The State Public Health Laboratory System

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SYNOPSIS

This article describes the development since 2000 of the State Public Health Laboratory System in the United States. These state systems collectively are related to several other recent public health laboratory (PHL) initiatives. The first is the Core Functions and Capabilities of State Public Health Laboratories, a white paper that defined the basic responsibilities of the state PHL. Another is the Centers for Disease Control and Prevention National Laboratory System (NLS) initiative, the goal of which is to promote public-private collaboration to assure quality laboratory services and public health surveillance.

To enhance the realization of the NLS, the Association of Public Health Laboratories (APHL) launched in 2004 a State Public Health Laboratory System Improvement Program. In the same year, APHL developed a Comprehensive Laboratory Services Survey, a tool to measure improvement through the decade to assure that essential PHL services are provided.

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Several events in the early years of the new millennium provided recognition of the necessity for improved laboratory surveillance and emergency response throughout the United States. Improved response would require the creation of state networks of public and private laboratories and health officials that depend on laboratory data for disease control and response.

EVOLUTION OF THE STATE PUBLIC HEALTH LABORATORY SYSTEM

Core Functions and Capabilities of State Public Health Laboratories

In 2000, the Association of Public Health Laboratories (APHL) published a white paper entitled "Core Functions and Capabilities of State Public Health Laboratories" (hereafter, Core Functions), which enumerated the 11 Core Functions that state public health laboratories (PHLs) provide or assure and described their expected capabilities in safeguarding the public's health.[1] One purpose of this report was to identify the state PHL's role in assuring that the 10 Essential Public Health Services[2] (hereafter, Essential Services) are adequately supported by laboratory-based scientific data. In 2002, the Core Functions white paper was published by the Centers for Disease Control and Prevention (CDC) Division of Laboratory Systems in *Morbidity and Mortality Recommendations and Reports*.[3] The article was published after the anthrax attack of October 2001 and, therefore, emphasized that any public health response required a high-quality, coordinated laboratory testing system throughout the United States. Because state PHLs vary so widely in the scope of their activities, any response must also ensure the quality and ready availability of critical laboratory information generated in the private sector.

National Laboratory System

Although the need to improve coordination, communication, and collaboration among state PHLs and clinical laboratories existed before the anthrax attacks, they were the wake-up call that provided the impetus to accelerate efforts, provide funding that could be used to enhance public-private relationships, and help clinical laboratorians recognize their role in public health testing. In 2000, the CDC Division of Laboratory Systems introduced the concept of a National Laboratory System (NLS) to crystallize the idea of a functional public health network of public and private laboratories.[4]

The NLS concept focuses on all public health testing, not just bio- or chemical terrorism, and is intended to assure timely and accurate public health testing and reporting. The NLS concept recognizes that a robust State Public Health Laboratory System (SPH Laboratory System) is an essential component. In addition to important national activities that include aggregating and interpreting surveillance data, establishing and promoting national guidelines for laboratory testing, and coordinating national testing programs, CDC's role in the NLS also includes helping states enhance and maintain their SPH Laboratory System.

Laboratory System Improvement Program

A collaborative effort between CDC and APHL was begun in 2004 to develop an SPH Laboratory System Performance Standards Program. This program was inspired by the National Public Health Performance Standards Program (NPHPSP)[5] and modeled after the NPHPSP and the Capacity Assessment for State Title V (CAST-5)[6] planning tool of the Association of Maternal and Child Health Programs. Major efforts by APHL, CDC, and representatives from 22 states produced an assessment tool and process that evaluates the effectiveness of the SPH Laboratory System in satisfying the 10 Essential Services[2] and the Core Functions.[1,3] In April 2008, the program name was changed to the Laboratory System Improvement Program (L-SIP) to more accurately reflect the program's long-term goals. L-SIP uses a performance measurement tool that is aimed at the optimal level of performance.[7,8]

The Comprehensive Laboratory Services Survey

Healthy People 2010[9] Objective 23-13 states: "Increase the proportion of tribal and state health agencies that provide or assure comprehensive laboratory services to support essential public health services." A key phrase in this objective is "provide or assure." This language gives recognition to the fact that the PHL may not itself provide the testing or other function, but assures that the service is provided by a partner such as a state agricultural or environmental laboratory or by a private clinical laboratory. To measure this objective, an APHL committee developed the Comprehensive Laboratory Services Survey to assess state PHL performance. The first survey was conducted in 2004 with 47 states and one territory participating.[10] By conducting the survey biannually through 2010, improvements in state PHL performance can be measured.[11]

THE SPH LABORATORY SYSTEM

Throughout the current decade, individual states have been working to develop laboratory networks. The ultimate goal for such efforts is to create a

comprehensive system that can respond to all public health needs and threats. In 2007, APHL defined an SPH Laboratory System as a network consisting of all the participants in PHL testing, including those who initiate testing and those who ultimately use the test results.[12] This definition of the SPH Laboratory System is consistent with the goals of the NLS.[4] A successful NLS supports voluntary, interdependent partnerships of public health, clinical, environmental, agricultural, and veterinary laboratories through public-private collaboration for assurance of quality laboratory services and public health surveillance.

