and surge-condition situations. In the 1960s and 1970s, as awareness grew of the long-term health effects of environmental hazards, PHLs became a first line of defense and developed important networking and communications skills.[6]

As the century drew to a close, threats became more diverse and more global. Localized outbreaks of food-borne illnesses and episodes of conditions such as Legionnaire's disease emerged as potentially national threats, as travel habits, technology, and economies changed rapidly.[6] Two crises brought home the importance of PHLs, their advanced science, their emergency response capabilities, and their importance as a hub in the public health network: the prospect of bioterrorism and the reality of human immunodeficiency virus (HIV)/acquired immunodeficiency syndrome (AIDS).[6] These pushed PHLs to develop technology, communication, and policy links and skills that will serve PHLs well against new health threats, such as the H1N1 pandemic, which is being fought worldwide as this is being written.

Today, state PHLs can be found in every state supporting America's national PHL network as well as individual state public health systems. At the local level, about 250 local PHLs are now in operation across the nation. The Association of Public Health Laboratories (APHL) describes a PHL as, "a local, state, or federal governmental entity. . .[that] provides testing for public health programs in assessing health status and preventing disease [and] fulfills core public health functions in partnership with private clinical, hospital, and commercial laboratories, healthcare organizations, and other institutions."[2]

Interestingly, the need for PHLs has often been debated during their history. For instance, in the 1970s and 1980s, an argument surfaced that, because antibiotics had reduced many of the major public health threats, the United States could discontinue tracking, detecting, or communicating data on diseases.[6] That was before the reality of HIV/AIDS or antibiotic-resistant infection set in. During the writing of this text, each day's news bears out the importance of PHLs: novel influenza viruses and new food-borne outbreaks are only two of the areas over which nations must be constantly vigilant to protect lives, peace, and economic stability.

Public Health Laboratories: A Unique Mission and Role

To shape a strong, secure, productive society, leaders must ask certain questions about health: How can we make sure environmental pollutants and disease does not take an economic and human toll? How can we help mothers and children thrive—and thus ensure our future? How do we keep a health emergency from compromising national security? This is where the mission of PHLs becomes clear. Environmental health, disease control and prevention, maternal and child health, epidemiology, and emergency response—the mission of a PHL is to support these kinds of programs on the federal, state, and local levels.[5]

PHLs do so in many ways. They perform analytic testing. They consult with lawmakers and regulators on the formation and implementation of public health policy. They help train laboratory professionals across the public and private sectors. In times of crisis, PHLs play a key role in emergency preparedness and response. In regions serving at-risk populations, PHLs can help community clinics provide primary laboratory services.[7]

This is only the tip of the iceberg. As needs and opportunities expand, so do the many roles of the PHL. To advance knowledge in the health and sciences, PHLs often are called upon to conduct epidemiologic studies and other applied research. As new technologies emerge, PHLs often are enlisted to evaluate and try out these innovations.

What Makes a Public Health Laboratory Different?

There are nearly 200,000 private-sector, clinical laboratories in the United States, as well as a few thousand public health, veterinary, food safety, and environmental testing laboratories. While PHLs often provide support or "surge capacity" for one another during crises, their main focus is to serve a local jurisdiction, a state, or, in the case of federal PHLs, the nation. Unlike laboratories in commercial settings, PHLs are integrated into the broader public health system. State health laboratorians, for example, work closely with public health agency epidemiologists to identify trends and "sentinel events" that may signal emerging health problems.[5]

Laboratories range in capacity from basic water testing services to more complicated testing involving human clinical samples or, in some cases, characterization of potential bioterrorism agents. State laboratories are available to local health agencies in the jurisdictions that lack resources to fund a local laboratory.[2] PHLs interact with federal laboratories and private laboratories run by hospitals, physicians' offices, and other independent parties. However, core distinctions exist.

PHLs must meet the requirements of the federal Clinical Laboratory Improvement Amendments of 1988 (CLIA) as well as the mandates of external agencies, which often include the US Environmental Protection Agency (EPA) or the US Food and Drug Administration (FDA). PHLs also conduct more training and regional and community interaction than federal laboratories. PHLs also differ from private-sector laboratories, even though their internal operations are similar. Private laboratories focus on individual patient care, which makes them vulnerable to cost containment pressures. Unlike private medical laboratories that perform tests to diagnose illnesses and conditions afflicting individual patients, PHLs safeguard entire communities.[5] In one way or another, the work of these laboratories affects the life of every American.

