The State Public Health Laboratory System

By:

Stanley L. Inhorn, MD[1]

J. Rex Astles, PhD[2]

Stephen Gradus, PhD[3]

Veronica Malmberg, MS, MT(ASCP)[4]

Paula M. Snippes, MT (ASCP), CLS (NCA)[5]

Burton Wilcke, Jr., PhD[6]

Vanessa A. White, MPH[7]

Word count of text (not including text and references): 14,529. 1 figure.

[1] Wisconsin State Laboratory of Hygiene, Madison, WI
[2] Division of Public Health Partnerships, Centers for Disease Control and Prevention, Atlanta, GA
[3] City of Milwaukee Health Department, Public Health Laboratories, Milwaukee, WI
[4] New Hampshire Public Health Laboratories, Concord, NH
[5] Minnesota Public Health Laboratory, Minneapolis, MN
[6] University of Vermont, Department of Medical Laboratory and Radiation Sciences, Burlington, VT
[7] Laboratory Systems and Standards, Association of Public Health Laboratories, Silver Spring, MD

Address correspondence to: Stanley L. Inhorn, MD, Wisconsin State Laboratory of Hygiene, 465 Henry Mall, Madison, WI 53706; tel.: 608-238-1680, fax: 608-262-3257, email: slinhorn@wisc.edu

SYNOPSIS

This report describes the development since 2000 of State Public Health Laboratory Systems in the United States. These state systems collectively are related to several other recent public health laboratory initiatives. The first is the *Core Functions and Capabilities of State Public Health Laboratories,* a white paper that defined the basic responsibilities of state public health laboratories. Another is the Centers for Disease Control and Prevention National Laboratory System 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 National Laboratory System, the Association of Public Health Laboratories launched in 2004 a State Public Health Laboratory System Improvement Program. In the same year, the Association of Public Health Laboratories developed a Comprehensive Laboratory Services Survey, a tool to measure improvement through the decade to assure that essential public health laboratory services are provided.

Core Functions and Capabilities of State Public Health Laboratories

In 2000, the Association of Public Health Laboratories (APHL) published a white paper –*Core Functions and Capabilities of State Public Health Laboratories*, which enumerated the 11 core functions that State Public Health Laboratories (SPHLs) provide or assure and described their expected capabilities in safeguarding the public's health.[1] One purpose of this report was to identify the SPHL's role in assuring that the 10 Essential Public Health Services[2] are adequately supported by laboratory-based scientific data. APHL's leadership recognized that, during the 1990s, the emergence of new infectious diseases, the revolution in genetic testing, the threats of chemical and biological terrorism, and the concerns about environmental exposures presented major challenges to SPHLs. In addition, there was recognition that SPHLs vary greatly in size, function, funding, and organization. For example, in some states, certain testing services are conducted, not in the SPHL, but in another governmental or local public health laboratory or by private laboratories, so that in these circumstances, the SPHL assures rather than directly provides the testing service. It was also recognized that SPHLs are a pivotal point in a loose national network of federal, state, and local laboratories that collaborate with private clinical and other laboratories. In 2002, the Core Functions white paper was published by the Centers for Disease Control and Prevention (CDC) Division of Laboratory Systems as an MMWR article.[3] The MMWR report came 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. Since SPHLs 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 between state public health laboratories and clinical laboratories existed before the anthrax attacks, they were the wake-up call that accelerated efforts, provided funding that could be used to enhance public-private relationships, and helped clinical laboratorians to recognize their role in public health testing of all types. 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 robust state public health laboratory systems are essential components. 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, the CDC's role in the NLS also includes helping the states to enhance and maintain their state public health laboratory systems. In 2001, to jump-start the NLS, CDC awarded cooperative agreement funds for four NLS demonstration projects, intended to show how SPHLs could improve coordination, communication and collaboration with private clinical laboratories.[5] The realization of a fully developed NLS would require functioning integrated laboratory systems in every state. Subsequently,

CDC funded additional cooperative agreement awards for projects to develop various components of state laboratory networks.

Laboratory System Improvement Program A collaborative effort between CDC and APHL was begun in 2004 to develop a State Public Health Laboratory System Performance Standards Program. This program was inspired by the National Public Health Performance Standards Program (NPHPSP)[6] and modeled after the NPHPSP and the Capacity Assessment for State Title V (CAST-5)[7] 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 of Public Health[2] and the Core Functions and Capabilities of State Public Health Laboratories.[1,3] In April 2008, the program name was changed to the Laboratory System Improvement Program (L-SIP) to more accurately reflect the long-term goals of the program. The L-SIP uses a performance measurement tool that is aimed at the optimal level of performance.[8]

L-SIP is intended to improve the quality of public health laboratory practice and the performance of public health laboratory systems by:

- Identifying performance standards against which state public health laboratory systems can measure performance
- Engaging and leveraging state laboratory system partnerships to build a stronger foundation for public health preparedness
- Promoting continuous improvement of public health laboratory systems

- Strengthening the science base for public health practice improvements
- Providing a basis for formalizing the National Laboratory System nationwide, with potential inclusion of clinical, veterinary, agricultural, and environmental laboratories
- Supporting the planned process for accreditation of state public health laboratories

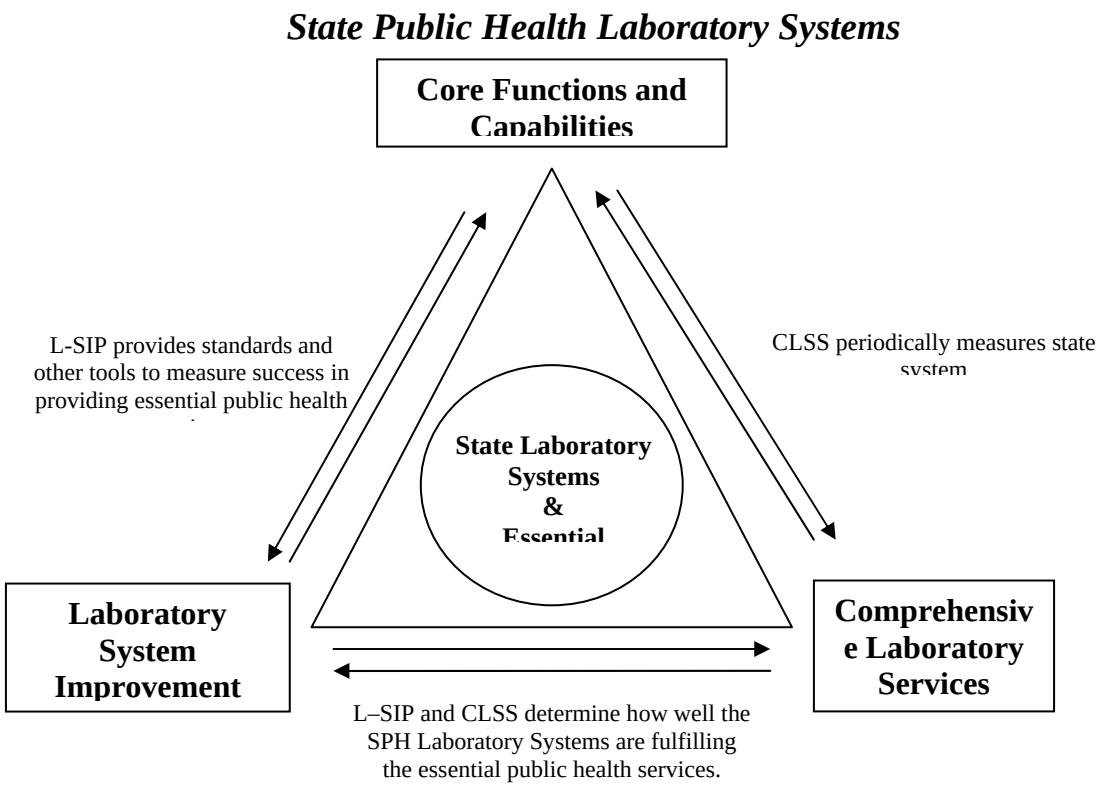
A wide variety of organizations and partners participate in different parts of the SPH Laboratory System as the nature of the public health issue changes. For example, law enforcement agencies become important partners in situations where terrorism is suspected; academia is vital in supporting training of the workforce. So even though all system partners need not weigh in on all issues affecting the SPH Laboratory System, they should be included in assessments of the system and in activities to improve the system.

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 agency, in this case the public health laboratory, 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 SPHL performance. To assure its validity, the survey was

developed in conjunction with the CDC's National Center for Health Statistics. The survey is based on the Core Functions of SPHLs and measures the degree to which state agencies fulfill the core functions**.**

The first survey was conducted in 2004 with 47 states and one territory participating.[10] A second survey was conducted in 2006, and a third was carried out in 2008. By conducting the survey biannually through 2010, improvements in SPHL performance can be measured.