The SPH Laboratory System should contribute to the assurance that:

1. Public health threats are detected and intervention is timely,
2. Stakeholders are appropriately informed of potential threats,
3. Reportable conditions are monitored in a comprehensive statewide system,
4. Specimens and isolates for public health testing are sufficient to provide comprehensive public health surveillance and response, and
5. PHL data are transmitted to designated local, state, and federal agencies responsible for disease prevention, surveillance, and control.

The state PHL has a leadership role in developing and promoting the SPH Laboratory System through active collaboration with stakeholders, including epidemiologists, public health program managers, first responders, environmental and agricultural professionals, private clinical and environmental laboratories, and local PHLs. To assure that the SPH Laboratory System is effective, the state PHL should:

1. Maintain a database that includes all stakeholders who rely on accurate PHL data,
2. Employ a full-time Laboratory Program Advisor,
3. Create a standing PHL Advisory Committee, and
4. Provide a system to maintain regular communication channels for system partners.

The leadership role and activities of the state PHL in promoting the SPH Laboratory System are based on assuring that the Core Functions are carried out to meet the needs of public health in the state. The role of the state PHL in promoting the SPH Laboratory System by providing or assuring each of the 11 Core Functions must include those activities that are conducted by the state PHL, as well as those performed by other partners. The local PHLs, including city, county, and regional PHLs, often maintain valuable networks with their constituents.

The 11 Core Functions are (*1*) disease prevention, control, and surveillance; (*2*) integrated data management; (*3*) reference and specialized testing; (*4*) environmental health and protection; (*5*) food safety; (*6*) laboratory improvement and regulation; (*7*) policy development; (*8*) emergency preparedness and response; (*9*) public health-related research; (*10*) training and education; and (*11*) partnerships and communication.

DISEASE PREVENTION, CONTROL, AND SURVEILLANCE

The state PHL and its partners in the SPH Laboratory System provide laboratory monitoring of the health status of communities and, thereby, contribute to the identification of community health problems. Partners in the system participate in processes to support health surveillance programs by generating accurate and timely laboratory data in many areas of public health (e.g., communicable, genetic/metabolic, and chronic diseases, as well as environmental exposures). Laboratory data are shared with all appropriate federal, state, and local agencies to enhance rapid disease detection and facilitate the implementation of disease control measures.

Communicable diseases

The state PHL fulfills several roles:

- It serves as a center of expertise for the detection and identification of infectious disease agents. In this role, the state PHL provides reference testing for clinical laboratories and other health-care facilities in the state, and surveillance testing to support the work of the state epidemiologists.
- It provides a variety of molecular testing methods to detect, identify, and subtype organisms associated with disease for enhanced surveillance.
- It provides testing for high-risk and emerging infectious diseases, such as tuberculosis (TB), rabies, and botulism, for which other diagnostic laboratories generally do not test.
- It serves as a conduit for state-national transmission of public health information by participating in current CDC and Food and Drug Administration (FDA) surveillance programs, including:
  - The Laboratory Response Network (LRN)
  - Emerging Infections Program/Epidemiology & Laboratory Capacity Program

— Foodborne Diseases Active Surveillance Network (FoodNet)
— Influenza Surveillance Network (CDC/World Health Organization [WHO])
— Arbovirus Surveillance Network
— Food Emergency Response Network (FERN)

Chronic diseases and environmental health

Chronic diseases are among the most common and costly health problems, accounting for about 70% of U.S. deaths and total medical care expenditures, as well as affecting the quality of life of 90 million Americans.[13] In 2005, CDC initiated efforts to develop a national environmental public health tracking (EPHT) network.[14] PHLs contribute to the EPHT network by providing or assuring data for the assessment of exposure to air pollution at home and at work and to chemical exposures from contaminated food, water, and consumer products. The data are obtained from measuring levels of toxic chemicals in environmental and human samples. The EPHT network will address how surveillance data can be linked to chronic disease assessment, an issue that will require much research and the merging of environmental and public health information systems.

Genetic/metabolic

From the inception of newborn screening (NBS), APHL has taken a leadership role in assuring the availability and quality of testing, and integration of screening into maternal and child health programs. APHL has worked with many partners including the Newborn Screening Quality Assurance Program at CDC, the Genetics Service Branch, Maternal and Child Health Bureau of the Human Resources and Services Administration, and the American College of Medical Genetics. In the area of quality assurance/control, APHL has provided leadership and serves as a liaison between CDC and state NBS programs. Through the efforts of APHL and its partners, NBS programs are now provided or assured in every state by the state PHL.[15] Through the years, APHL has sponsored NBS and genetic testing symposiums, which have helped to improve and standardize the provision and quality of these testing programs.

INTEGRATED DATA MANAGEMENT

The ultimate goal of every SPH Laboratory System is standards-based interoperability—the ability for different types of systems, including computers, networks, operating systems, and applications, to work together effectively to exchange information in a useful and meaningful manner.[16] For the individual laboratory, this means the receipt, analysis, and rapid multidirectional dissemination of verified laboratory data to support public health programs at the local, state, federal, and international levels. As a vital component of the SPH Laboratory System, this network must also be compatible with other state and federal health communication systems and include the following:

- Data collection: The SPH Laboratory System should assure the ability to collect and maintain laboratory data using currently accepted formats for epidemiologic analysis and decision-making at the local, state, and federal levels.
- Data dissemination: The SPH Laboratory System should assure that timely laboratory data and associated information are provided to partners involved in rapid detection of, rapid response to, and management of infectious disease outbreaks and other public health emergencies.
- Data exchange: The SPH Laboratory System should assure a mechanism for exchanging test-order and linked-result information with private, local, and federal laboratory partners in support of electronic laboratory messaging.