Protecting the Nation: The National Laboratory System

Despite differences in capacities, function, and mission, all of these parties, and PHLs across the nation, work together to protect and preserve the health of our communities. But because a specimen that indicates the first sign of an outbreak could show up at any type of laboratory, it is important to link the efforts of all types of laboratories across the nation. A national laboratory system—one overarching network of state laboratories coordinating efforts among the states and federal agencies such as the Centers for Disease Control and Prevention (CDC)—has existed in practice for many years.[2] However, only recently have organizations more formally articulated their roles and responsibilities. Linking these laboratories to create seamless systems within each state, for public health surveillance and laboratory support and improvement, is the mission of the National Laboratory System (NLS) initiative. While the NLS is being built state by state (as reflected in the vignettes that follow), the eventual goal is to connect 50 individual state laboratory systems into a national system that promises even greater value to America.[8]

Since 2000, the CDC and APHL have sponsored many projects to explore creative ways public and private stakeholders can communicate and coordinate. Some of these have been put to the test in crisis situations. For instance, in the aftermath of Hurricane Katrina, hospital laboratories along the Gulf Coast of Mississippi were able to continue operations, thanks in part to an influx of reagents and state-owned vehicles for specimen transport arranged by the Mississippi Department of Health laboratory.[8]

Fast and First: The Laboratory Response Network

In the late 1990s, biohazards and biological and chemical terrorism became a looming global threat, and PHLs throughout the United States began to prepare to meet any possible incident. At that time, the vast majority of PHLs in the United States were not able to test for some of the most virulent biological agents. Those that could were using testing methods that were inordinately time-consuming. New procedures had yet to be developed or validated.[2]

In 1999, to address this situation, the CDC and APHL established the Laboratory Response Network (LRN). The network is an integrated, multitiered system of state and local PHLs as well as national laboratories at the CDC, FDA, Federal Bureau of Investigation (FBI), the Department of Defense (DOD), and other federal agencies. The LRN also includes select private clinical, veterinary, and agricultural laboratories that are seen as the front lines of detecting microbial agents of bioterrorism. The goal of the LRN is to bring the most accurate and rapid testing methods closer to the patient, as well as assure laboratory capabilities and capacity adequate for rapidly responding to biological terrorism and other public health emergencies. The role of the LRN is not confined to responding to terrorism events; however, it is also equipped to respond to emerging infectious disease, natural disasters, and other public health threats.[2]

The LRN is just one more example underscoring the importance of networking, communication, and enhanced scope in today's PHL. State and local PHLs support the network with advanced diagnostics and disease monitoring; hospital and clinical laboratories refer suspicious specimens to LRN reference laboratories.[9] Through practice, a structure evolved to deal with events:

- Thousands of clinical and hospital laboratories serve as sentinel laboratories, monitoring for possible agents in clinical specimens or environmental samples.
- All state PHLs serve as reference or confirmatory laboratories, with the ability to isolate and definitively identify threats.
- Federal LRN laboratories at the CDC and the DOD conduct investigations and provide oversight, training, and new technology.

Within the LRN, state PHLs are recognized as first-responder laboratories. In the event of a confirmed biological or chemical attack, they are the first point of contact for public safety officials to arrange testing. The structure of the LRN and the role of PHLs are described in more detail in Chapter 9.

Sidebar 1-1 Public Health Laboratories Networking Put to the Test[2]

The LRN was tested—and rose to the challenge—during the anthrax events of September 2001, when an employee in a Florida tabloid publishing company was infected with anthrax. Between October and December 2001, the LRN conducted nearly 122,000 work-ups based on environmental samples, the results of which guided hundreds of decisions to evacuate or reoccupy buildings, as well as to determine what areas to deem "affected." This was accomplished even though the LRN was originally structured to test clinical, not environmental, samples. Thanks to the collaboration of CDC and state laboratorians working around the clock, an environmental test protocol for anthrax was quickly developed and disseminated in time for the crisis.

Training, relationships, and communication were key to a timely and effective response. First, the LRN, though still in its infancy, was up and running before the crisis hit. Second, a protocol to identify anthrax in human specimens had already been developed, validated, and broadly disseminated to state laboratorians. Third, the state PHL in Jacksonville, Florida, had a good working relationship with the clinical laboratories in the state. When a laboratory worker in a Boca Raton hospital received the specimen from a physician who suspected that his patient had anthrax, the hospital laboratorian knew the name and phone number of the appropriate contact in the Florida Bureau of Laboratories who was able to perform confirmatory testing for anthrax in a clinical specimen.

In any emergency situation demanding quick response, triage is essential, and this event was no different. LRN circumvented bottlenecks to a certain degree through structuring a "pyramid" of laboratories, each level designed to respond to a certain category of threat. Initial screening was conducted by thousands of sentinel laboratories across the United States. Samples for which analysts could not rule out the presence of a potential bioterrorism agent were then sent to a confirmatory laboratory. At the top of the pyramid, two federal LRN laboratories had the capacity to conduct highly sophisticated forensic and epidemiological investigations. Lessons learned from the 2001 anthrax response provided laboratorians with real experience upon which to improve their ability to triage potentially contaminated items.[2]

What Public Health Laboratories Do: The Core Functions[10]

In 2002, through an article in the *Morbidity and Mortality Weekly Report*, the core functions of PHLs were formalized.[1] This listing (see Sidebar 1-2) continues to work as a practical and complete framework for evaluating the specific functions and services provided by a laboratory.[1,7] The list does not necessarily mean the laboratory will provide all these functions, but that the laboratory is responsible for assuring these functions are available. PHLs do not exist in a vacuum, and as these core functions are refined over the years, it will be apparent that other types of laboratories sharing the PHL goals may share in providing these services.