Figure 1. The State Public Health Laboratory System Components and Their Interactions



State Public Health Laboratory Systems 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. (Figure 1) In 2000, the Healthy People 2010 initiative specifically acknowledged the unique role of public health laboratories.[9] To quote from Healthy People 2010, "Public Health Laboratories, in conjunction with clinical, environmental, and agricultural laboratories, constitute a national laboratory network that fulfills a critical role in assessing and assuring the health of populations and the environment. This role includes such activities and services as laboratory quality assessment and improvement, outbreak investigation, emergency preparedness and response, laboratory-based surveillance, population screening, and technology transfer. The national laboratory network also operates for the benefit of public health by helping to assure safe water, food, and air and by supporting programs such as newborn screening and lead-poisoning prevention."

In 2007, APHL defined a *State Public Health Laboratory System* (SPH Laboratory System) as a network consisting of all the participants in public health laboratory testing, including those who initiate testing and those who ultimately use the test results.[11] The SPH Laboratory System is part of the larger state public health system. The system includes individuals, organizations, and agencies that are involved in assuring that laboratory data support the 10 Essential Services of Public Health.[2] The concepts of a SPH Laboratory System are also embedded in the APHL Core Functions and Capabilities of State Public Health Laboratories.[1,3] Within the SPH Laboratory System are primary

stakeholders who are directly involved in creating and using laboratory data. Additional stakeholders include those who are concerned with complementary Essential Services, such as policy development and public health-related research. This definition of the SPH Laboratory System is consistent with the goals of the National Laboratory System.[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
5. public health laboratory data are transmitted to designated local, state and federal agencies responsible for disease prevention, surveillance, and control.

The State Public Health Laboratory (SPHL) 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 public health laboratories. To assure that the SPH Laboratory System is effective, the SPHL should as a minimum:

1. maintain a database that includes all stakeholders who rely on accurate public health laboratory data
2. employ a full-time Laboratory Program Advisor
3. create a standing Public Health Laboratory Advisory Committee
4. provide a system to maintain regular communication channels for system partners

The *Local Public Health Laboratory*, including city, county, and regional public health laboratories, often maintain valuable networks with their constituents. Such networks contribute to the SPH Laboratory System.[12]

THE CORE FUNCTIONS AND CAPABILITIES OF STATE PUBLIC HEALTH LABORATORIES

In the 2002 MMWR report on the Core Functions, it was noted in the Summary: *Defining public health laboratory functions in support of public health programs is the beginning of the process of developing performance standards for laboratories, against which state public health laboratories, and eventually local public health and clinical laboratories, will establish and implement best laboratory practices. Public health is changing, and as*

part of that change, public health laboratories must advocate for and implement improvements for public health testing and surveillance.

In the Introduction to this same report, the following observation was made: *These recommendations for core functions enable state leaders and stakeholders (e.g., State epidemiologists, state and local health officers, and state legislators) to assess the adequacy of the public health systems, allocate resources, and encourage relationships between the public health system and the health-care delivery system. Further, these recommendations provide a guide for assessing and monitoring the service and value of the public health laboratories by serving as a basis for creation of policy development. From this foundation, development of laboratory performance standards and laboratory quality assurance can evolve in the United States.*

The leadership role and activities of the SPHL 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 SPHL in promoting the SPH Laboratory System by providing or assuring each of the 11 Core Functions must include those activities that are carried out by the SPHL as well as those performed by other partners. As public health priorities change in the future, new core functions may be identified for the SPH Laboratory.

The eleven **Core Functions and Capabilities (CFC)** are:

CFC 1- Disease prevention, control, and surveillance

CFC 2- Integrated data management

CFC 3- Reference and specialized testing

CFC 4- Environmental health and protection

CFC 5- Food safety

CFC 6- Laboratory improvement and regulation

CFC 7- Policy development

CFC 8- Emergency preparedness and response

CFC 9- Public health-related research

CFC 10- Training and education

CFC 11- Partnerships and communication

CFC 1- Disease Prevention, Control, and Surveillance

The SPHL 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, 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 SPHL serves as a center of expertise for the detection and identification of infectious disease agents. In this role, the SPHL provides reference testing for clinical laboratories and other healthcare facilities in the state and surveillance testing to support the work of the state epidemiologists.
- The SPHL provides a variety of molecular testing methods to detect, identify and subtype organisms associated with disease for enhanced surveillance.
- The SPHL provides testing for high-risk and emerging infectious diseases such as tuberculosis, rabies and botulism for which other diagnostic laboratories generally do not test.
- The SPHL serves as a conduit for state-national transmission of information by participating in current CDC and FDA surveillance programs:
    - Laboratory Response Network (LRN)
    - Emerging Infections Program/Epidemiology & Laboratory Capacity Program (EIP/ELC)
    - Foodborne Diseases Active Surveillance Network (FoodNet)
    - Influenza (CDC/WHO) Surveillance Network
    - Arbovirus Surveillance Network (ArboNet)
    - National Respiratory and Enteric Virus Surveillance System (NREVSS)
    - National Molecular Subtyping Network for Foodborne Disease Surveillance (PulseNet)
    - Food Emergency Response Network (FERN)
    - Electronic Laboratory Exchange Network (ElexNet)

- Laboratory Identification of Parasites of Public Health Concern (DPDx)

Chronic Diseases

- 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] Surveillance to monitor chronic diseases and their risk factors has relied on population surveys such as the Behavioral Risk Factor Surveillance System. The Council of State and Territorial Epidemiologists and chronic disease program directors at the state and federal level have developed a number of indicators with which to monitor chronic diseases. Public health laboratory testing was not included as a measure in these indicators.
- In 2005, CDC initiated efforts to develop a national environmental public health tracking network (EPHT).[14] Public health laboratories contribute to the EPHT network by providing or assuring data for the assessment of exposure to air pollution at home and at the workplace and to chemical exposures from contaminated food, water, and consumer products. Air quality degradation is especially critical to those with chronic respiratory diseases such as asthma and chronic obstructive pulmonary disease (COPD). The data are obtained from measuring levels of toxic chemicals in environmental and human samples. The EPHT program 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 in the U.S. 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 HRSA, the American College of Medical Genetics, among others. APHL has issued policy statements on issues such as Newborn Screening Follow-Up, Quality Assurance in a Newborn Screening Laboratory, and Residual Newborn Screening Specimens.
- In the area of quality assurance/control, the APHL Quality Assurance/Quality Control/Proficiency Testing Subcommittee has provided leadership and serves as a liaison between the CDC and state NBS programs. The subcommittee has provided web conferences on topics such as unsatisfactory NBS specimens and tandem mass spectrometry.
- Through the efforts of APHL and its partners, NBS programs are now provided or assured in every state by the SPHL.[15] Through the years, APHL has sponsored newborn screening and genetics testing symposiums, which have helped to improve and standardize the provision and quality of these testing programs throughout the U.S.

CFC 2- Integrated Data Management

A health informatics revolution is sweeping the United States with an ever-increasing emphasis on speed, accuracy, accessibility and security of data. Nationally, that emphasis is being realized in many ways, including the creation of a US Department of Health and Human Services (HHS) organization called the American Health Informatics Community (AHIC) focused on addressing the broad challenge of electronic medical health information. Laboratory test results must be available to the health care provider and public health authority in a timely fashion

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 in order to exchange information in a useful and meaningful manner.[16] For the individual laboratory, this means the receipt, analysis, and rapid multi-directional 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 System should assure that laboratory data and associated information are provided to partners involved in detection of, rapid

response to, and management of infectious disease outbreaks and other public health emergencies.

- *Data Exchange* – The 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.

CFC 3- Reference and Specialized Testing

In the United States, 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 SPHL and larger local public health laboratories as reference laboratories has increased greatly with the PHL serving a pivotal role in the Laboratory Response Network (see "Emergency Preparedness and Response" – Section 8).

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

- *Emerging and Re-Emerging Infections*. Public health laboratories (PHLs) have a major role in preparing for and responding to emergent and re-emergent infectious diseases. Recent disease threats include SARS, monkeypox, West Nile virus, dengue fever, and antibiotic-resistant infections such as multi-drug resistant tuberculosis and methicillin-resistant *Staphylococcus aureus* (MRSA).
- *Viral Reference Testing*. PHLs provide additional virus reference testing for detecting and characterizing HIV, noroviruses, enteroviruses, arboviruses, herpesviruses and others. Many PHLs carry out serologic

tests for vaccine-preventable diseases such as chicken pox/shingles, measles, mumps and rubella as well as for viruses such as West Nile virus and Hantavirus.

