Public Health Laboratories

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Learning Objectives
1. Understand the role Public Health Laboratories have in the public health and clinical healthcare landscape.
2. Explain the organizational structures in which Public Health Laboratories operate.
3. Identify the laboratory core functions that are supported by a Laboratory Information Management System (LIMS).

Introduction
Public Health Laboratories sit at the intersection of clinical care and disease surveillance, providing routine and advanced diagnostic testing services to support patient care in conjunction with population-based surveillance activities.

Working at federal, state, and local levels, these institutions serve as the first responders of the laboratory world—detecting and monitoring health threats ranging from rabies and dengue fever to environmental contaminants, genetic disorders in newborns and agents of chemical nature and bioterrorism.

This chapter will outline the essential role and structure of public health laboratories and will describe the informatics components necessary to support diagnostic testing as well as routine and emergency public health response, all of which rely on accurate, timely data.

The Public Health Laboratory
In 1876, Dr. Robert Koch proved that *Bacillus anthracis* was the causative agent of anthrax [1], launching the field of medical microbiology and a new era for public health science, including the modern Public Health Laboratory (PHL). The PHL described in this chapter has evolved greatly over the last century [2]. Yet, however much these institutions have changed due to political, technical, or financial reasons, they remain essential to protecting the health and security of the public. As the then CDC Deputy Director, Dr. Walter Dowdle, stated in his 1993 article entitled *The Future Of The Public Health Laboratory*, “Of all the functions of public health, the public health laboratory is vital for assessing, investigating, and analyzing the health needs, effects, and health in the community, the state, and the nation” [3], p. 650.
In 2014, the Association of Public Health Laboratories released an updated version of the white paper, The Core Functions of Public Health Laboratories, originally published in 2000 [4]. This document provides readers a thorough overview of the PHL ecosystem and the particular capabilities associated with each of these eleven functional roles listed in Table 15.1.

The Public Health Laboratory System

PHLs function within the greater public health enterprise, providing a public service to their jurisdiction while collaborating at the regional, national, and even international level to identify, monitor, assess, and respond to newly emerging and re-emerging diseases and threats. Each US state and territory and the District of Columbia has a central public health laboratory that provides diagnostic testing and highly specialized services for human, animal, environmental, agricultural samples and food products. Newborn screening programs offer an example of specialized testing done primarily at PHLs. Ninety-seven percent of the 4 million babies born each year have their first laboratory test analyzed for genetic and metabolic disorders, providing critical information necessary for early intervention. Many health departments also manage laboratory services through a network of local public health laboratories located in metropolitan areas, counties, or regionally within a state. Local PHLs are an intrinsic part of the safety network in underserved populations—they are highly integrated with Public Health Department (PHD) clinics, providing routine diagnostic testing as well as screening tests for disease prevention. Lead abatement programs and monitoring of sexually transmitted diseases are other examples of the community support functions of a local PHL. Their work informs public health officials in state government, allowing for targeted disease surveillance and quicker response to disease outbreak, as well as population based data that may lead to new guidelines or policies to protect residents.

PHLs at all levels work independently for their constituents and in concert with each other,
Forming local and national alliances known as public health laboratory networks. One example of a public health laboratory network is the Laboratory Response Network (LRN), which is on call 24/7 to respond to biological, chemical, and other public health emergencies across a wide range of public and private partners [5]. Figure 15.1 exemplifies a generic laboratory-based surveillance network, illustrating a tiered, coordinated network that strengthens public health practice and response and supports patient diagnoses and treatment options [6].

During surveillance activities, the state PHL takes a leadership role through active collaboration with federal agencies, state epidemiologists, first responders, and environmental professionals. Key PHL federal partners include the Centers for Disease Control and Prevention (CDC), the Health Resources and Services Administration (HRSA) the Environmental Protection Agency (EPA), the Food and Drug Administration (FDA), the Federal Bureau of Investigation (FBI), and the Department of Homeland Security (DHS).