Sidebar 1-2 Eleven Core Functions of State Public Health Laboratories[1]

1. *Disease prevention, control, and surveillance* by providing diagnostic and analytical services to assess and monitor infectious, communicable, genetic, and chronic diseases and exposure to environmental toxicants.
2. *Integrated data management* to capture, maintain, and communicate data essential for public health analysis and decision-making.
3. *Reference and specialized testing* to identify unusual pathogens, confirm atypical laboratory results, verify results of other laboratory tests, and perform tests that are not typically performed by private sector laboratories.
4. *Environmental health and protection*, including analysis of environmental samples and biological specimens to identify and monitor potential threats and ensure regulatory compliance.
5. *Food safety assurance* by testing specimens from people, food, and beverages implicated in food-borne illnesses and monitoring radioactive contamination of foods and water.
6. *Laboratory improvement and regulation*, including training and quality assurance.
7. *Policy development*, including development of standards and providing leadership.
8. *Emergency response* via provision of rapid, high-volume laboratory support as part of state and national disaster preparedness programs.
9. *Public health-related research* to improve practice of laboratory science.
10. *Training and education* for laboratory staff in the private and public sectors in the United States and abroad.
11. *Partnerships and communication* with public health colleagues at all levels and with managed care organizations, academia, private industry, legislators, public safety officials, and others to participate in state policy planning and to support the core functions outlined here.

Core Functions in Action

These core functions include several that were previously viewed as outside the realm of PHL responsibilities, but which have, in recent years, been recognized as important and have been fulfilled by PHLs. Specifically, these functions involve surveillance, furnishing finished "data products" to all parts of the health system, creating meta-data, and developing policy.

After clinical specimens and environmental samples come into the laboratory, PHLs convert them into useable information, which is then confirmed, organized, analyzed, stored, and communicated to those with a need to know—ideally, in real time. In a meningitis outbreak in Minnesota, PHL analysis played a crucial role in stopping an outbreak. Information gained then provided a valuable foundation for pinpointing the source of a second outbreak, enabling the state to target vaccinations only to those at risk.[11] In South Salt Lake City, Utah, environmental chemists at the state's PHL tested and analyzed material from a tanker crash to reveal the cause to be simple negligence, rather than chemical terrorism as first responders initially feared.[7,11]

PHL research can contribute to the meta-data that shapes key findings and, consequently, health practices. For example, the director of California's Genetic Disease Laboratory heard of a new technology, tandem mass spectrometry (MS/MS), that identified dozens of treatable genetic diseases that previously had gone undetected in newborns. Over a period of 18 months, the PHL performed MS/MS testing on the blood samples of roughly 375,000 babies, 51 of whom tested positive for one of the new conditions. As a result, the state enacted a law mandating the addition of the new genetic conditions to the standard panel of tests for all infants born in California. With informed parental consent, babies would be tested free of charge at the state PHLs.[11]

PHLs increasingly play a pivotal role in how governmental agencies and other authorities shape policy, as well as set, interpret, and revise regulations. In 2001 and 2004, because of concerns about mercury levels, both the EPA and the FDA issued nationwide advisories that women of childbearing age restrict consumption of fish. However, fish is a key nutritional staple for many rural Alaskans. Targeted testing by Alaskan PHL scientists and state epidemiologists over the course of 2 years reported mercury levels well below the "no observed effect level" set by the World Health Organization. Based on these findings, the Alaska Division of Public Health recommended unrestricted consumption of fish caught in Alaskan waters.[11]

Funding and Oversight for Public Health Laboratories: General Structures and Practices

All this laboratory activity costs money and needs to be regularly evaluated for quality performance. Where do PHLs get their funding? What are the policies and practices that govern their operations? Because so many different types of PHLs exist, these essential activities will be carried out differently. What remains constant are the changes in politics and local and national needs to which laboratories will need to respond, and the lifesaving missions that continue to require top-quality resources and performance.

In the beginning, it was not uncommon for a PHL to receive a significant amount of its funding from one source, whether a university, a federal agency, or a state department of health. Today, PHLs tap numerous funding streams, including:

- Appropriated state or local revenue
- Direct federal funding
- Indirect federal funding (through other departmental grant recipients)
- Fees or other earned income
- Third-party reimbursement, such as Medicaid

In the 1970s and 1980s, debate began on privatizing PHLs and has since been a perennial topic of discussion.[5] Outsourcing regulatory oversight and data integration are two of the most obvious sticking points to privatization. Furthermore, proposals have been unable to model cost savings from privatization. This being said, PHLs have needed to become adept at making their case, and advocating for, their public role (for more information concerning the role of PHLs visible to the public, see Chapters 10 and 12).