- *Influenza Surveillance.* All SPHLs and key local public health laboratories perform virus isolation for influenza as members of the World Health Organization (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 physician offices during various stages of the influenza season, and by the provision of molecular subtyping, the PHLs generate valuable surveillance information. This information enables local to global preparation for the possible emergence of new influenza strains as vaccine development progresses.
- *Bacterial, Parasitic and Fungal Reference.* PHLs serve as a valuable resource, especially to hospitals and clinics, for identifying and typing microbial pathogens. In recent years, isolates of toxin-producing *E. coli* 157:H7, *Salmonella* and *Shigella* species, *Cryptosporidium, Acanthamoeba, and* AIDS-related pathogens have been referred to PHLs for identification and/or confirmation.
- *Molecular Methods.* SPHLs are increasingly incorporating molecular technology in order 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, and

other nucleic acid amplification techniques permit rapid identification and characterization of organisms. In some cases, detailed information about subtype or strain can be gained using nucleic acid and restriction fragment length polymorphism analysis.

- *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 (see Core Function 4) and Food Safety (see Core Function 5). Many PHLs also provide alcohol and drug testing for law enforcement agencies

CFC 4- Environmental Health and Protection

The level of involvement of SPHLs in environmental testing varies widely across the country. Development of coordinated environmental testing systems presents great challenges due to the number of partners involved at the local, state, and federal levels. The majority of SPHLs conduct environmental testing, but some states have a separate laboratory facility that is located in an environmental protection department, university, or other organization. To assist in system improvement, APHL serves as a resource and focal point for all state environmental testing laboratories. APHL also serves as a conduit to the US Environmental Protection Agency (EPA), which has responsibility to protect Americans' health and the environment, in part by providing direct support to the states and tribes to implement the nation's environmental laws. In addition, APHL works closely with the CDC's National Center for Environmental Health, which is committed to

safeguarding the health of populations that are especially vulnerable to particular environmental hazards.

The SPH Laboratory System, as it relates to environmental testing, includes: city, county and state agencies; private environmental testing laboratories; other scientists who investigate problems of air, soil and water quality; drinking water and waste water treatment plants; industrial hygienists; environmental health specialists; rule-makers and other stakeholders. The SPH Laboratory System provides testing and surveillance in the following areas:

Drinking and Recreational Water

- *Microbiological Standards*. Regulations and approved laboratory methods and standards serve to assure the safety of public drinking and recreational water in the U.S. All laboratories within the state that analyze public drinking and recreational water supplies for compliance monitoring under the Clean Water Act, Safe Drinking Water Act, and the BEACH Act must be certified by EPA or an EPA-approved accrediting body.[18] Total coliform, fecal coliform, enterococci and *E. coli* have been the primary indicators of fecal pollution for drinking and recreational waters. Other microorganisms on the EPA Contaminant Candidate List (CCL) are recognized as emerging pathogen threats.[19] Currently, EPA does not impose requirements on public water systems for CCL organisms, but EPA may develop regulations in the future if certain unregulated contaminants are shown to present a public health risk. At

present, SPHLs/ELs and local PHLs conduct much of the drinking and recreational water testing, and they also assist municipal water supply operators wastewater treatment plant operators, and other stakeholders in responding to changes in regulatory requirements.[20]

- *Chemical Standards*. Drinking water, as well as recreational and ground water, can be contaminated with toxic substances such as heavy metals, pesticide residues, volatile organic compounds, and radionuclides. EPA and consensus methods organizations have approved analytic methods that must be used by certified testing laboratories. The Drinking Water Contaminant Candidate List also includes a large number of chemicals for which standards have been developed.[19] The SPHLs/ELs conduct much of this testing and, along with their agency partners, assist other water testing laboratories in meeting federal and state requirements.
- *Surveillance for Waterborne Diseases*. SPHLs/ELs and their agency partners maintain records of waterborne disease and outbreaks associated with recreational water and drinking water. Reports are sent to the CDC, EPA and the Council of State and Territorial Epidemiologists Waterborne Disease Registry at CDC, which maintain surveillance on all reported outbreaks.[21]

Air Monitoring

- *Outdoor Air Quality*. SPHLs/ELs began air quality testing in the 1970s with the advent of the Clean Air Act. Since then, air quality has emerged as a major environmental issue.[22] *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. High ozone levels, measured on an EPA scale called the air quality index, may especially adversely affect people with respiratory diseases and children.

- *Indoor Air Quality*. SPHLs/ELs test for substances in the ambient air that threaten human health. Indoor air quality analyses may be directed at detecting such substances as asbestos, formaldehyde, solvents, diesel exhaust components, and heavy metals.

Biomonitoring

The direct measurement of environmental chemicals and their metabolites in human tissues and fluids has been called the "gold standard" for assessing human exposure to pollution. Biomonitoring can distinguish innocuous events from significant exposure. CDC maintains an ongoing registry of chemicals of interest, including metals, PCBs, pesticides, and endocrine-disrupting compounds,[23] and can reliably measure human exposure to more than 300 chemicals. However, this registry is limited; there are tens of thousands of chemicals used today in the U.S. – most having unknown health effects.

Biomonitoring requires the availability of expensive, sensitive instruments, such as high-resolution spectrometers, that can detect very low levels of environmental chemicals and their metabolites in human samples. Federal chemical terrorism funding has enabled a limited number of states to purchase this special equipment. An example of the use of CDC Biomonitoring funds is the four-state Rocky Mountain Biomonitoring Consortium,

which was formed to maximize resources in order to conduct surveillance in this region. To assist in the effort to understand the health implications of environmental exposures, CDC's National Center for Environmental Health has developed a National Environmental Public Health Tracking (EPHT) program to analyze and communicate data on environmental pollutants, human exposures to those pollutants (biomonitoring) and health outcomes and to link this information to geographical data.[24] Currently there are no systems that exist at the state or national level to track many of the exposures and health effects that may be related to environmental hazards. As SPHLs/ELs and other research groups acquire more data from exposure studies, methods for interpreting and communicating results will become clarified.[25]

Environmental Lead Exposure

Despite the banning in 1978 of lead-containing paint, lead exposure persists in and around older homes from paint chips and dust and soil contaminated with lead. Soil contamination from leaded gasoline, phased out in 1996 by the EPA for use in on-road vehicles, also remains a problem. Occupational exposure is a concern in such industries as construction and demolition, painting, radiator repair, battery manufacturing, and glassmaking. 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 assisted the Childhood Lead Poisoning Prevention Advisory Committee and health professionals around the country in developing strategies to reduce exposures to lead.[26]

Occupational Health

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

Solid and Hazardous Waste and Wastewater Management

- *Solid and Hazardous Waste*. Certain industrial and manufacturing processes produce animal, chemical, metallic, or radioactive wastes, while hospitals and health care facilities produce medical wastes, many of which have the potential of being hazardous to human health. In addition, waste management facilities process large quantities of household and business trash. Wastes that have spilled, leaked, or that have been improperly discarded are of particular concern to the EPA and individual states. Hazardous waste management programs may be delegated to a state, which then enforces the regulations on behalf of EPA.[28] Regulatory programs are implemented to control the disposal or storage of hazardous wastes. SPHLs/ELs assist in detecting suspected environmental releases at industrial sites and waste management facilities.
- *Wastewater*. Water pollution degrades surface waters and recreational waters. Point sources that discharge pollutants into waters are regulated by an EPA permit program, which in most cases is administered by authorized states.[29] Testing water quality and properties at point sources and at accidental spill sites

by SPHLs/ELs, using approved standard methods, assists regulatory agencies in enforcing the regulations.[30]

CFC 5- FOOD SAFETY

Since 1973, CDC has maintained a collaborative surveillance program of foodborne-disease outbreaks. Bacterial, viral, parasitic, and chemical agents have been causative agents of many of these outbreaks.[31] In addition, the Foodborne Diseases Active Surveillance Network (FoodNet) of CDC collects data from 10 U.S. states regarding disease caused by pathogens commonly transported through food.[32] The primary public health laboratory mission, as it relates to foodborne disease, is to quickly identify agents that have entered the food supply that could potentially affect a population, either locally or over a multi-state region. Once the agent is identified, the underlying cause of contamination can often be eliminated. The SPH Laboratory System and the PHL have a crucial role in the investigation of foodborne outbreaks. To protect the food supply and to control outbreaks, many agencies and organizations at the federal, state, and local levels are also involved:

- *Federal Level* APHL interacts with CDC, the Food and Drug Administration (FDA), the Association of State and Territorial Health Officials (ASTHO), the National Association of City and County Health Officials (NACCHO), the Conference of State and Territorial Epidemiologists (CSTE), the National Environmental Health Association (NEHA), the Association of Food and Drug

Officials (AFDO), the U.S. Department of Agriculture (USDA), and the National Association of State Departments of Agriculture (NASDA) in the over-arching Council to Improve Foodborne Outbreak Response (CIFOR), in an effort to coordinate surveillance and control.[33] 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 community between the various laboratories and regulatory agencies that make up our nation's food and agricultural sectors. Through secure, integrated resources, health and agricultural departments, as well as laboratories, can communicate with peers in other states.[34]

- *State and Local Level* PHLs have a major role in investigation of foodborne outbreaks, disease surveillance, and confirmatory testing. [35] In this new millennium, SPHLs continue to provide or assure microbiological, chemical, and radiological analytic capabilities. In addition, they work collaboratively with their respective epidemiology and environmental health programs to support appropriate interventions, as necessary, to mitigate foodborne outbreaks. Public health laboratories are also asked to assist with federal investigations of foodborne outbreaks. Particularly at the local level, some public health laboratories respond to suspect or confirmed foodborne outbreaks within their communities in real-time as part of a local PH team, which includes sanitarians and nurses.