To ensure the public health laboratory system can function when it is most needed, PHLs have surge capacity and/or shared services agreements with partner laboratories. Surge capacity agreements create a safety net for the laboratories during outbreaks and emergency response periods by allowing a PHL to transfer excess test volume to a partner PHL. Shared services agreements provide PHLs an opportunity to reduce or share cost and increase efficiencies by referring low volume, high cost/high complexity testing to a partner lab that has the capacity and capability to perform that testing. Since PHLs provide many unique or critical services to the public, these laboratories have also established continuity of care agreements to ensure that, in the event one PHL is affected by a natural or man-made disaster, another lab or group of laboratories can assume the responsibilities and duties of the affected PHL. Figure 15.2 illustrates these and other use cases in the Public Health Laboratory. In 2005, Hurricane Katrina put these agreements to the test—particularly within the newborn screening program. These specimens and test requests were successfully transferred to partner PHLs, assuring that timely screening was performed to detect hereditary disorders that depend on early intervention to prevent long-term disability and death.
Differences Between PHLs and Other Laboratory Types

At the typical clinical lab, human biological samples are sent in for routine testing, such as blood chemistries, presence of bacteria, or screening for cancers. At a PHL, in addition to human samples, they also perform testing on non-human samples and even inanimate objects. Animal samples are received at the PHL for a number of reasons including rabies testing, West Nile virus surveillance, and safety of food animals through feed testing. Water samples are also tested at the PHL for a variety of reasons under EPA Safe Drinking Water Act Standards, but most importantly, the PHL monitors both well water and public water systems. Food, be it peanut butter or spinach, is tested on a regular basis to detect pathogenic bacteria. Soil, building materials, and even cups and plates are tested to protect citizens from high levels of toxic chemicals such as lead and, in some cases, radionuclides. PHLs work closely with first responders and the federal government to test for agents of bioterrorism; these samples can range from “white powder” to human-based samples such as blood, urine, sputum, or tissues.

PHLs also perform regularly scheduled tests on samples collected from designated sentinel (guard) sites. For example, some samples may come from animals that are more susceptible to a disease, are living in close proximity to people, and are being tested regularly to gauge when a new disease can be expected. The monthly testing of samples from a chicken population for West Nile Virus is one example. Chickens are more susceptible to West Nile Virus infec-
tions than humans are; when West Nile Virus is detected in the chicken population, it is a good indicator that human cases can be expected soon in the same area.

While commercial laboratories are required to report the detection of certain infectious diseases to their respective public health jurisdictions, based on state or local notifiable disease laws, it is the PHLs that are at the frontline when an infectious disease outbreak occurs. PHLs provide support to the public health department in identifying the cause of the latest foodborne outbreak that may have been first detected at a clinical laboratory. PHLs also spend a significant amount of time developing new assays and test methods for emerging infectious diseases, such as the detection of the newest influenza virus strain that may cause the next epidemic or even a pandemic. Because of their efficacy, some of these newly developed tests are adopted by commercial laboratories and offered to their customers at a later point in time. Finally, PHLs play an important role in advancing quality laboratory practice (Core Function 9) by overseeing state-based laboratory improvement programs and ensuring compliance with local, state, and federal regulations and laws [4].

**Informatics in the Public Health Lab**

Since the advent of computers, the laboratory, with its capacity to produce and manage important data, has been at the forefront of health informatics. What initially began as a database for local results, over time developed into a Laboratory Information Management System (LIMS) that provides capacity for improved workflow management, inventory tracking, and most importantly, patient management. Testing is often performed on stand-alone instruments. These results need to be incorporated into the LIMS, in order to be included in the final result sent to the submitter. In the beginning, the LIMS captured those results; yet these had to be printed to be sent back to the submitter. With the improvement of PHL informatics knowledge and instrumentation capabilities, more instruments are being interfaced using industry developed standards. This greatly improves the quality of data and workflow efficiency. Informatics practice has transformed several laboratory workflows as organizations migrate from paper-based to electronic system-based tracking. Being able to draw data from a database in an electronic format facilitates secondary use of this information for forecasting or event detection. This information can then be shared with partners in the Public Health Laboratory system (e.g., the public health department, a regional taskforce, preparedness coordinators, policy makers, and federal agencies). The capability of the laboratory and its public health partners to share data in the same format, through adoption of an electronic data interchange (EDI), can greatly reduce communication delays between partners, resulting in faster, better outcomes for both patient and population-based responses compared to paper or even facsimiles. In 2019, 90% of reportable laboratory results in the US are shared with state public health departments electronically, due to the adoption of national standards like HL7® v2.5.1, LOINC® and SNOMED CT® being incentivized by meaningful use regulation [7, 8]. Table 15.2 illustrates examples of laboratory data at the center of public health events.

The LIMS Functional Requirement Document [9], developed by APHL and the Public Health Informatics Institute (PHII), lists 16 core business processes for every Laboratory Information system:

1. Laboratory test processing—this business process includes four segments:
   a. Test request and sample receiving
   b. Test preparation
   c. Testing, result recording and result verification, including interfacing with large volume analyzers using data exchange standards to allow for transfer of result data without manual entry.
   d. Test result report preparation and exchange
2. Test scheduling—includes assignment of resources and prioritizing of the order of testing
Sample collection logistics and workload projections—this includes distribution of sample collection kits and order forms to partners.