New funding streams have opened up in response to the expanded roles of PHLs. A recent and significant example is homeland security. For instance, in the event of a confirmed biological attack, state PHLs are recognized as first-responder laboratories. This has significantly impacted funding trends for the decades around the turn of the 21st century and will likely continue to do so into the future. A focused effort to build basic public health infrastructure as a matter of national security began in the early 1990s with the CDC's strategy for preventing emerging infectious diseases. It led to the creation of two federal programs: the Epidemiology and Laboratory Capacity Program and the Emerging Infections Programs, through which states can compete for funding. In 1998, the CDC strategy was revised to include an explicit reference to bioterrorism.

At the same time, the US Congress authorized specific bioterrorism preparedness activities at the CDC, including an extramural program through which all states were funded to build public health capacity to respond to a deliberate release of infectious organisms. State PHLs used these new resources for various purposes, such as purchasing advanced instrumentation, upgrading safety facilities, hiring coordinators to oversee bioterrorism preparedness activities, improving information management and communications systems, and helping to upgrade other state laboratories that agree to provide surge capacity in a serious bioterrorism attack. But after this surge, economic constraints led to funding cutbacks in many areas affecting PHLs. A look at future challenges that might affect funding and what laboratories might do to weather those challenges is at the end of this chapter.

Just as PHLs get funding from multiple sources, they also receive oversight from multiple organizations, agencies, and regulatory groups. Most PHLs must meet quality standards established by the CLIA, which were established in 1988 and finalized in 1992. The aim of these standards is to ensure accurate, reliable, and timely diagnostic test results for clinical specimens, no matter where testing is performed. Sites that conduct testing of clinical specimens for diagnosis, treatment, or prevention of disease must obtain a CLIA certificate corresponding to the complexity of the tests performed.[11] PHLs may also need to comply with relevant laws and regulations such as the Clean Water Act, as well as oversight by other agencies.[5] In addition, today's PHLs are often seeking ways to improve quality and service, and are using tools such as performance management to achieve this.

Distribution and Staffing

Public Health Laboratories at the National, State, and Local Levels

The organizational structure of a PHL can vary based on where it fits within its governmental department or university system, when and how it serves agencies and customers outside of its host institution, how much testing is conducted in-house, and several other factors. PHL funding and organizational structures generally follow three models, each with advantages and challenges. Most commonly, PHLs are housed within a state health department. This structure enables them to access facilities a local agency might not have and increases opportunities for communication and collaboration, often with other organizations of the health agency and local health departments.[5]

However, an increasing number of PHLs (such as those in Massachusetts, Nevada, and Nebraska) are affiliating themselves with a state university system. This not only provides access to an extensive library and skilled workforce, but it also frees a PHL from the political influence and funding fluctuations that can be experienced at a state agency. A university-affiliated PHL also has the freedom to create separate funding streams.[5]

Still other PHLs are "consolidated laboratories," which means they are housed in a state agency that is not a health agency. A successful example can be found in the state of Virginia, where the Virginia Department of Government Services supports the Virginia Division of Consolidated Laboratory Services to serve a number of state agency "clients," from Agriculture and Consumer Services to Criminal Justice Services. Shared infrastructure and economies of scale across a comparatively large "customer base" often means that these kinds of PHLs can adopt new technologies more quickly.[5]

Federal agencies operating laboratories related to public health include:

- The CDC
- The FDA
- The DOD
- The FBI
- The US Department of Agriculture (USDA)
- The NIH
- The EPA[5]

Staffing Trends: Past, Present, and Future

Workforce needs will vary according to type of PHL. However, key staff members often include the following.

- A laboratory director
- A leadership team of section directors and managers
- Supportive administrative staff
- Highly trained employees such as epidemiologists and laboratory technicians to perform core laboratory functions
- Specialists in areas such as environmental health, global disease, and bioterrorism
- A quality assurance officer
- Communications professionals who can relate the PHL's work to media, policymakers, clients, leading scientists and public health practitioners, and other key audiences.[7]

PHLs have found they need to augment their staff during critical emergencies. As these emergencies have compounded around the turn of the 21st century, many PHLs have been faced with a serious workforce shortage. Options they use to cope include cross-training laboratory personnel, establishing pools of volunteer microbiologists, or making arrangements to "borrow" staff from private laboratories.[2]

Public Health Laboratories Outside of the United States

In the latter half of the 20th century, it became clear to public health workers worldwide that all capacities would need to be better connected and aligned. Several factors lent urgency to this global view:

- Emergence of HIV/AIDS and drug-resistant tuberculosis
- Economic interdependence and global trade making health and stability of all nations a priority
- Loss of life and productivity in developing nations because of malaria and other infectious diseases
- The pandemic potential of influenzas and acute respiratory disease
- Increased immigration and travel among all countries

It is worthwhile to note that training and education of laboratorians abroad was made part of the formal listing of PHL core functions. Around the time of this writing, the World Health Organization adopted standards for all member states to develop surveillance capacity to detect, report, and respond to public health risks and emergencies. To these ends, US PHLs participate in several initiatives to strengthen laboratory systems and practices and workforce development, as well as connect and mutually improve PHL services worldwide. Here's a closer look at two such efforts:

World Health Organization Twinning Program

This program matches laboratories in developing countries with more established institutions to improve the quality of their laboratory practice and their surveillance of and response to international infectious diseases. Accordingly, US PHLs set up matching programs with national laboratories in developing countries; for instance, the California State PHL is matched up with the Ethiopia Health and Nutrition Research Institute and the Michigan State Laboratory and the Los Angeles County Laboratory are matched up with the NIH Immunology Laboratory in Mozambique. The US PHLs provide expertise, technical assistance and training to improve capacity and quality. For example, Guyana has a new national public health reference library for which the North Carolina PHL is providing mentorship in quality assurance and biosafety activities.[12]

George Washington University-Association of Public Health Laboratories International Institute for Public Health Laboratory Management

The George Washington University School of Public Health and Health Services in Washington, DC, and the APHL developed this international educational resource. Advanced seminars are provided for laboratory professionals who manage laboratory systems and hold responsibility for the planning, managing, and direction of national PHL systems in developing countries. Again, a major focus is surveillance, as well as quality assurance, policy development, and public health program planning. The senior health professionals participating are provided with practical knowledge conferring competency and leadership in quality PHL practice.[13]

Interstate Coordination and Training

Because threats and pandemics do not respect state boundaries, PHLs continually need to learn how to work seamlessly across them. Concurrently, PHLs also must uphold their responsibility to provide training across the nation to ensure the quality of all medical and environmental laboratories. Here are a few examples of how PHLs and the organizations with which they work are paving the way toward a more integrated, more skilled public health infrastructure.

The Centers for Disease Control and Prevention

PHLs have collaborated with the CDC from the time the agency was created in 1946. Throughout the 1950s and 1960s, the Association of State and Territorial Public Health Laboratory Directors (ASTPHLD), the predecessor organization of APHL, worked hand in hand with CDC staff and scientists. The CDC worked on the federal level and ASTPHLD on the state and local levels, enabling both to stay current on the latest developments in the laboratories and on the ground.[6] By the 1980s, despite the influx of federal funding for HIV/AIDS testing, the relationship between PHLs and the CDC was less close, particularly in the area of training, which was strongly affected by the CDC reorganization of the early 1980s.[6] This left a workforce gap that local and state PHLs had difficulty filling. The result was an agreement that led to the formation of the National Laboratory Training Network (NLTN; see later in the chapter).[6]

PHLs and the CDC collaborate on dozens of essential programs in areas from infectious diseases to newborn screening. The May 2009 novel H1N1 influenza crisis provides a good case in point as to how PHLs work with the CDC: The CDC developed and deployed novel H1N1 diagnostic kits, delivering them to over 60 state and local PHLs in only 10 days. Confirmatory testing, which previously had been handled only by the CDC, then could be conducted by these laboratories. Such a step meant that results could be produced in less time and disease control measures put into place faster.[14] These improvements could not have happened without the CDC and PHLs working together.

Public Health Laboratories and Federal Departments and Agencies

PHLs find themselves interacting on several levels with multiple federal departments and agencies. To give a picture of the complexity of these collaborations, here are just a few examples.

- PHLs work with the FBI in bioterrorism and chemical terrorism event planning and response.
- The US Department of Health and Human Services (DHHS) has launched programs such as Healthy People 2010, which has objectives that necessitate laboratory involvement.
- The President's Emergency Plan for AIDS Relief has tapped PHL knowledge to help with PHL systems building and training abroad.
- The EPA needs laboratory information to implement pollution-control programs under acts such as the Clean Water Act and the Clean Air Act.

- PulseNet, the nation's food-borne disease surveillance laboratory network, has become an essential partner to epidemiologists concerned with food-borne outbreaks. PulseNet also has a growing international component.