In 2005, APHL convened a meeting to examine the operations and interactions between state and larger local public health laboratories, food industry regulators, and

epidemiologists to help close the gap between current and recommended investigation practices and to develop solutions for improving communication among partners that include hospitals/clinics, state and local epidemiologists, state and local environmental health agencies, state departments of agriculture, USDA, FDA and CDC. Gaps were identified in: a) electronic and agency-to-agency communication; b) standard operating procedures for sample processing; c) training; and d) political and legal issues. Solutions were developed to correct the problems identified in the four areas. Recommendations focused on processes, accountability, training, and resources. Since this meeting, APHL has promoted SPHL involvement in food safety by enhancing relationships, standardizing processes, and clarifying responsibilities. APHL continues to promote relationships between state and local agencies through PulseNet regional meetings. SPHLs, epidemiologists, local health agencies, agriculture laboratory representatives are encouraged to develop regional projects that promote collaboration and coordination between agencies and states.

Epi-Ready Team Training is a nationwide collaborative between CDC and the National Environmental Health Association and is supported by APHL.[36] This program is intended to provide up-to-date foodborne disease outbreak investigation and surveillance training to public and private sector environmental health professionals bringing together local teams of laboratorians, epidemiologists and sanitarians to improve foodborne outbreak response. Over 1,500 individuals have been trained through this program through 2008 since its inception in 2003. The training includes group exercises, Q&A sessions and didactic lectures conducted over 2 days.

Food Safety Laboratory Capacity In 2003, APHL conducted a laboratory capacity assessment based on a survey carried out in August 2001 and a consensus conference in 2002.[37] The assessment identified a shortage of doctoral-level and other food safety scientists in public health laboratories, especially in food chemistry. The assessment also revealed that a complex mix of entities and jurisdictions in states hindered coordination of food testing efforts. Many public health laboratories lacked space, staff, and/or equipment to handle foodborne emergencies. The conference resulted in many recommendations to improve laboratory infrastructure, submission of samples, and analytic processes. Follow-up surveys were conducted in 2004 and 2007, adding to our knowledge about SPHL preparedness for an intentional attack against the food supply.[38] In 2007, 57% of SPHLs indicated that they required non-governmental laboratories to send food and/or clinical samples associated with foodborne illness to the state laboratory 72% had a written plan for coordination in a food emergency with other state epidemiology, environmental or agricultural programs or nongovernmental laboratories.

Advanced diagnostic methods The culture and isolation of microorganisms from various food source matrices presents many challenges using conventional microbiological methods. However, once isolated, identification and further characterization of organisms may be done by antigenic and biochemical analysis. Molecular techniques in the food testing sections of SPHLs and larger local PHLs permit PHLs and their state and federal partners to respond more effectively to the numerous food-related incidents that occur every year. Some PHLs are beginning to employ the next generation of subtyping

methods, such as multi-locus variable number tandem repeat analysis. These techniques provide even greater discriminatory power to outbreak investigations.

Food networks and surveillance

- *PulseNet and Foodborne Disease Surveillance* PulseNet USA is a network of public health laboratories that perform advanced testing to investigate foodborne disease outbreaks and food terrorism.[39] PulseNet was created by CDC and APHL in 1996 to link PHLs that perform a standardized DNA fingerprint technique, called pulsed-field gel electrophoresis (PFGE) on organisms associated with foodborne disease. PFGE creates a DNA "fingerprint" pattern that is unique to an individual organism strain. Using PFGE, both food and human isolates can be compared to determine their relatedness, and thus possibly their association to an outbreak.[40] Connected PulseNet systems have been established in Canada, Europe, Latin America, the Middle East, and Asia Pacific, with new sites planned for Africa and Eurasia.
- *Food Emergency Response Network (FERN)* This collaboration between 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.[41] FERN is organized with national and regional centers coordinating bioterrorism and chemical terrorism food testing activities in public health, agricultural, environmental, and veterinary laboratories. FERN- supported programs include monitoring, proficiency testing, method development/validation, training, and communication.

- *The Electronic Laboratory Exchange Network (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 is the data capture and communication system for the Food Emergency Response Network (FERN). eLEXNET captures data for microbiological analytes, antibiotic residues, chemical compounds, mycotoxins, naturally occurring toxins, parasites, radionuclides, and toxic elements. eLEXNET houses over 3700 analytes and more than 800 detailed test methods. As of October, 2008, 110 federal, state, and local laboratories in 50 states had joined the eLEXNET partnership.[42]

Public health laboratories form the backbone of foodborne outbreak responses, such as those associated with leafy vegetables, peanut butter, ground beef, and others that have been recognized in recent years. Laboratory networks, such as PulseNet, have enabled investigators to find the source of these outbreaks and remove the offending foods from the supply chain, as well as assist the food industry in changing harmful practices. The food safety system continues to improve, but there is still a need for federal and state support of PHLs to sustain the gains that have been made.

CFC 6- LABORATORY IMPROVEMENT AND REGULATION

Demands for quality assurance directed toward the health laboratory industry have come from governmental regulatory bodies as well as the public – individuals and advocacy groups alike. In response to requirements for safe food, milk, and water and later for pure

air, safety in the workplace, and proper handling of radioactive material, a number of national standards and regulations were developed for applicable laboratories. Regulation of the clinical laboratory field was a later development. As a result of regulatory requirements and quality assurance activities developed primarily by committees within professional societies, the reliability of laboratory testing within the U.S. has improved dramatically. Organizations such as the American Public Health Association and the Clinical and Laboratory Standards Institute publish and update standards for a variety of laboratory disciplines. SPHLs are often instrumental in promoting laboratory improvement within their states.

Laboratory Improvement

- *Consultation and Outreach.* SPHLs and the APHL have been involved in laboratory improvement for many decades and have assisted clinical and environmental laboratories in meeting federal and state regulations and mandates. As noted in the section on Training and Education, many of these activities for clinical laboratories have expanded with the advent of CLIA-67 and more intensely with CLIA-88. Small hospital laboratories and clinic and doctors' office laboratories are especially targeted. With the recognition of emerging infections and the advent of bioterrorism, even greater laboratory improvement efforts have occurred between federal, state, and private partners. In addition to training for laboratory personnel, outreach to users of laboratory resources has been critical to improving testing accuracy. For example, owners of private wells are provided instructions and often shipping containers for submitting samples in a timely

fashion. In those states that provide alcohol and drug testing for determining driving impairment, significant outreach activities provide training to law enforcement officers, attorneys, and laboratory personnel.[43]

- *Quality Assurance/Proficiency Testing Programs* A number of professional societies and a few SPHLs, such as the Wisconsin State Laboratory of Hygiene, provide proficiency testing programs to clinical laboratories, as well consultation.[44] A newborn screening (NBS) quality assurance program has been operated for 30 years by CDC, with the APHL as a cosponsor as well as consultation. This quality assurance service primarily supports NBS testing performed by state laboratories, but the program also accepts other laboratories and international participants.[45]
- *CLSI* The Clinical and Laboratory Standards Institute (CLSI) is a global, nonprofit, standards-developing organization that promotes the development and use of voluntary consensus standards and guidelines within the health care community.[46] The process balances input from the viewpoints of industry, government, and the healthcare professions. CLSI produces gold standards accepted throughout the public health and clinical laboratory profession. Standards are documents developed through the consensus process that clearly identify specific, essential requirements for materials, methods, or practices for use in an unmodified form.
- *Performance Standards.* In order to assess the success of the SPH Laboratory System in meeting the challenges of infectious disease control, acts of biological or chemical terrorism, and quality public health laboratory performance, APHL

launched the Laboratory System Improvement Program (L-SIP) in 2007. The goal of this program is to determine how well the SPH Laboratory System supports the ten essential public health services. States will be able to determine areas needing strengthening to improve the quality of public health laboratory practice. Further, specific tools, model practices and quality improvement materials are being provided to address shortcomings.[8]

Regulatory Activity

Environmental Laboratories. The U.S. Environmental Protection Agency (EPA) certifies the state primacy laboratories under the Safe Drinking Water Act, as noted in Section 4 on Environmental Health and Protection.[18] Furthermore, EPA promulgates regulations and establishes methods and standards to assure drinking water safety.[47] In a similar fashion, EPA regulates air monitoring under the Clean Air Act.[48]

- *Environmental Laboratory Certification Programs.* EPA requires that laboratory data submitted for the Safe Drinking Water Act be generated either by the state primacy laboratory or by laboratories certified, through EPA's delegated authority, by the state's environmental laboratory certification program.[49] These certified laboratories include commercial laboratories, municipal water systems, and other local, regional or federal laboratories. In some states, the state's environmental laboratory certification program is housed within the SPH/EL, and

in some states, laboratory scientists in the SPH/EL serve as expert technical consultants to the state environmental laboratory certification program.