Sufficient accurate data are essential for laboratory management to respond appropriately to public health emergencies. A mechanism should be available to provide, on a timely basis to the PHL management, relevant epidemiologic information, outbreak notification, unusual environmental findings, and emerging public health threats from local, national, and international agencies and organizations. Such notification would enable management to assure that potential staffing, capacity, capability, and mutual assistance needs are accurately determined and incorporated into surge planning.

A standards-based laboratory information management system and corresponding robust technical infrastructure will assure appropriate communication with state and federal partners to provide situational awareness in public health needs, such as disease surveillance, environmental threats, and food safety.

REFERENCE AND SPECIALIZED TESTING

In the U.S., a number of commercial, academic, and governmental laboratories serve as reference laboratories, providing specialized testing for the diagnosis of metabolic, genetic, and infectious diseases in addition to detecting environmental contaminants. Since 2001, however, the responsibility of the state PHL

and larger local PHLs as reference laboratories has increased greatly, with the PHL serving a pivotal role in the LRN.

In addition to providing high-quality reference testing, PHLs perform research and validation of new testing methods and training on specimen collection and transport, biosafety, test-result interpretation, and regulatory requirements for both private clinical and public health sector personnel. PHLs have the expertise and equipment to detect, identify, and characterize a multitude of infectious agents and chemical analytes. Examples of reference roles of PHLs in the SPH Laboratory System include:

- Emerging and reemerging infections: PHLs have a major role in preparing for and responding to emergent and reemergent infectious diseases. Recent disease threats include West Nile virus, dengue fever, and antibiotic-resistant infections such as multidrug-resistant TB and methicillin-resistant *Staphylococcus aureus*.
- Viral reference testing: PHLs provide additional virus reference testing to detect and characterize human immunodeficiency virus, noroviruses, enteroviruses, arboviruses, herpes viruses, and others. Many PHLs conduct serologic tests for vaccine-preventable diseases such as chicken pox/shingles, measles, and rubella, as well as for viruses such as hantavirus.
- Influenza surveillance: All state PHLs and key local PHLs perform virus isolation for influenza as members of the WHO and CDC Collaborating Laboratories Network and the National Respiratory and Enteric Virus Surveillance System.[17] Through the collection of specimens from clinical laboratories and sentinel physicians' offices during various stages of the influenza season, and by the provision of molecular subtyping, the PHLs generate valuable surveillance information, as demonstrated in the 2009 novel H1N1 global pandemic.
- Bacterial, parasitic, and fungal reference: PHLs serve as a valuable resource, especially to hospitals and clinics, for identifying and typing microbial pathogens. Isolates of shiga toxin-producing *Escherichia coli* O157:H7, *salmonella* and *shigella* species, *cryptosporidium, acanthamoeba*, and acquired immunodeficiency syndrome-related pathogens have been referred to PHLs for identification and/or confirmation.
- Molecular methods: State PHLs are increasingly incorporating molecular technology to provide rapid and accurate diagnosis of infectious diseases and to assist in epidemiologic investigation and response. Real-time polymerase chain reaction, pulsed-field gel electrophoresis (PFGE), and other nucleic acid amplification techniques permit rapid identification and characterization of organisms.
- Chemistry and toxicology testing: A majority of the reference services of PHLs in the sciences of chemistry and toxicology are in the areas of environmental health (Core Function #4) and food safety (Core Function #5). Many PHLs also provide alcohol and drug testing for law enforcement agencies.

ENVIRONMENTAL HEALTH AND PROTECTION

The level of involvement of state and local PHLs in environmental testing varies widely across the country. Development of coordinated environmental testing systems presents great challenges due to the number of partners involved. The majority of state PHLs conduct environmental testing, but some states assure that testing is provided elsewhere. APHL serves as a resource for all state environmental testing laboratories (ELs) and a conduit to the Environmental Protection Agency (EPA) and CDC's National Center for Environmental Health.

The SPH Laboratory System provides testing and surveillance in the following areas:

Drinking and recreational water

- Microbiological standards: State PHLs/ELs and local PHLs conduct much of the drinking and recreational water testing based on the Clean Water Act,[18] Safe Drinking Water Act (SDWA),[19] and the BEACH Act.[20] They also assist municipal water supply and wastewater treatment plant operators in responding to changes in regulatory requirements.[21]
- Chemical standards: Drinking water, as well as recreational and groundwater, can be contaminated with toxic substances such as heavy metals, pesticide residues, volatile organic compounds, and radionuclides. EPA regulations include a large number of chemicals for which standards have been developed.[22] State PHLs/ELs conduct much of this testing and, along with their agency partners, assist other laboratories in meeting federal and state requirements.
- Surveillance for waterborne diseases: State PHLs/ELs and their agency partners maintain records of waterborne disease and outbreaks associated with

recreational and drinking water in collaboration with CDC, EPA, and the Council of State and Territorial Epidemiologists Waterborne Disease Registry.[23]

Air monitoring
State PHLs/ELs began air quality testing in the 1970s with the advent of the Clean Air Act. In situ monitors located in urban and rural areas can reveal levels of pollutants, including ozone, carbon monoxide, sulfur dioxide, lead and other metals, and particulates.[24] State PHLs/ELs also test for substances in indoor air that may threaten human health. Such substances include asbestos, formaldehyde, solvents, diesel exhaust components, and heavy metals.