Challenges—and opportunities—also exist in the area of technology, as the data systems used by nontraditional public health partners, such as the FBI and other law enforcement agencies, are not likely to be revamped to comply with Public Health Information Network (PHIN) standards.[2]

Association of Public Health Laboratories

Since 1951, when its predecessor organization ASTPHLD was founded,[6] the APHL has served as both a resource for its member PHLs and as a liaison among these members, federal officials, and other partners. Its mission is to promote the role of PHLs in support of national and global objectives and to promote policies and programs that assure continuous improvement in the quality of laboratory practice. The APHL provides guidance on federal protocols and directives as well as advises federal agencies on the development and implementation of national initiatives that involve PHLs.[6] Reading about the diversity of skills and responsibilities in the PHL, it is understandable that current or prospective laboratorians and administrators would ask how one could cover all these bases and keep a laboratory running. APHL is the primary place for the answer to this question—as well as a link to the resources needed to fulfill these responsibilities.[3]

Other Associated Organizations

After the 2001 anthrax crisis, it became clear that a broader umbrella of individuals, organizations, and responders must work collaboratively to plan and practice response activities. This wider network includes the National Guard, emergency management personnel (hazardous material teams, fire departments, and other safety workers), and law enforcement personnel. It is now commonplace to have public health and clinical laboratory leaders involved in all aspects of bioterrorism response planning at the state and local levels.[15]

In addition, outside of the emergency response area, PHLs often work with other organizations nationally and globally. Here are a few examples.

- The World Health Organization has looked to US PHLs in training programs and for data collection.
- In response to infectious diseases such as influenza easily crossing borders, US PHLs have collaborated with their counterparts through the Pan American Health Organization and the Canadian Public Health Laboratory Network.
- Organizations such as the World AIDS Foundation, the World Bank, and more have been sources of funding and expertise for PHLs, and PHL laboratorians have worked with these organizations to teach, learn, and improve quality and alignment of PHLs worldwide.

The National Laboratory Training Network

The NLTN, a partnership between CDC and APHL, operates toward one ambitious overarching goal: to be the best possible laboratory training vehicle in the United States. In operation since 1989, the NLTN provides training on a regional level to laboratorians performing testing of public health significance, on subjects ranging from molecular diagnostic techniques to food-borne disease investigations. In keeping with the overall PHL mission to collaborate and connect, and bridging regional differences, the training programs are available in diverse formats and re-evaluated with greatest access in mind. NLTN provides its consistently highly rated, reasonably priced, laboratory-specific, credit-earning continuing education via traditional "wet" workshops, seminars, and distance learning programs, including teleconferences, webinars, and computer-assisted resources, and it is flexible and receptive to new formats and content.[16]

The Emerging Infectious Diseases Laboratory Fellowship Program

To build PHLs' capacity to respond to new health threats, as well as provide unique opportunities to explore careers in PHL science, APHL and the CDC developed the Emerging Infectious Diseases (EID) Laboratory Fellowship Program. It trains and prepares selected scientists for careers in PHLs and supports public health initiatives related to infectious disease research. Areas of training and research include development and evaluation of diagnostic techniques, antimicrobial sensitivity and resistance, principles and practices of vector or animal control, emerging pathogens, and laboratory–epidemiology interaction. Fellows participate in either a 1-year program designed for bachelor's or master's level scientists, with emphasis on the practical application of technologies, methodologies, and practices related to EID, or a

2-year program in which doctoral level (PhD, MD, or DVM) scientists conduct high-priority research in infectious diseases. PHLs have the opportunity to host an EID fellow.

Credentialing

The PHL community has grappled with the issue of licensure since the middle of the 20th century. Initiatives began on the state level. In the 1940s and 1950s, the state of California created a model adapted by many others. The 1965 passage of Medicare legislation, however, brought with it sweeping changes with the CLIA. This evolved into the 1988 CLIA, and CLIA certification is now required by all clinical laboratories that receive Medicare or Medicaid payments. The CLIA regulations of 1992 further codified certification,[5] most notably stipulating stringency of requirements based on the complexity of an individual test. The Centers for Medicare and Medicaid Services provides oversight and enforcement for CLIA compliance, so PHLs need to be aware of their relationships with this agency. The CDC and the FDA also play roles in support and test categorization.

Yet, as the role of the PHL evolves, work still remains to make sure laboratory credentialing keeps pace. Today, a minority of states have licensure or credentialing requirements for medical and PHL scientists. Most states have no such requirements and rely only on local institutional policies and practices or job descriptions to specify the minimum knowledge, skills, and abilities required of laboratorians.[2] However, CLIA certification or credentialing through the College of American Pathologists can ensure laboratorian competency.