- *National Environmental Laboratory Accreditation Program (NELAP)* An avenue of voluntary accreditation for environmental laboratories is NELAP accreditation. This accreditation evolved for several years under the auspices of the National Environmental Laboratory Accreditation Conference (NELAC) and the Institute for National Environmental Laboratory Accreditation (INELA). In 2006, the respective boards of directors of these two organizations formed The NELAC Institute (TNI) to facilitate the process.[50] The NELAP board conducts evaluations of state accreditation bodies. As of April 2008, nine SPH/ELs have chosen to become accredited by a NELAP accreditation body, and thirteen state environmental certification programs (representing twelve states) have chosen to become NELAP accreditation bodies.
- *Environmental Lead Testing Accreditation Program.* Under the statutory authority of the Residential Lead-Based Paint Hazard Reduction Act of 1992--Title X, implemented by the Department of Housing and Urban Development, EPA has established the National Lead Laboratory Accreditation Program (NLLAP) to recognize laboratories that demonstrate the ability to accurately analyze paint chip, dust, or soil samples for lead.[51] All laboratories recognized by NLLAP are required to undergo on-site audits conducted by accrediting organizations participating in the NLLAP, and to perform successfully on a continuing basis in the Environmental Lead Proficiency Analytical Testing (ELPAT) Program. ELPAT is a proficiency testing program established by the

National Institute for Occupational Safety and Health (NIOSH), the American Industrial Hygiene Association (AIHA), and EPA. EPA currently recognizes the AIHA and the American Association for Laboratory Accreditation (A2LA) as accrediting organizations for the NLLAP.

- *Laboratory Quality Assurance Evaluation Program for Analysis of* Cryptosporidium *under the Safe Drinking Water Act.* EPA implements laboratory approval programs for contaminants not covered under State certification programs. This includes the program for *Cryptosporidium* monitoring under the Long Term 2 Enhanced Surface Water Treatment Rule and the program for analyses under the Unregulated Contaminant Monitoring Rule – Cycle 2.[52] The purpose of this Laboratory Quality Assurance Program is to maintain a list of laboratories that can reliably measure the occurrence of *Cryptosporidium* in surface water using EPA Method 1622 and/or EPA Method 1623. Laboratories are evaluated on: 1) equipment required; 2) experienced personnel; 3) successfully completing an initial demonstration of capability by on-site evaluation, and 4) on-going proficiency of precision and recovery data.
- *Additional Environmental Certification Programs* While EPA offers certification only for the Safe Drinking Water Act, a few of the NELAP accreditation bodies and several of the state environmental laboratory certification programs also offer certification for other regulatory programs that protect human health and the environment. Certification offerings may include analyses germane to the Clean Air Act (CAA), the Clean Water Act (CWA), the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA, a.k.a. Superfund), and the

Resource Conservation and Recovery Act (RCRA). Moreover, environmental laboratories that wish to demonstrate their capacity to adhere to quality systems and to demonstrate competency of staff, methodology, and equipment may seek accreditation by organizations that are recognized by the International Organization for Standardization (ISO).

Clinical Laboratories Regulatory and standards-setting activities for clinical laboratories were sporadic until the late 1960s, when Medicare regulations and the clinical Laboratory Improvement Act of 1967 (CLIA -67) extended federally promulgated standards to hospital-based and independent clinical laboratories. Subsequently, the Clinical Laboratory amendments of 1988 (CLIA-88) extended the mandate to approximately 200,000 laboratories, including doctors' offices, in the U.S.[53] Many SPHLS, as well as APHL, have been at the forefront of efforts to improve laboratory testing in laboratories in doctors' offices, clinics, and hospitals.

- *Clinical Laboratory Certification Programs* Professional organizations such as the Board of Registry of the American Society for Clinical Pathology (ASCP), the National Credentialing Agen and the American Society for Microbiology (ASM) have developed certification programs for personnel. Others, such as the American Association of Blood Banks (AABB) and the College of American Pathologists (CAP) have established laboratory accreditation programs. A few states, such as New York, license clinical laboratories that perform tests on their

residents. Eleven states and Puerto Rico license clinical laboratory science practitioners, and many others are in some phase of personnel licensure activity.

- *The National Select Agent Registry Program.* 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,[54] or to animal or plant products.[55] The Laboratory Response Network (LRN) laboratories fall under this definition and must meet strict federal mandates and undergo a biennial inspection by the Select Agent Program. The facility must meet biosafety requirements that are commensurate with the risk that the select agent or toxin poses and must establish security measures that provide graded protection in accordance with the threat that the agent or toxin poses.

CFC 7- POLICY DEVELOPMENT

Public health laboratories and other components of the SPH Laboratory System are increasingly subject to changes in laws, regulations, and funding decisions at the state, local, and federal levels. Representatives of the public health laboratory community are vital for assuring that good scientific data drives sound public health policy. As public awareness of the important role public health laboratories play in assuring safe food and a safe environment, controlling epidemics of emerging and re-emerging infections, and responding to terrorism increased, support for the public health infrastructure has improved.

Public Health Policy Development

- State and local public health laboratories 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 public health laboratories are to be used and what services will be offered. In many states, a portion of services are tax-supported, while others are offered on a fee-for-service basis. Fiscal decisions are often the result of legislative hearings in which representatives from societies and advocacy groups have significant input. Outcomes of these policy decisions, consequently, reflect the level of partnership development that the public health laboratory has established with various stakeholders.
- Quality public health laboratory data, at local and state levels, provide a scientific basis for sound public policy decision-making. APHL initiatives are directed at assuring that quality data create a measurable basis for effective legislation. For example, public health laboratory 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 screening of newborns.
- The APHL standing committees develop policy statements on issues such as: HIV rapid testing; quality assurance in newborn screening, federal accreditation of state environmental testing laboratories, the laboratory role in pandemic response plans, and others. The policy statements are sent to APHL members and other

interested parties to use in advocating for development of legislation and rule-making at the federal, state and local levels.

- APHL provides its membership with updates on issues important to state and local PHLs. For example, the director of public policy periodically informs members about the status of federal public health appropriations that affect the SPH Laboratory System.[56] This is especially important since most of the public health laboratory appropriations for programs come from the CDC.

Advocacy and Promotion

- At the federal level, public health laboratories have become more effective 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 screening for genetic and hereditable disorders in newborns.[57] APHL regularly surveys public health laboratories on topics of national import such as laboratory preparedness for crisis response, and 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 the US House of Representatives responded with a funding increase of $7.4 million that was subsequently authorized by the US Senate. APHL representatives also emphasized the need for increased funds for laboratory-based influenza surveillance to improve state and local preparedness for a possible pandemic.

- APHL has initiated an annual “Hill Day”, during which a select group of APHL members travel to Washington, DC to discuss priority issues with congressional representatives and staff from their home states. In 2007, Emergency Preparedness and Response committee members met with House and Senate staffs.[58]
- State and local public health laboratory personnel have been active individually and as members of their state and national professional societies in efforts to address weaknesses 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. (See section on Training and Education)

CFC 8- EMERGENCY PREPAREDNESS AND RESPONSE

Clearly, the most significant changes imposed on public health laboratory services this decade, and the major impetus for creating State Public Health Laboratory Systems, have resulted from the anthrax attacks in 2001, the fear of pandemic avian influenza, the occurrence of natural disasters like the hurricanes of 2005, the impact of large food-borne disease outbreaks, and the recognition of highly publicized emergent infectious diseases. But even before these events occurred, planning for laboratory emergency response capability and capacity had started in earnest as leaders at CDC in the 1990s recognized the need for a national laboratory system[59] and public health laboratory directors

nationwide affirmed the importance of strengthening state and regional laboratory networks.[4] Since then, several federal initiatives have provided the funding to augment the ability of state and local public health laboratories to respond to accidental, deliberate, or naturally occurring emergencies.