Biomonitoring
Biomonitoring is the direct measurement of environmental chemicals and their metabolites in human tissues and fluids, and has been called the "gold standard" for assessing human exposure to pollution. CDC's National Center for Environmental Health has initiated development of a biomonitoring program to monitor human exposures to pollutants and to associate the data with health outcomes.[25] State PHLs will become increasingly involved in this testing as biomonitoring programs evolve.

Environmental lead exposure
Lead exposures persist in the U.S. from remnants of lead paint, leaded gasoline, and other lead-using industries. In recent years, improvements in analytic techniques for determining blood lead levels, coupled with the extensive testing that occurs in the SPH Laboratory System, have been important in reducing exposures to lead.[26]

Occupational health
Many state PHLs/ELs provide or assure analyses for metals, solvents, pesticides, polychlorinated biphenyls, silica, toxic gases, molds, various carcinogens, and materials used or generated by industry. They work closely with industrial hygienists in states as well as the U.S. Department of Labor's Occupational Safety and Health Administration to protect the health of vulnerable employees.[27]

Solid and hazardous waste and wastewater management
Solid and hazardous waste includes wastes that have been spilled, leaked, or improperly discarded. Hazardous waste management programs may be delegated by the EPA to the states.[28] State PHLs/ELs also assist in detecting suspected environmental releases at industrial sites and waste management facilities.

Water pollution degrades surface waters and recreational waters. Testing of water quality and properties at point sources and at accidental spill sites by state PHLs/ELs, using approved standard methods, assists regulatory agencies in enforcing wastewater regulations.[29]

FOOD SAFETY

Since 1973, CDC has maintained a laboratory-dependent collaborative surveillance program for foodborne disease outbreaks.[30] CDC's FoodNet collects data from 10 U.S. states regarding disease caused by pathogens commonly transported through food.[31] Once an agent is identified, the underlying cause of contamination can often be eliminated. To protect the food supply and control outbreaks, many agencies and organizations at the federal, state, and local levels are involved.

Federal level
APHL participates in the overarching Council to Improve Foodborne Outbreak Response. The Council is a multidisciplinary working group of governmental, regulatory, and association stakeholders convened to increase collaboration across the country to reduce the burden of foodborne illness.[32] In addition, the Department of Homeland Security's National Center for Food Protection and Defense has developed FoodSHIELD, a Web-based platform designed to create a community among the various laboratories and regulatory agencies.[33]

State and local level
PHLs have a major role in investigating foodborne outbreaks, disease surveillance, and confirmatory testing.[34] Particularly at the local level, PHLs may respond to foodborne outbreaks within their communities in real time as part of a local public health team, which includes sanitarians and nurses. Epi-Ready Team Training is a nationwide collaborative between CDC and the National Environmental Health Association, supported by APHL,[35] to train local teams of laboratorians, epidemiologists, and sanitarians to improve foodborne outbreak response.

Food safety laboratory capacity
In 2004, APHL conducted a laboratory capacity assessment and identified a shortage of food safety scientists in PHLs, especially in food chemistry.[36] In 2005, APHL convened a stakeholders meeting of regulators, public health, and state and federal agency personnel to

address gaps and find solutions in the system related to (*1*) electronic and agency-to-agency communication, (*2*) standard operating procedures for sample processing, (*3*) training, and (*4*) political and legal issues.

Advanced diagnostic methods

In addition to conventional culture and isolation of microorganisms from various food source matrices, new molecular techniques and subtyping conducted by state PHLs and larger local PHLs permit investigational partners to respond more effectively to the numerous food-related incidents that occur every year.

Food networks and surveillance

A number of initiatives have been developed to improve responses to possible foodborne outbreaks:

- PulseNet and Foodborne Disease Surveillance: PulseNet USA is a network of PHLs that perform advanced testing to investigate foodborne disease outbreaks and food terrorism. PulseNet, created by CDC and APHL in 1996, links PHLs that perform a standardized deoxyribonucleic acid (DNA) fingerprint technique, PFGE, on organisms associated with foodborne disease to a nationally standardized computerized database.[37]
- FERN: This collaboration between the U.S. Department of Agriculture (USDA) and FDA attempts to integrate the nation's public health, environmental, agricultural, and veterinary laboratories for a response to threats to our food supply.[38]
- The Electronic Laboratory Exchange Network (eLEXNET): eLEXNET is a seamless, integrated, Web-based information network that allows health officials at multiple government agencies engaged in food safety activities to compare, share, and coordinate laboratory analysis findings. eLEXNET houses a database of more than 3,700 analytes and more than 800 detailed test methods for use by the current membership of 110 federal, state, and local laboratories in 50 states.[39]

LABORATORY IMPROVEMENT AND REGULATION

Demands for quality assurance directed toward the health laboratory have come from government as well as the public. National regulations were developed in response to requirements for safe food, milk, and water, and for pure air, safe shellfish, safety in the workplace, and proper handling of radioactive material. Regulation of the clinical laboratory was a later development. As a result of regulatory requirements and quality assurance activities, the reliability of laboratory testing has improved dramatically. State PHLs are instrumental in promoting laboratory improvement within their states.