4. Chain of custody tracking for samples

5. Manufacturing of media, reagents, and other test related supplies

6. Inventory and forms management

7. General Laboratory Reporting—is part of the general systems requirements—all electronic data management systems need to be able to create reports

8. Statistical analysis and surveillance—provides value added to the test results to both the submitters of the sample as well as public health partners

9. Billing for services

10. Contract and Grant management—unlike clinical laboratories, PHLs often are funded through grants to provide services free of charge to the submitters of the sample, so tracking funding amounts and requirements is important

11. Training, education and resource management—to comply with regulations and to document capacity of laboratory personnel and equipment

12. Lab certifications and licensing—PHLs, mostly at the state level, are responsible to ensure compliance in laboratories operating in their jurisdiction, which includes inspections of those laboratories

13. Customer feedback tracking

14. Quality Control (QC) and Quality Assurance (QA) management—both involve audit functionality about the tests performed—QC tracks the parameters for each method and instrument at the test level and allows for over time analysis of the control parameters, while QA defines specific measures across all the tests performed to ensure accurate testing

15. Laboratory safety and accident investigation

16. Laboratory mutual assistance and disaster recovery to support surge capacity and continuity of care operations

This functional requirements document describes interdependencies between the lab and outside partners and using the informatics principle of separating each of the core business processes into their individual steps with related functional requirements for the system, based on detailed laboratory workflow analysis [9]. The publication of this requirements document has created a functional standard vendors can utilize to build more useful systems that are conformant with these requirements. Although much variability between information systems still exists, this document still stands as a solid basis to identify and pinpoint these variations.

The PHLs use several kinds of codes in their daily operations: codes for the tests they offer and perform, codes for pre-defined results, and codes

| Disease outbreak                           | Year | Natural disaster/ bioterrorism |
|-------------------------------------------|------|--------------------------------|
| Severe acute respiratory syndrome (SARS)  | 2001 | Anthrax letters                |
| West Nile virus                           |      |                                |
| Several foodborne outbreaks               | 2002 |                                |
| Worst Hepatitis A outbreak in US          | 2003 |                                |
| E. coli outbreak in spinach               | 2006 |                                |
| Salmonella in salsa                       | 2007 |                                |
| Pandemic influenza (H1N1)                 | 2009 |                                |
| Salmonella in eggs                        | 2010 | Tornado in Joplin, MO          |
| Multiple foodborne outbreaks, including the second deadliest on record due to Listeriosis in cantaloupe | 2011 |                                |
| Salmonella outbreak in Salmon             | 2012 | Hurricane Sandy                |
| Ebola virus pandemic                      | 2015 |                                |
| Zika virus epidemic                       | 2016 | Hurricane Matthew              |
| –                                         | 2017 | Hurricane Maria                |
| Ebola outbreak in Africa                  | 2018 | Hurricane Florence             |
for patient demographics. In order to make data comparable across locations, the PHLs map their local codes to national data standards. These data standards include the Logical Identifiers Names and Codes (LOINC®) [10] for the tests they perform, Systematized Nomenclature of Medicine (SNOMED®) [11] to identify organisms and ordinal results, and codes from Health Level Seven (HL7®) [12] for patient demographics like gender, race, and ethnicity. To exchange standardized data between PHLs and their partners, the order and format of the data to be exchanged needs to be defined. For individual point-to-point exchanges, simpler formats can be agreed upon; for example, comma-separated files (CSV) or MS Excel spreadsheets can be exchanged. However, in order to accommodate larger scale data exchange with multiple partners across multiple information systems, standards such as HL7® messages (in version 2.x) or the XML-based clinical document architecture (CDA) formats should always be considered as part of the normal business process. In addition to utilizing these standards, transport mechanisms need to be defined and agreed upon by electronic data interchange (EDI) partners [13].

All these functions are covered by informatics principles—from database design to queries, as well as application of format and content standards. As discussed earlier, in order to support these critical public health functions, PHLs create support networks among themselves. These PHL networks form alliances between laboratories that perform the same kinds of tests and exchange results within the same networks, usually under the guidance of a federal program. Utilization of the requirements document among PHLs has advanced the application of informatics in the PHL realm, and has made several of these networks quite successful. Examples of functional PHL networks in the US are summarized in Table 15.3.