Laboratory Response Network (LRN)

Founded in 1999 by CDC, in collaboration with APHL and the Federal Bureau of Investigation (FBI), the LRN is the nation's premier system for identifying, testing and characterizing potential agents of biological and chemical terrorism.[60] The LRN was initially structured to test only human clinical specimens for agents of biological terrorism. However, in 2001 more than one million anthrax tests were performed by the LRN on a wide variety of samples that were both clinical and environmental. Since then, the LRN has continued to evolve and expand. In 2003, the capability to detect chemical terrorism agents in human clinical specimens was added. The LRN now provides essential support for several surveillance activities, which include the nation's Biowatch program and the United States Postal Service's (USPS) Biohazard Detection System (BDS). The LRN is comprised of state and local public health, agricultural, military, food testing, veterinary and environmental laboratories. In addition, its operational partnership includes seven governmental agencies and professional organizations. By means of the Cooperative Agreement on Public Health Preparedness and Response for Bioterrorism, now called the Public Health Emergency Preparedness (PHEP) Cooperative Agreement, CDC funded equipment and personnel for state and some local public health laboratories, as well as the necessary supplies needed to support the specific tests developed for the

LRN. This funding enables these state and local public health laboratories to fulfill their LRN Reference laboratory functions.[61]

The LRN has two primary groups in place that contribute to development of the network: (1) the Joint Leadership Committee, which oversees key strategic planning for the LRN, is comprised of representatives from APHL's membership, the CDC/Coordinating Office of Terrorism Preparedness and Emergency Response, CDC/Division of Bioterrorism Preparedness and Response, CDC/National Center of Environmental Health, and Federal Bureau of Investigation; (2) The LRN Partners Working Group, comprised of several federal agencies and scientific organizations, is responsible for discussing issues surrounding and affecting the network and its members. Key issues include preparedness regulations, emerging technologies, and federal, state, and local coordination.

In 2006, APHL began working with EPA to develop an environmental arm of the LRN, the Environmental Response Laboratory Network (ERLN), which will include equipment standards, testing protocols, and training modules for the detection of biological, chemical and radiological agents in air, water and soil. The volume of testing of environmental samples is continually increasing as PHLs are asked to test letters and packages, powders, drinking water, medications, and supplements, among other things. Requests come from post-offices, law enforcement, state officials, first responders, civilian defense agencies, and other laboratories.

Bioterrorism

- *Bioterrorism Preparedness.* The biological component of the LRN has a three-tiered structure made up of: 1) sentinel laboratories that represent the thousands of mostly hospital-based laboratories located at the front line whose responsibility is to rule-out or refer suspicious agents, 2) reference laboratories that perform specialized tests to detect and confirm the presence of threat agents, and 3) national laboratories that have special resources to identify specific threat agents and perform more complex testing for strain characterization. The LRN reference laboratories include more than 160 state and local public health, military, veterinary, environmental, agricultural, food, and water testing laboratories. APHL, the American Society for Microbiology and CDC have provided guidance on the development of standard microbiology protocols to assist LRN sentinel laboratories in detecting suspected bioterrorism agents, and for referring agents they are unable to rule-out to the LRN reference laboratories. CDC, in collaboration with APHL and other partners, has provided standard protocols, training and proficiency testing to assist LRN reference laboratories in testing for bioterrorism agents.
- *Outreach Activity.* As LRN reference laboratories, PHLs have an obligation to prepare the sentinel clinical laboratories for their role in the LRN. PHLs collaborate with partners to provide activities such as wet workshops, drills and exercises and other trainings. APHL works with the College of American Pathologists to offer a robust preparedness testing exercise to test the LRN notification system and the sentinel-reference laboratory relationship.

- *Bioterrorism Capacity.* In 2005, APHL published an issue brief on bioterrorism capacity[62] which contained data on federal funding for public health laboratories. This brief included information based on a 2004 APHL survey assessing capacity and capability of LRN reference laboratories to respond to threats. Data indicated that federal funds have improved public health infrastructure and enhanced the capability of PHLs to detect and respond to acts of terrorism as well as naturally occurring infectious disease outbreaks. Recent assessments of state public health laboratories have shown that although federal funding has improved the capabilities of SPHLs to assume new responsibilities in dealing with bioterrorism, emerging diseases, and all-hazard threats, continued reductions in federal funding, competing priorities, workforce shortages, incompatible computer and information systems, and aging facilities present major challenges.[63]

Chemical Terrorism

- *Chemical Terrorism Preparedness.* Federal funding to improve chemical terrorism response capabilities in all SPHLs has only been available since 2003. The chemical LRN (LRN-C) consists of three levels of member laboratories. Many territorial, city and county, and all state PHLs have LRN-C Level 3 capabilities. These laboratories work with first responders and first receivers in their jurisdiction to promote proper specimen collection and shipping practices using approved chain-of-custody procedures. They provide training in recognition of chemical exposure and common chemical agents, and they work

to develop a coordinated response plan for their jurisdictions. Approximately two-thirds of SPHLs are recognized as Level 2 laboratories. These facilities are capable of detecting a limited number of toxic chemical agents in blood or serum. Ten SPHLs are characterized as Level 1 laboratories, which can detect an expanded number of chemicals such as mustard and nerve agents. These level 1 laboratories function as national surge capacity assets to help CDC test human samples during large-scale emergencies.

- *Chemical Terrorism Capacity.* In the summer of 2002, APHL began a chemical terrorism project to assess national laboratory readiness for a chemical terrorism attack. The study, which involved site visits and a workshop to develop consensus recommendations from the 50 states, two territories and the District of Columbia, unveiled significant gaps in preparedness for a chemical attack. As a result of this study, APHL published a comprehensive report in July 2003, *"Ready or Not: Findings and Recommendations of the APHL Chemical Terrorism Project"*, calling for a more integrated Laboratory Response Network capable of responding to all-hazard threats.[64] Following the 2002 study, APHL conducted subsequent Chemical Terrorism Laboratory Preparedness Surveys in 2004, 2005 and 2006. In 2007, APHL combined their chemical and biological terrorism preparedness assessments and launched the first ever, All-Hazards Laboratory Preparedness Survey. The 2007 All-hazards assessment demonstrated that SPHLs had made significant progress in chemical terrorism preparedness, especially in coordination with other state and federal agencies.[65]

Radiological Terrorism

Radiological Terrorism Preparedness. There is a need to improve radioanalytical capabilities. Laboratory directors realize that the identification, analysis, and characterization of radiological contaminants are a key to all-hazards preparedness. A radiological component of the LRN (LRN-R) has been proposed, and CDC is currently working to develop this program. EPA plans to include radiation detection as part of the developing ERLN.

Food Emergency Response Network (FERN)

FERN was created in response to Homeland Security Presidential Directive 9 in 2004. It is coordinated by HHS/FDA and USDA/FSIS. The network includes biological, chemical, and radiological components and collaborates with CDC where FERN activities intersect with those of the Laboratory Response Network. Training of laboratorians in state, federal, and local laboratories is a major focus, and proficiency testing challenges are distributed to FERN member laboratories through the federal partners. Cooperative agreement funding has been allocated from both USDA/FSIS and HHS/FDA to network laboratories for equipment, validation studies, special projects, and other needs. Communication among network laboratories is via a secure web portal called eLexnet. eLexnet houses protocols, reagent information, and announcements of training opportunities in addition to allowing for the reporting of results from tests performed on food samples. Over 180 laboratories in all 50 states are FERN members, including state, local, and federal laboratories performing chemical (98 labs), microbiologic (114 labs), and radiologic (32 labs) methods.

Continuity of Operations Plan (COOP)

In preparing for emergencies, SPHLs must be able to function in the event that their facility is incapacitated by power outages, equipment failures, failed communication systems, supply chain disruptions or building damage due to natural disasters such as flooding or hurricanes. A continuity of operations plan (COOP) includes all procedures, policies, and logistics necessary to ensure an effective response to such an emergency. Laboratories must establish a list of vital testing and support activities, and develop an action plan to assure the continuation of these activities in a timely manner. SPHLs must identify alternative laboratories and make arrangements for supplies and equipment at these alternative workstations to perform testing and to provide training and regular exercises. Plans must be reviewed on an ongoing basis. At the 2007 APHL annual meeting, guidelines for developing a laboratory COOP were presented.[66] As might be anticipated, creating and maintaining a COOP requires continual vigilance and assessment. Other strategies required in an effective COOP include the ability to respond to a sudden demand for specific testing, such as receipt of large numbers of unknown white powders in the event of an anthrax threat. To respond to such requests, the laboratory's surge capacity must be predetermined. In such an event, the PHL plan may be to reassign personnel, to send other testing to a partner laboratory, or to postpone routine surveillance testing. For example, when Hurricane Katrina devastated the Gulf Coast in 2005, the Louisiana SPHL contracted with the Iowa Hygienic Laboratory at the University of Iowa to process newborn screening samples from Louisiana.

Enhanced Emergency Response Capabilities

Since 1999, emergency preparedness and response funding through the CDC/APHL Cooperative Agreement and other funding streams has supported surveillance and detection of agents associated with bioterrorism. Comparable funding for chemical terrorism preparedness became available in 2003. This infusion of federal funding has served a dual-use purpose for public health laboratories by enhancing their capabilities for early detection, enhanced interventions, and improved communications in addressing nationwide, regional and local public health emergencies and outbreaks that otherwise would not have been possible or greatly diminished. Major events that benefited from improved public health laboratory responses in recent years include pertussis and mumps resurgence, the *E. coli* 0157:H7 spinach contamination, periodic outbreaks of norovirus and responses to local disasters such as the massive accidental propane explosion at a local manufacturing facility near downtown Milwaukee as well as the laboratory emergency response that occurred with Hurricane Katrina.