Laboratory improvement

State PHLs have been involved in laboratory improvement for decades, assisting laboratories in meeting mandates. Small hospital, clinic, and doctors' office laboratories are especially targeted. With the recognition of emerging infections and the advent of bioterrorism, even greater improvement efforts have occurred. Some professional societies and state PHLs provide proficiency testing programs.[40] An NBS quality assurance program is operated by CDC, with APHL as a cosponsor.[41] To assess the success of the SPH Laboratory System in meeting the challenges of infectious diseases, acts of terrorism, and quality PHL performance, APHL launched L-SIP in 2007. L-SIP's goal is to determine how well the SPH Laboratory System supports the 10 Essential Services.[7,8]

Regulatory activity

Environmental laboratories. The EPA certifies state primacy laboratories under the SDWA.[19] The EPA also promulgates regulations and establishes methods and standards to assure drinking water safety[42] and regulates air monitoring under the Clean Air Act.[43] The EPA requires that data submitted for the SDWA be generated by the state primacy laboratory or by laboratories certified by the state's environmental laboratory certification program.[19]

The National Environmental Laboratory Accreditation Program is a voluntary accreditation that evolved for several years under the auspices of the National Environmental Laboratory Accreditation Conference and the Institute for National Environmental Laboratory Accreditation. In 2006, these two organizations formed The National Environmental Laboratory Accreditation Conference Institute to facilitate the process.[44] The National Environmental Laboratory Accreditation Program board conducts evaluations of state accrediting bodies.

Under the authority of the Residential Lead-Based Paint Hazard Reduction Act of 1992, implemented by the Department of Housing and Urban Development, the EPA established the National Lead Laboratory Accreditation Program to recognize laboratories that demonstrate the ability to accurately analyze paint, dust, or soil for lead.[45]

The EPA implements approval programs for

contaminants not covered under state certification programs. These include programs for *cryptosporidium* monitoring and analyses, such as the Laboratory Quality Assurance Evaluation Program for Analysis of *cryptosporidium* under the SDWA.[46]

The FDA and USDA regulate food products such as dairy products, shellfish, meat, and bottled water. State PHLs assist in implementing the laboratory components of these regulations.

Clinical laboratories. Regulatory and standards-setting activities for clinical laboratories were sporadic until the 1960s, when Medicare regulations and the Clinical Laboratory Improvement Act of 1967 (CLIA-67) extended federally promulgated standards to hospital and independent laboratories. The CLIA Amendments of 1988 (CLIA-88) extended the mandate to approximately 200,000 laboratories, including doctors' offices.[47]

Organizations such as the Board of Registry of the American Society for Clinical Pathology, the National Credentialing Agency, and the American Society for Microbiology have certification programs for personnel. Others, such as the American Association of Blood Banks and the College of American Pathologists, have laboratory accreditation programs. Some states license clinical laboratories that perform tests on their residents and/or license clinical laboratory science practitioners.

The National Select Agent Registry Program oversees the possession and transfer of biological agents and toxins that have the potential to pose a severe threat to public, animal, or plant health,[48] or to animal or plant products.[49] The LRN reference laboratories must meet these strict federal mandates.

APHL is exploring a voluntary accreditation program for PHLs. This accreditation process would evaluate how well the laboratory performs operations and functions within the larger public health system. The program would integrate existing domestic and international standards for quality management systems and organizational performance standards with performance standards based on the Core Functions. APHL does not intend to replace existing regulatory programs to which PHLs must comply but, rather, to enhance what is currently required.

POLICY DEVELOPMENT

PHLs and the SPH Laboratory System are continually challenged by the dynamic nature of regulations, laws, funding, and policy decisions at the local, state, and federal levels. The involvement of representatives of the PHL community is vital for assuring that good scientific data drive sound public health policy. Awareness of the important role PHLs play in policy development has increased since 1988, when the Institute of Medicine identified policy development as one of the three Core Functions of Public Health.[50]

Public health policy development

State and local PHLs interact with legislative bodies, administrative councils, agency officials, and representatives of professional societies in the development of policies and procedures that determine their provision of services. Funding decisions by governmental bodies affect how the resources of PHLs are used and what services will be offered. Fiscal decisions are often the result of legislative hearings in which representatives from advocacy groups have significant input. Outcomes of these policy decisions, consequently, reflect the level of partnerships that the PHL has established with its key stakeholders.

Quality PHL data at local and state levels provide a scientific basis for sound public policy decision-making. APHL initiatives assure that quality data create a measurable basis for effective legislation. For example, PHL data regularly impact policies, regulations, and legislation related to food and water safety; control of local, state, and national outbreaks; control of environmental hazards; and NBS.

APHL regularly provides its membership with updates on issues important to state and local PHLs. The APHL director of public policy periodically informs members about the status of federal public health appropriations that affect the SPH Laboratory System.[51] This is especially important because most of the APHL programs are supported by appropriations from CDC.