Unfortunately, at this stage each of these networks is using a different set of data exchange

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### Table 15.3 Examples of laboratory networks in the United States [8]

| Network | Description |
|---------|-------------|
| LRN [5] | The CDC manages the Laboratory Response Network (LRN). This includes the CDC LRN-Biological (LRN-B) and CDC LRN-Chemical (LRN-C). The mission of the LRN is “to maintain an integrated national and international network of laboratories that are fully equipped to respond quickly to acts of chemical and biological terrorism, emerging infectious diseases, and other public health threats and emergencies” [5]. Due to the sensitive nature of CDC’s bioterrorism preparedness activities, details of LRN-B operations are protected against general public access and distribution. These details, designated as “Sensitive But Unclassified,” are maintained at CDC, and require coordination with the LRN LIMS Integration team to obtain. The LRN provides specifications about the message format (HL7® v2.x) and data content, including standardized vocabulary (for example LOINC® and SNOMED CT®) |
| ELRN [14] | The Environmental Response Laboratory Network (ERLN) is managed by EPA. The ERLN consists of federal, state, and commercial laboratories that focus on responding quickly to an environmental chemical, biological, or radiological terrorist attack, as well as natural disasters affecting human health and the environment. The ERLN provides an Electronic Data Deliverable (EDD), which can be either a spreadsheet or the recommended XML format and a Data Exchange Template (DET) with data element definitions and groupings. The ERLN also provides a web-based electronic data review tool that automates the assessment of EDDs by providing web access for upload by the laboratory and review by project personnel |
| FERN [15] | The Food Emergency Response Network (FERN) is managed by the US Department of Agriculture (USDA) Food Safety and Inspection Service and the Food and Drug Administration (FDA). The primary objectives of FERN are to help prevent attacks on the food supply through utilization of targeted food surveillance; prepare for emergencies by strengthening laboratory capabilities to respond to threats, attacks, and emergencies in the food supply; and assist in recovery from such an incident. FERN uses the Electronic Laboratory Exchange Network (eLEXNET) that allows multiple government agencies engaged in food safety activities to compare, communicate, and coordinate findings of laboratory analyses |

(continued)
methods. ARLN, LRN and NAHLN use HL7® v2.x messages as a data exchange standard, while FERN and ERLN use XML-based Electronic Data Deliverables (EDDs). This forces the PHL to support a variety of formats and vocabularies in order to properly report to the respective partners during an investigation. A significant obstacle to the development of consistent data exchange deliverables is the sheer number of networks and reporting requirements. Table 15.4 shows what a laboratory must do, after the discovery of a food-borne illness outbreak due to consumption of tainted hamburgers.

### Table 15.3

| Network | Description |
|---------|-------------|
| NAHLN [16] | The National Animal Health Laboratory Network’s (NAHLN) purpose is to enhance the nation’s early detection of, response to, and recovery from animal health emergencies. Such emergencies might include bioterrorist incidents, newly emerging diseases, and foreign animal disease agents that threaten the nation’s food supply and public health |
| GSN [17] | The WHO Global Influenza Surveillance Network (GSN) receives result reports and samples of isolates from participating state and municipal PHLs to monitor influenza disease burden, detect potential novel pandemic strains, and obtain suitable virus isolates for vaccine development |
| ARLN [18] | The Antibiotic Resistance Lab Network (ARLN) includes labs in 50 states, four cities, and Puerto Rico, including seven regional labs and the National Tuberculosis Molecular Surveillance Center (National TB Center). The ARLN supports nationwide lab capacity to rapidly detect antibiotic resistance and inform local responses to prevent spread and protect people |

### Table 15.4

| Reason for data exchange | Receiver of the data from PHL | Syntax standard in use |
|--------------------------|-------------------------------|------------------------|
| Contamination related to food (lettuce, ketchup, mayo, bun), but NOT the meat | Food and Drug Administration (FDA) | HL7® v3 messages or XML based EDD |
| Contamination related to meat | US Department of Agriculture (USDA) | XML based EDD |
| A person became ill | Centers for Disease Control and Prevention (CDC) | HL7® v2.x message |
| | Local and/or state public health department based on patient’s residence | HL7® v2.x message |
| | Local and/or state public health department based on lab’s location, if different from patient’s residence | HL7® v2.x message |
| Offending contaminant is biologic, e.g., a bacteria, virus, or biological toxin | Centers for Disease Control and Prevention (CDC)—biological network | HL7® v2.x message |
| Offending contaminant is chemical, e.g., a fertilizer or other chemical toxin | Centers for Disease Control and Prevention (CDC)—chemical network | HL7® v2.x message |
| Contamination is related to environmental reasons, e.g., flooding | Environmental Protection Agency (EPA)—several networks for water, air, waste or response mitigation | XML based EDD |
| Follow-up testing of food animals | National Animal Health Laboratory Network (NAHLN) | HL7® v2.x message |