Since the inception of the Laboratory Response Network in 1999, and the subsequent work on the LRN-C, ELRN and FERN, it is clear that a very robust laboratory response to an act of biological or chemical terrorism is possible now, where it would not have been before. 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 State Public Health Laboratory System activities. All components of emergency preparedness must work together to assure an effective response to any impending public health crisis.

CFC 9- Public Health Related Research

From the time that state and local public health laboratories (PHLs) were first established in the U.S. in the latter half of the nineteenth century, they have engaged in research and development to improve the reliability of laboratory services for disease prevention and control. As breakthroughs in laboratory science increasingly provide a larger array of scientific and technological options, PHLs continue to contribute to method development and the application of laboratory methods to public health surveillance and prevention. PHLs must also assure that accurate and vital scientific data are available in response to new public health threats. Research in PHLs is predominantly “applied” or “activity-driven”, such as in response to an outbreak, rather than “basic” or “hypothesis-oriented”. PHLs are often involved in studies of new and improved analytic methods and services that are necessary to meet changing public health surveillance activities and environmental regulatory requirements. However, in recent years, the emergence of molecular methods and technologies has engaged many PHLs in scientific studies, often in association with federal agencies, academic researchers, industry associates, and private clinical and environmental laboratory partners. At the SPH Laboratory System level, PHLs may engage in systems research to improve the effectiveness of laboratory reporting by investigating: weaknesses in information systems; preanalytic, analytic, and postanalytic deficiencies; and other quality assurance issues. Research efforts in PHLs are funded from a variety of sources: state and municipal tax support; federal grants; and contracts with industry and other private sources. In a relational sense, many of the

activities of PHLs and SPH Laboratory Systems can be considered as applied research, since laboratory data often supports epidemiological investigations, disease surveillance, and other ongoing public health studies, both statewide and nationally.

The scope of public health-related laboratory research encompasses all 11 core functions of PHLs. In the preceding sections of this monograph, examples of ongoing research are cited in environmental health, food safety, and emergency response. The following paragraphs provide a few examples of laboratory system disease surveillance research.

Newborn Screening (NBS) As primary providers of NBS testing in the U.S., SPHLs have been at the forefront of exploring and implementing new procedures, which have added the potential to test for a much larger number of disorders. Research into biochemical, instrumental, and molecular sciences by SPHLs has enabled these procedures to be standardized and controlled relative to their sensitivity and specificity. For example, studies conducted in SPHLs showed that testing for thyroid-stimulating hormone (TSH) by immunochemistry was more reliable than using thyroxine levels as the primary procedure for detecting hypothyroidism. When cystic fibrosis (CF) 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 CF mutation.[67] Later, the number of mutant CF alleles for which screening was available was expanded. In the late 1990s, the introduction of tandem mass spectrometry technology allowed for the routine testing for three classes of metabolic disorders: fatty acid oxidation, organic acidemias, and aminoacidopathies.

SPHLs have also carried out extensive applied research on the conduct of NBS programs by examining such aspects as: elution of cellular contents and serum from dried blood spots; sample storage reliability; quality assurance; and issues unique to follow-up laboratory testing. The provision and standardization of NBS programs in the U.S. has involved state health departments, CDC, the Maternal and Child Health Bureau of the Health Resources and Service Administration (HRSA), many professional societies and organizations, including the American College of Medical Genetics, the Coalition of State Genetic Coordinators, and the March of Dimes. The APHL Newborn Screening and Genetics in Public Health Committee has provided leadership by developing position statements, presenting national symposia,[68] and initiating web conferences.[69] As NBS has evolved, state programs have been faced with difficult questions regarding whether testing should include population screening for genetic susceptibility to common diseases or carrier status.[70] NBS as a program will continue to face difficult practical as well as bioethical decisions that have resulted from the explosion in molecular science and technology. Despite on-going challenges, the successes and lives saved continue to validate the importance of these programs.

Communicable Disease Control SPHLs 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 tuberculosis was based on the standard smear for acid-fast bacilli (AFB) and cultures on solid media for isolation and drug-susceptibility testing.[71] However,

results of culture are usually not available for several weeks. SPHLs have collaborated in research on the use of fluorochrome stains for AFB-smear identification, automated broth systems for culture, molecular methods (DNA probes) for the identification and genotyping of *M. tuberculosis* and the use of nucleic acid amplification (NAA-TB) in smear-positive patients. As a result of these collaborations by public health laboratories, CDC has developed and revised guidelines for more rapid processing and reporting of results that include microscopy, culture, and NAA technology.[72]

As examples of systems research in April 2003, Washington State completed a survey of clinical laboratories to understand the factors that were preventing full implementation of MMWR guidelines for screening women to detect Group B Streptococcus colonization, which can be life-threatening if passed to neonates during vaginal delivery. Problematic areas included: obtaining both a vaginal and a rectal specimen, informing physicians when improper specimens were submitted for analysis, and initiating antimicrobial susceptibility testing (AST) for penicillin (PCN) allergic patients. The results were used to help Washington and the CDC to understand the magnitude of the problems, elicit the underlying causes (primarily communication), and design solutions. In 2008, Wisconsin collaborated with the CDC to create a model approach for all states to use to identify clinical laboratories that perform influenza testing. Clinical laboratories that disclosed that they perform influenza testing were asked which CPT codes they used to request reimbursement from the Centers for Medicare and Medicaid Services. It was determined that although this approach could miss some laboratories that were not requesting CPT-coded reimbursement, it was nevertheless an important way to help states to identify

additional clinical laboratories, which would be critically important for preparing for, and responding to, pandemic influenza.

Although the state public health laboratory systems have historically been involved in applied research particularly as it relates to methodology and surveillance, more recently there have been closer relationships developed with academia and the opportunity for greater contributions to both basic and translational research activities. Furthermore the area of public policy and systems research is now extending into the areas of laboratory practice and outcomes.

CFC 10- TRAINING AND EDUCATION

The workforce for the SPH Laboratory System is composed of a variety of scientists, including chemists, microbiologists, medical technologists, radiation physicists, molecular biologists, forensic scientists, as well as computer specialists, managers, and service personnel. In the U.S., critical shortages of personnel in clinical and public health laboratories have caused concern among laboratory directors. Several societies and agencies have identified reasons for these shortages.[73] Clinical laboratories have been facing the scaling back or closure of medical technology (clinical laboratory science) programs, as hospitals have eliminated such programs as a cost-savings measure. Public health laboratories have had difficulty recruiting college science graduates, who are often lured into graduate research, fellowships, science industry jobs, and new biotechnology companies. Other challenges to the SPH Laboratory System workforce may include aging

of the workforce, difficulties retaining competent staff, unattractive salary differentials, requirements for credentials in some states, closure of laboratory science-based academic programs, and requirements for continuing education. Many clinical and public health laboratory professional organizations have assessed these workforce challenges with surveys that have resulted in policy initiatives.[74] Public health agencies and professional societies are also taking additional measures to address the task of maintaining the skills of the current workforce, while building "the pipeline" to ensure a workforce ready to meet future challenges.[75] In particular, the Coordinating Council on the Clinical Laboratory Workforce is coordinating the interests and efforts of many laboratory stakeholder organizations.[76]

- *Continuing Education* Traditionally, continuing education in laboratory science has been offered by professional societies and academic institutions. As meeting costs escalated and clinical and public health laboratories budgets decreased, 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 public health laboratory practice has been the National Laboratory Training Network (NLTN), a collaborative effort between APHL and CDC.[77] Since its inception in 1989, the NLTN has offered more than 4,500 courses reaching well over 275,000 public health and clinical laboratorians. NLTN is staffed by laboratory specialists who collaborate with SPHL personnel and CDC educational specialists and subject-matter experts to provide cost-effective training in a variety of formats. NLTN offers a number of

training products such as teleconferences, web conferences, on-demand programs, traditional lecture-based seminars and four-to-five day hands-on laboratory workshops. Courses are developed to respond to current demands for training. In 2006, 2007, and 2008 teleconferences were presented on well over 100 topics, including bioterrorism preparedness, influenza pandemic planning, quantitative PCR, fungal molecular diagnostics.[78] In the summers of 2007 and 2008, more than 40 hands-on laboratory workshops were presented, including two held at CDC on advanced diagnostic mycobacteriology. These hands-on workshops are critically important for public health laboratorians to update and maintain their technical knowledge and skills.