Advocacy and promotion

PHLs have become more effective in influencing federal policy by working through APHL. Public health and environmental laboratories can serve as a source of scientific expertise for policy makers on subjects as diverse as terrorism preparedness and NBS for genetic and hereditable disorders.[52] APHL provides expert testimony, guidance on legislative proposals, and comments on federal rulemaking. In 2007, APHL members informed congressional leaders that the CDC Newborn Screening Quality Assurance program was in dire need of consistent funding, and Congress responded with a funding increase of $7.4 million. In 2009, APHL representatives also successfully advocated for increased funds for laboratory-based influenza surveillance to improve state and local preparedness for a possible pandemic.

State and local PHL personnel have been active individually and as members of their state and national professional societies in efforts to address weaknesses and build collaboration in the SPH Laboratory System. An example is the action taken in recent years to address the current and foreseen future workforce shortages of scientific personnel in public health, food, environmental, and clinical laboratories.

EMERGENCY PREPAREDNESS AND RESPONSE

The major impetus for creating SPH Laboratory Systems resulted from several events, including anthrax attacks, the fear of pandemic avian influenza, the occurrence of natural disasters (e.g., Hurricane Katrina), the impact of large foodborne disease outbreaks, and the recognition of highly publicized emergent infectious diseases. Planning for laboratory emergency response capability and capacity began as leaders at CDC in the 1990s recognized the need for the NLS.[53]

Laboratory Response Network

Founded in 1999 by CDC, in collaboration with APHL and the Federal Bureau of Investigation, the LRN is the nation's premier system for identifying, testing, and characterizing potential agents of bio- and chemical terrorism.[54] The LRN comprises state and local public health, hospital-based, agricultural, military, food testing, veterinary, and environmental laboratories. The LRN has evolved and expanded to now include both biological and chemical testing for threat agents in appropriate clinical and environmental samples. The LRN also provides essential support for the national Biowatch program and the U.S. Postal Service's Biohazard Detection System. In 2006, APHL also began working with the EPA to develop the Environmental Laboratory Response Network to detect biological, chemical, and radiological agents in air, water, and soil.

Bioterrorism

The biological component of the LRN comprises sentinel laboratories representing thousands of mostly hospital-based laboratories responsible for rule-out or referral of suspicious agents; reference laboratories that rule out or confirm bioterrorism agents; and national laboratories that perform complex agent characterization. As LRN reference laboratories, PHLs prepare sentinel laboratories for their role in the LRN by collaborating with partners to provide wet workshops, drills, exercises, and other trainings. Assessments of state PHLs have shown that although federal funding has improved their ability to deal with bioterrorism, emerging diseases, and all-hazard threats, major challenges still exist, including later reductions in federal funding, workforce shortages, incompatible computer systems, and aging facilities.[55]

Chemical terrorism

The chemical LRN was implemented in 2003 and consists of three levels of member laboratories. Many territorial and city/county laboratories and all state PHLs have chemical LRN Level 3 capabilities. These laboratories work to provide a coordinated response for their jurisdictions, and to offer chemical agent training to appropriate partners. Approximately two-thirds of state PHLs are recognized as Level 2 laboratories that are capable of detecting a limited number of toxic chemical agents in blood. Ten state PHLs are characterized as Level 1 laboratories, which can detect an expanded number of chemicals and function as national surge capacity assets for CDC during large-scale emergencies.

In 2002, APHL began a project to assess national laboratory readiness for a chemical terrorism attack, resulting in a comprehensive report calling for a more integrated LRN capable of responding to all-hazards threats.[56] APHL conducted annual chemical terrorism surveys and, in 2007, combined chemical- and bioterrorism preparedness assessments. The 2007 all-hazards assessment demonstrated that state PHLs had made significant progress in chemical terrorism preparedness, especially in their coordination with other state and federal agencies.[57]

Radiological terrorism

The identification, analysis, and characterization of radiological contaminants are requirements for all-hazards preparedness. A radiological component of the LRN has been proposed to improve states' capabilities. CDC is currently working to develop this program, and the EPA plans to include radiation detection as part of developing the Environmental Response Laboratory Network.

Food Emergency Response Network

FERN was created in response to Homeland Security Presidential Directive 9 in 2004. It is coordinated by the Department of Health and Human Services/FDA and the USDA/Food Safety and Inspection Service. The network includes biological, chemical, and radiological components and collaborates with CDC where FERN activities intersect with those of the LRN.[38] Training of laboratorians in state, federal, and local laboratories is a major focus. FERN member laboratories in all 50 states include state, local, and federal laboratories

performing chemical, microbiological, and radiological methods.

Continuity of Operations Plan (COOP)
In preparing for emergencies, state PHLs understand the need to be able to function in the event that their facility is incapacitated by any man-made or natural disaster. COOP is essential and includes all procedures, policies, and logistics necessary to ensure an effective and timely response to such an emergency.[58] An example of the need for COOP was demonstrated when Hurricane Katrina devastated the Gulf Coast. The Louisiana state PHL contracted with the Iowa Hygienic Laboratory to perform NBS testing on Louisiana infants.

Enhanced emergency response capabilities
The infusion of federal funding for bio- and chemical terrorism has served a dual purpose for PHLs by enhancing their capabilities for early detection, enhanced interventions, and improved communications in addressing nationwide, regional, and local public health emergencies and outbreaks. Since the inception of the LRN, and the subsequent work on the chemical LRN, environmental LRN, and FERN, it is clear that a very robust laboratory response to an act of bio- or chemical terrorism is now possible. As the networks mature, sustainability of funding and other resources will be crucial to maintain this laboratory infrastructure. In looking to the future, emergency preparedness will continue to be a large component of SPH Laboratory System activities.