To address this, APHL has collaborated with the American Board of Bioanalysis to offer board certification in public health microbiology. The certification will afford doctoral level scientists in PHLs a new means to qualify for certification under CLIA, as well as establish the qualifications for nonphysician laboratory directors in medical and PHLs that conduct high-complexity testing on human specimens. The certification will be the first to specifically examine the training and experience required to direct a state or large municipal PHL. This represents one influential step into a changing landscape of certification that will affect PHLs into the future.[17]

Future Directions[15]

PHLs are part of a rapidly evolving era in public health—one in which global, flexible, and immediate response is essential to saving lives. The future challenges for these laboratories include:

- Standardized, multidirectional electronic communication of data and information
- Molecular biological assays
- Rapid, nonculture point-of-care infectious disease assays
- Ultrasensitive chemical analysis instrumentation
- Emergency response preparedness
- All-hazard surveillance
- Population biomonitoring
- Expanded newborn screening
- Genetic testing
- Emerging chemical contaminants
- Potential terrorism
- Emerging pathogenic microorganisms

PHLs also face a changing laboratory culture: a culture of connectivity and high expectation. The need for communication, collaboration, and cooperation with a multitude of essential partners, both within and outside governmental agencies, demands new goals and skills. Cultivating this new culture will strengthen PHLs and public health overall. Following is a look at a few of the areas that will drive these changes.

Emergency Response

America's increased focus on emergency response has deep repercussions for PHLs. While only one core function of a PHL is explicitly developed to emergency response, it is important to note that the entire laboratory infrastructure—skilled staff, instrumentation, specimen containment facilities, information management systems, linkages with private sector laboratories, and more—must be in place and functioning well in advance of a crisis in order to maintain the vigilance necessary to detect the unannounced release of an infectious organism or emergence of a new disease and the readiness to mount a swift and appropriate crisis response.

Achieving success will demand a continued commitment to partnerships and collaboration:

- Infectious disease and environmental epidemiologists

- Sentinel clinical laboratories
- Local and state first responders
- Federal agencies including CDC, FBI, FDA, USDA, the US Department of Homeland Security, DOD, and the DHHS
- State and local health officials

These broader working relationships will subject PHLs to new responsibilities. For instance, when working with first responders in field tests, PHLs will need to communicate the possible drawbacks and the importance of proper collection.

Biomonitoring investigations will undoubtedly be part of the new frontier. Biomonitoring is the direct measurement of people's exposure to environmental contaminants by measuring substances or their metabolites in blood, urine, or other specimens. With the early 21st-century influx of emergency preparedness funding through the CDC, many PHLs now have the technical expertise and instrumentation to support biomonitoring. To design biomonitoring studies, laboratories need to work in close partnership with environmental and chronic disease epidemiologists, as well as others in the environmental health community.[15]

Technological Advancements

For PHLs to provide optimum value to infectious disease surveillance and investigation, they will need to operate in as close to real time as possible. In surveillance, delay exposes more people to a possible pathogen, decreasing the efficacy of prevention and control measures.[2]

Technology will continue to play a big role in speeding up the flow of information. To this end, the CDC and partner organizations are continuing to build the PHIN. The purpose of the PHIN is to enable the secure transmission of population-based healthcare data across a patchwork of public health-related data streams for the purposes of surveillance and detection of emerging national health threats. These streams—which include FoodNet, PulseNet, and eLEXNET—currently function in isolation. Awareness of the vital importance of healthcare-related information flow has been increasing in all levels of government. The DHHS established the National Health Information Network (NHIN) in 2004 to improve the quality and efficiency of transmission of all healthcare data—both personal and population-based. It is a goal of the NHIN to promote the adoption of electronic medical record technology across the nation so ultimately every American can have unfettered access to their healthcare information. The PHIN works in collaboration with the NHIN to ensure that responders to the nation's population-based health care have access to and are providing appropriate data to protect the public's health.

A Workforce Crisis

In the early part of the 21st century, as infectious diseases multiply, environmental contaminants turn up in human tissues, and biological terrorism looms as a credible threat, it is scary to contemplate a scarce supply of scientists skilled in laboratory testing. Yet, the United States is now in the midst of a severe shortage of PHL scientists that threatens the nation's emergency response capability.[18] This highlights the concurrent needs for training and credentialing. For instance, the analysts who conduct bioterrorism testing must be trained in the standard methods and must be able to demonstrate competency before they are called on to run tests for actual events. The use of laws and regulations to assure the competency of laboratory staff in clinical and PHLs differs widely among states. Given the importance of public health testing, it is imperative that the analysts who perform these services receive standardized training with an established means to assess their understanding and abilities in method performance.

A 2007 survey showed that the United States had 50,000 fewer public health workers than it had in 1987.[19] Senior qualified PHL staff were retiring in large numbers, with no one to replace them. At this writing, organizations such as APHL are taking steps, from promoting PHL careers to advocating for national policy changes, in order to address this problem. Yet the confluence of increasingly demanding technical training and increasingly urgent emergency needs against decreasing numbers of scientists entering the workforce and decreasing amounts of money to pay them point to a "perfect storm" condition in the PHL workforce. Everyone in the larger health sector, from emergency response to private practice, should be aware of this trend in PHLs and how it could affect their fields in the next several decades.