### Issues with Interoperability

The following barriers to effective electronic laboratory information exchange were identified in the APHL-PHDSC White Paper, “Assure Health IT Standards for Public Health, Part 1: Health IT Standards in Public Health Laboratory Domain” [13]:

- Barrier I—The **incomplete and inconsistent adoption of existing standards** by the wide array of laboratories responsible for reporting laboratory results as well as by the Electronic Health...
Record systems (EHR-S) and public health information systems to which they report.

- **Barrier II**—The lack of adoption of EHR-S with functionality supporting electronic test ordering and result receiving) preventing electronic communication between providers and LIMS [19].

- **Barrier III**—The use of proprietary, non-standardized information systems in public health preventing electronic communication between LIMS and public health programs (i.e., receivers of test results on public health threat conditions).

- **Barrier IV**—The absence of a sustainable approach and funding to support the development of laboratory standards and their testing, and of certification and adoption of standards-based IT products in clinical, laboratory and public health settings.

- **Barrier V**—The need for informatics-savvy personnel in PHLs to operate in a new HIT and information communication environment.

## Public Health Laboratories and Informatics Standards

Public health science, laboratory methods, data needs, and the technology necessary to create, capture, store, and exchange data are continuously evolving. As such, PHLs and their partners must work independently and in concert to overcome the barriers identified in the preceding section, ensuring that existing standards are adopted, and that gaps in standards development and harmonization work are identified and remedied.

To address this important need, PHLs actively participate in national standards harmonization activities for laboratory-related use cases, ensuring that unique, yet important public health use cases are addressed in a standardized manner. PHLs were instrumental in creating an implementation guide for newborn screening, working alongside Standards Development Organizations (SDOs) like Health Level 7 and the Regenstrief Institute, who maintains the standard for newborn screening laboratory tests LOINC®, information exchange standards for electronic laboratory test orders and results (ETOR), and functional standards for Electronic Health Record System (EHR-S) interactions with laboratories.

Due to the cyclic nature and often-limited informatics funding available to PHLs, coupled with an ongoing challenge to find and retain informatics trained specialists, PHLs actively engage with and collaborate through the Association of Public Health Laboratories (APHL). APHL is a national non-profit organization, whose mission centers on representing PHLs and their directors in all 50 states, territories, and local jurisdictions. APHL’s informatics program serves as an incubator for ideas, a peer to peer network, informatics policy support, and hands-on standards development and technical infrastructure solutions to support PHL’s and their partners.

On a national scale, when the Office of the National Coordinator for Health Information Technology (ONC) certification process for commercial Electronic Health Record products was announced, PHL expertise was utilized to provide real-world testing scenarios to ensure that specific result formats were properly represented in this information exchange paradigm. By ensuring a basis in reality, these types of efforts will ensure greater patient safety, and improve public health’s response to emerging diseases, terrorism, and natural disasters.

## Summary

In summary, PHLs are a critical public health resource and service. They detect, identify, and monitor infectious disease outbreaks and chemical or biological contamination in people, animals, food, and the environment. They provide testing that other labs cannot provide and screen for diseases that have not even shown symptoms yet (e.g., newborn screening). PHL testing supports food and environmental safety law enforcement, and PHL data contributes vital information to support local, state, and federal health policies.

Information systems can assist PHLs to forecast testing demand and human resource allocation during an outbreak or emergency response. Data derived from these systems can aid with both state and federal efforts to forecast disease and help with outbreak management as well as health policy development. To ensure the long-term operational capacity of PHLs to provide
these services and remain relevant in patient and population care, informatics must be considered a critical, core business function.

When communicating electronically between inter-organizational systems about test orders, specimen receipt, and sample processing statuses and results, the use and continual development of national data exchange standards is essential. The work in this field has barely begun, yet the continual evolution of standards will drive greater collaboration and cooperation between all levels of PHLs (local, state, and federal), as well as their commercial partners.

### Review Questions

1. List at least 6 of the 11 core functions of a Public Health Laboratory and discuss how informatics supports disease prevention, control, and surveillance in particular.
2. List the different partners of a PHL and their importance for public health.
3. Discuss the importance and role of a public health laboratory as a data producer. Who needs these data and why? How does their role differ from that of a commercial laboratory?
4. What are some of the informatics challenges facing public health laboratories?

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