PUBLIC HEALTH-RELATED RESEARCH

From the time that state and local PHLs were first established in the U.S. in the latter half of the 19th century, they have engaged in research and development to improve the reliability of laboratory services for disease prevention and control. Research in PHLs is predominantly applied or practice-based and serves to support epidemiologic investigations and other public health studies at the local, state, and national levels.

PHLs are routinely engaged in studies of new and improved analytic methods and services that are necessary to meet changing public health threats and related surveillance activities. In recent years, the emergence of molecular methods and technologies has engaged many PHLs in scientific studies of their performance to test for emerging pathogens, often in association with federal agencies, academic researchers, industry associates, and clinical and environmental laboratory partners. At the SPH Laboratory System level, PHLs may engage in systems research to improve the effectiveness of laboratory testing and reporting by investigating weaknesses in information systems; preanalytic, analytic, and postanalytic deficiencies; and other quality system issues. Research efforts in PHLs may be funded from a variety of sources. The scope of public health-related laboratory research encompasses all 11 Core Functions. Following are two examples of laboratory systems and services research.

Newborn screening
As primary providers of NBS testing in the U.S., state PHLs have been at the forefront of exploring and implementing new procedures, adding capability to test for a much larger number of disorders. Research by state PHLs into biochemical and molecular sciences and analytical methodologies has enabled these procedures to be standardized and controlled relative to their sensitivity and specificity. When cystic fibrosis was added to some state NBS programs in 1994, a two-tiered protocol included an initial test for a pancreatic enzyme followed by DNA analysis for the most common cystic fibrosis mutation.[52] Later, the number of mutant cystic fibrosis alleles for which screening was available was expanded. In the late 1990s, the introduction of tandem mass spectrometry allowed for the routine testing of three classes of metabolic disorders.

Communicable disease control
State PHLs and SPH Laboratory Systems have also benefited from advances in laboratory science to deliver more timely reports to those who rely on laboratory data for disease control in outbreaks and epidemics. For many years, the diagnosis of TB was based on the standard smear for acid-fast bacilli and cultures on solid media for isolation and drug-susceptibility testing. However, results of culture are usually not available for weeks. State PHLs have collaborated in research on the use of fluorochrome stains for acid-fast bacilli smear identification, automated broth systems for culture, DNA probes for the identification and genotyping of *Mycobacterium tuberculosis,* and nucleic acid amplification in smear-positive patients. As a result, CDC developed and revised guidelines for more rapid processing and reporting of results that include microscopy, culture, and nucleic acid amplification technology.[59]

More recently, closer relationships have been developed with academia, and the opportunity exists for greater contributions to both basic and translational research. Furthermore, the area of public policy and systems research is now extending into the realm of laboratory practice.

TRAINING AND EDUCATION

The workforce for the SPH Laboratory System comprises a variety of highly educated and trained scientists including, but not limited to, chemists, microbiologists, medical technologists, radiation physicists, molecular biologists, forensic scientists, as well as computer specialists, managers, and service personnel. Nationwide critical shortages in clinical laboratories and PHLs are multifactorial,[60] including the scaling back or closure of medical technology (clinical laboratory science) programs, the aging workforce, difficulties retaining competent staff, unattractive salary differentials, requirements for credentials, and requirements for continuing education. Many clinical laboratory and PHL professional organizations, such as the Coordinating Council on the Clinical Laboratory Workforce, have assessed these challenges with surveys that have resulted in policy initiatives.[61–63]

Continuing education

As scientific meeting costs escalate and budgets at clinical laboratories and PHLs decrease, laboratory scientists have turned increasingly to on-demand training, including Web-based distance learning, CD-ROMs, and archived teleconferences. A major source of continuing education in the area of PHL practice has been the National Laboratory Training Network, a collaborative effort between APHL and CDC.[64] Since its inception in 1989, the National Laboratory Training Network has offered more than 4,500 courses reaching more than 275,000 public health and clinical laboratorians. Offerings include teleconferences, Web conferences, on-demand programs, traditional lecture-based seminars and, in 2007 and 2008, more than 40 four- to five-day hands-on workshops.[65]

Fellowships

The Emerging Infectious Diseases laboratory fellowship program, sponsored by APHL and CDC, prepares graduate and postgraduate scientists for careers in PHLs.[66] After orientation at CDC, about half of the fellows are placed in local or state PHLs and half are stationed at CDC for their training. The Environmental Health Traineeship offers a similar experience with relevant laboratory practice in a state laboratory setting.[67]

Internships

PHLs provide practical experience for undergraduate students and working professionals to gain experience in specific areas of PHL science, including relevant bench experience. To provide such training, however, PHLs must be able to allocate resources adequately.