Politics, Policy, and Funding

PHL funding, and even to some extent practice, has always been affected by politics and policy. This is as it should be, because the laboratories serve the needs of the country and community. However, it also sets up a situation in which funding and resources are released in response to a crisis—sometimes only after significant efforts in political advocacy—and then laboratories are forgotten in the interim. This makes sustaining an adequate workforce and essential equipment difficult and compromises public safety. No one can predict when the next crisis will hit, and PHLs are at constant risk of being caught unprepared when they are underfunded.

The response to the novel H1N1 virus in 2009 is a good case in point. As the crisis emerged, PHLs were themselves in crisis. A global economic downturn caused federal and state funding shortages; laboratory workers had been laid off or placed on leave. Although the United States developed an economic stimulus package, PHLs did not benefit from any increased funding. After weeks of operating under surge conditions with staff shortages, laboratories received help in the form of emergency funding. However, in some cases it was "too little, too late" for bringing back the resources that had been lost in the downturn.

This typical "funding roller coaster" demands that today's PHL workers become adept at politics and advocacy. This may necessitate additional skills; once again, collaboration and communication are keys to success. PHL leaders are better learning how to state their case and make their needs known and how to communicate the value of laboratories in order to strengthen the chances for obtaining consistent, reliable funding. A perennial issue in the United States is the reform of the healthcare system. PHLs are positioned to play an important role in increasing efficiencies and quality of care; however, they must be proactive in both looking for opportunities to do so and to communicate their capabilities.

Cultivating a "Culture of Quality"

Given the scope of people and decisions that depend on their data, quality is a top priority for PHLs. Their operations are regulated by several national agencies, including the Centers for Medicare and Medicaid Services (for diagnostic testing performed on specimens of human origin), the EPA (through the Safe Drinking Water Act), and the FDA (for testing milk that will be transported across state lines). The standards are multifaceted and rigorous. For instance, to ensure operations are up to standard, an incoming PHL director will often review the following.[10]

- The current CLIA license
- The state license (if applicable)
- Select agent registration
- Any EPA certificates and related correspondence
- Other relevant laws and regulations (e.g., Clean Water Act, Interstate Milk Shippers Act)
- The activities the PHL can legally engage in

In keeping with the spirit of partnerships and collaboration in today's public health world, PHLs often work with regulatory agencies to support their efforts. This can involve developing a jurisdictional laboratory response network, facilitating coordination among the many private and public sector players, and conducting training and outreach programs. Does the state have a laboratory improvement and regulation initiative? If not—or if the current one needs to be improved—PHLs can provide a vital role.

But in addition to quality assurance—meeting important regulatory compliance and internal standards—PHLs are also striving toward quality improvement. This is part of an evolving role that will position them for greater flexibility and stronger performance. For instance, APHL and the CDC partnered to create the Laboratory Systems Improvement Program, which has a mission to establish a system that measures the performance of state public health systems and supports their continuous improvement. It provides an assessment tool, technical assistance, and a wealth of accessible resources in quality improvement.[20]

Too often over the years, the PHL has been seen as a "black box"—separate unto itself, sometimes slow-moving, and reluctant to reach out. As a consequence, the PHL's lifesaving mission and its importance to national and global health have been overlooked. Significant leaps forward in PHL functioning have always come in response to crises, and the future certainly will not lack for comparable opportunities. Yet as this overview of the history and challenges in PHLs shows, it is the decisions and changes made between the crises that set the foundation for these advances.

Discussion Questions

1. Should funding be allocated for creating more and better equipped PHLs at the local level? Why or why not?
2. PHLs are expensive to create, maintain, and staff. What major activities do they perform that are worth this expense?
3. PHLs at the state level are critical components of the national response to terrorism and other emergencies

(e.g., influenza). Should PHLs be funded by the federal government as part of national security? Why or why not?

4. PHL work is increasingly technical, yet there are serious shortages in the available workforce. What might be done, and what types of training required, to alleviate the shortfall in qualified laboratory workers?
5. What types of analyses or research should PHLs become involved with in the coming years?
6. Given that PHLs are expensive to maintain and often provide services at reduced or no charge, why should a PHL offer a test which is also available commercially (e.g., for sexually transmitted diseases)?
7. Many countries are just now developing their first, comprehensive PHL at the state/regional level. Given often limited resources for start up and maintenance, what types of analyses should they first focus on, and why?
8. Describe at least two manners in which PHLs differ from private laboratories.
9. Of the 11 core functions of PHLs, of which two are the general public least likely to be aware? Why might that be, and how can it be changed?
10. Describe how state PHLs and the CDC complement each other in their response to infectious disease of bioterrorism events.
11. Funding for PHLs is frequently inconsistent and subject to "roller coaster" effects. Federal funds may provide for analytical instruments and personnel for several years, but are likely to taper off. What should state PHLs consider before accepting the funding for instruments and personnel given that it may be short lived?

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