Leadership training

Management positions in clinical and environmental laboratories and PHLs are often necessarily filled by scientists with little formal management training. In response to the impending management void caused by retiring state and local PHL directors and administrators, APHL launched the National Center for Public Health Laboratory Leadership in 2002.[68] The Center provides information, training, and technical assistance to PHL professionals and works with health organizations in the public and private sectors and government decision-makers to expand knowledge and awareness of public health issues. The Center also offers an orientation for new directors, and conducts forums and skill-building workshops. The Center has drafted a research agenda, identified best practices to address major challenges facing PHL leadership,[69] developed a leadership recruitment tool kit, and published "A Practical Guide for Public Health Laboratory Leaders."[70]

Global training initiatives

For many years, APHL member institutions have engaged in training laboratory professionals from other countries within their facilities or sent staff members to countries that have requested assistance, in collaboration with other agencies such as WHO. In 2006, APHL initiated efforts on four continents and 17 countries, from Haiti to Mozambique.[71,72] In addition, a two-week course on PHL management was offered by APHL and the George Washington University School of Public Health and Health Services in Washington, D.C.

PARTNERSHIPS AND COMMUNICATION

In the 21st century, state PHLs have advanced from being primarily providers of scientific data to serving as focal points in a national system of public health surveillance and response. Many state PHLs have established partnerships with other laboratory entities within their jurisdictions and are linking these facilities to agencies such as CDC and the EPA. Efforts to create truly comprehensive SPH Laboratory Systems go beyond the traditional partnerships to include emergency response leaders, law enforcement, academia, and private industry to develop a system that addresses the 10 Essential Services and the 11 Core Functions.

State systems

State laboratory-based disease control programs have been in existence for many years. Creation of comprehensive PHL systems is a more recent initiative, with all 50 states at some level of development. A new

program that affords states the opportunity to measure progress in meeting standards and creating an effective PHL system is L-SIP.[8] As systems mature, lessons learned about partnerships, system development, quality improvement, political issues, marketing, and data collection will help promote and refine the concept of the NLS and SPH Laboratory Systems throughout the U.S.

Communication modalities

Many PHLs provide information to laboratories and other partners through newsletters or electronic messaging. These communications may notify users about changes in policies or procedures or give important disease updates. PHL websites also serve as sources of information about current PHL issues. Multidisciplinary Laboratory Advisory Committees also enhance communication channels by fostering collaboration.[73] Key state PHL staff receive media training to help them understand how information can be communicated effectively, especially in a crisis. PHLs work closely with their agency public information officers as they interpret scientific data for public consumption and awareness.

Relationship building

For one-to-one personal linkages, many state PHLs employ a Laboratory Program Advisor, especially for enhancing the response of the SPH Laboratory System to communicable diseases and other public health emergencies.[74] The Laboratory Program Advisor implements strategies to build relationships with system partners and resolve problems in the SPH Laboratory System. They maintain information on the capabilities and capacities of in-state laboratories and engage them in the mission of the SPH Laboratory System. An important function of the Laboratory Program Advisor is to provide or facilitate training for SPH Laboratory System partners.

National linkages

There are a number of linkages among the SPH Laboratory System, the NLS, and other federal programs. State PHLs serve as data sources for a number of national surveillance programs such as FoodNet, the Arbovirus Surveillance Network, Calcivirus Network, PulseNet, and the Influenza Surveillance Network. In addition to reporting directly to these national surveillance programs, state PHLs also maintain strong connections with state health officials, state epidemiologists, sexually transmitted disease directors, TB control directors, chronic disease directors, maternal and child health officials, and environmental program directors to provide pertinent laboratory-based results for reporting systems maintained in their agencies that may have national linkages.

FUTURE OF THE SPH LABORATORY SYSTEM

There are many incentives and stimuli for state PHLs to develop strong SPH Laboratory Systems. CDC has made the development of the NLS a major focus. Congress has allocated considerable resources for homeland security, which includes measures to prevent or contain bio-, chemical, and radiological terrorism. The American public is demanding a better national response to naturally occurring disasters such as Hurricane Katrina and the 2008 outbreak of *salmonellosis* that was associated with jalapeno peppers. Recognition of the importance of including all facets of the health community in emergency planning has helped to bring nongovernmental laboratories into the SPH Laboratory System.

On the other hand, developing these systems state-by-state remains a daunting task. The complexity and economics of the U.S. health-care system require that the impetus for developing successful PHL systems must come from state PHLs. The cost of developing and sustaining a fully integrated, mature system is unknown, and all state PHLs face customary budget constraints and competing priorities. How many resources should be allocated for staffing, electronic networking, partner meetings, and laboratory training? Other unknowns include state and municipal budgetary shortfalls as a result of periodic economic downturns, as well as other competing health department priorities.

Success in developing and maturing SPH Laboratory Systems throughout the U.S. will depend on strong leadership at the national level by CDC, at the organizational level by APHL, and at the state level by state PHLs. States with large state PHLs and more resources clearly have an advantage, as they generally have greater latitude in allocating personnel and the communication expertise to sustain multiple partnerships. Those states with more limited resources may have to demonstrate greater innovation and cost sharing with partners to accomplish the same ends.

Despite these possible barriers, development of a successful SPH Laboratory System in the U.S. looks promising because of the planning and progress that has been made in just a few years by APHL and its members. Development of L-SIP has defined the required components, competencies, and capacities of state and local PHLs at a gold standard level. Performance standards assessments allow participants to determine the strengths and weaknesses of the individual system.

Information gathered at the assessment meetings can help to improve and better coordinate PHL activities at the state and local levels. By strengthening the multiple partnerships, a strong foundation for public health preparedness will be achieved. As challenges to public health programs are continually changing, establishing a strong SPH Laboratory System will permit continuous quality improvement and will strengthen the science basis for PHL practice and response in support of the Essential Services.

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