- *Fellowships* As college students complete their undergraduate and graduate educations, their careers may be determined by the availability of competitive fellowships and internships. APHL now provides such opportunities with programs made available through CDC funding.[79] The Emerging Infectious Diseases (EID) laboratory fellowship program, sponsored by APHL and CDC prepares scientists for careers in public health laboratories. The EID Laboratory Training Fellowship is a one-year program designed for bachelors- or masters-level scientists. The EID Laboratory Research Fellowship is a two-year program for doctoral-level scientists, with an emphasis on research. After orientation at CDC, about half of the fellows are placed in local or state public health laboratories and half are stationed at federal (CDC) public health laboratories for their training. The Environmental Health Traineeship offers a similar experience

with specialized training in environmental health laboratory practice in a state laboratory setting.[80]

- *Internships*. Public health laboratories often provide practical experience for undergraduate students and working professionals to gain experience in specific areas of public health laboratory science. For undergraduates, such training may consist of laboratory-bench experience lasting weeks or months as part of a formal laboratory degree program. For professionals in the field, an internship may be requested in certain specialty areas or to develop expertise in newer technologies.

- *Leadership Training.* Management positions in clinical, environmental and public health laboratories are often necessarily filled by scientists who have had little formal education in management. Often, they have no experience in personnel management, budgeting, or systems operation. In response to the impending management void caused by retirements of state and local PHL directors and administrators, APHL launched the National Center for Public Health Laboratory Leadership in 2002.[81] The Center provides information, training, and technical assistance to PHL professionals and works with health organizations in the public and private sectors and with government decision-makers to expand knowledge and awareness of public health issues. The Center also offers an orientation for new directors, and it conducts forums and skill building workshops in areas such as risk and media communication, grant writing,

change management, strategic planning and legislative policy. In 2005, supported by a grant from the Robert Wood Johnson Foundation, the Center began to address the imminent leadership crisis in PHLs nationwide. The Center also convened regional forums to draft a research agenda and identify best practices to address major challenges facing PHL leadership.[82] Another focus of the Center was to develop a leadership recruitment toolkit as a means to cultivate leaders in their management of U.S. public health laboratories. The toolkit provides information on personnel standards, the core academic and professional courses required for PHL practice, criteria for graduate programs in PHL practice for current PHL personnel, recruitment and retention strategies, and salary benchmarks. In 2006-2007, the Center published a "Practical Guide for Public Health Laboratory Leaders" to guide leaders in their first 100 days on the job.[83]

- *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 most cases, activities were executed in collaboration with partners that included WHO, CDC, the Canadian PHL Network, regional health organizations, academic institutions, professional organizations and corporations. In 2006, APHL initiated efforts on four continents and 17 countries, from Haiti to Kenya to Vietnam.[84] In Kenya, supervisors from Kenya, Uganda, Namibia, and Tanzania learned managerial methods to improve laboratory practice and to begin strategic planning. In Mozambique, technical training was provided to implement quality

testing to support anti-retroviral therapy in more than 30 laboratory sites.[85] A two-week course was offered by APHL and the George Washington University School of Public Health and Health Services, entitled "The George Washington University-APHL International Institute for Public Health Laboratory Management." Many directors and staff from several public health laboratories generously contributed their time, effort, and expertise to assist other countries in improving their national PHL capabilities. For these individuals and for others in the PHL system, there is recognition that disease control and prevention is not confined to one country or continent, but that we are all linked in efforts to successfully contain man-made or naturally occurring disease threats.

CFC 11- Partnerships and Communication

In the 21st Century, State Public Health Laboratories (SPHLs) 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 SPHLs have established, while others are just developing partnerships with other laboratory entities within their jurisdictions and linking these facilities to national health agencies such as CDC and EPA. Efforts to create truly comprehensive SPH Laboratory Systems go beyond the traditional partnerships to include emergency response leaders, law enforcement, health care institutions, academia, and private industry and to develop a system that addresses the 10 Essential Services of Public Health and the 11 Core Functions of State Public Health Laboratories.[1] As described in the Introduction, the systems of which SPHLs are a part are comprised of

1332 those who initiate public health testing, those who perform the analyses and those who
1333 use the information generated. This approach of broad inclusivity is consistent with, and
1334 underpins, the goals of the National Laboratory System. While systems may consist of
1335 different partners within each state, to assure inclusion and connection with all partners
1336 the SPHL should, at a minimum, employ a Laboratory Program Advisor and have a
1337 standing Laboratory Advisory Committee (LAC).[86] A LAC is a
1338 multidisciplinary committee established by the state public health laboratory. Other terms
1339 used to identify this entity include Laboratory Advisory Council and Clinical Technical
1340 Advisory Group. The main goals of a LAC are to foster communication and collaboration
1341 and to provide the SPHL with advice from key supporters and constituents.[87]
1342 *State Systems.* State laboratory-based disease control programs have been in existence
1343 for many years. Creation of comprehensive public health laboratory systems is a more
1344 recent initiative, with all 50 states at some level of development. A new program that
1345 measures progress in laboratory system development is the Laboratory System
1346 Improvement Program (L-SIP).[8] L-SIP affords states the opportunity to measure progress
1347 in meeting standards and creating an effective public health laboratory system. As states
1348 go through their first L-SIP assessment with multiple partners, awareness of system
1349 benefits inspire partners and strengthen the system. As stakeholders continue to enhance
1350 various components of the system, their efforts help identify the resources needed to
1351 assure sustainability and improvement of the system. In addition, the results will help
1352 guide APHL in its future activities for continuous public health laboratory systems
1353 improvement. In coming years, as systems mature, lessons learned about partnerships,
1354 system development, quality improvement, visibility of the SPH Laboratory System,

participation by different system sectors, political issues, marketing, data collection – all will help to promote and refine the concept of the National Laboratory System (NLS) and SPH Laboratory Systems throughout the U.S.[11]

Communication Modalities Many PHLs provide information to other public and private laboratories and to other partners by means of newsletters or electronic messaging. These communications may notify users about changes in policies or procedures or give important disease updates. For example, the Tennessee SPHL used an on-line newsletter, to describe a state law requiring clinical laboratories to refer cultures of specific organisms to the Department of Health. The publication also provided news about *H influenzae* vaccine shortfalls and benefits of a new trace metal analyzer. For first responders and HazMat Team members, sample collection and transport methods are described, along with information about regional Laboratory Response Network laboratories. State and local public health laboratory websites also serve as sources of information about current public health laboratory issues. LACs may also function to enhance communication channels.

State Public Health Laboratory Directors and key members of their staff receive media training to help them understand how information can be communicated effectively, especially in a crisis. State and local PHLs often work closely with their agency Pubic Information Officers (PIOs) as they formulate and interpret scientific data and results for public consumption and awareness. Public health messaging related to laboratory results or requiring laboratory knowledge may require laboratory subject matter experts to

participate in interviews and press conferences. Topics may range from public health emergencies or incidents to prevention, intervention and education.

Relationship Building. For one-to-one personal linkages, many SPHLs now employ a Laboratory Program Advisor (LPA), especially for enhancing the response of the SPH Laboratory System to communicable diseases and other public health emergencies. This individual implements strategies to build relationships with system partners and resolve problems in the statewide laboratory system for public health. Another task is to maintain information on the capabilities and capacities of other in-state laboratories and to engage these facilities in the mission of the SPH Laboratory System. The LPA also establishes relationships with academia, medical and public health partners, and other agencies that could be involved in a public health or emergency response. An important function of the LPA is to provide or facilitate training for System partners and to promote meetings of the system laboratories. The LPA also facilitates the work of the state's Laboratory Advisory Committee.

State and some local infectious disease laboratory networks have been organized by PHLs to standardize methodologies and information exchange for surveillance purposes. Examples include networks of virology and TB laboratories in Wisconsin that provide monthly data and information statewide through the SPHL.[71] The City of Milwaukee Public Health Laboratory coordinates local clinical microbiology laboratories reporting for disease surveillance, public health emergencies, and local disease trends.

National Linkages There are a number of linkages between the SPH Laboratory System, the NLS and other federal programs. SPHLs serve as data sources for a number of national surveillance programs such as FoodNet, the Arbovirus Surveillance (ArboNet), CaliciNet, PulseNet, and the Influenza Surveillance Network. In addition to reporting directly to these national surveillance programs, SPHLs also maintain strong connections with state and county health officials, state epidemiologists, STD 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 and departments that may have national linkages. Many of these record systems allow program directors, legislators, and state budget developers to appreciate the magnitude of disease prevalence and the effectiveness of programs designed to control health care discrepancies and emergencies

Clearly, in the first decade of the 21st Century, SPH Laboratory Systems have laid the groundwork for development of multiple networks that, as they evolve, will become the backbone of disease control efforts. Local, state and national linkages collectively bring the State Public Health Laboratory Systems into a "National Laboratory System" - a collaboration between public and private partners to prepare for and respond to public health threats.

Future of the State Public Health Laboratory System

There are many incentives and stimuli for State Public Health Laboratories (SPHL) to develop strong SPH Laboratory Systems. CDC has made the development of a National Laboratory System (NLS) a major focus. Congress has allocated considerable resources for homeland security, which includes measures to prevent or contain bioterrorism and chemical and radiological terrorism. The American public is demanding a better national response to naturally occurring disasters such as hurricane Katrina and man-made health threats such as the 2006 contaminated spinach outbreak. 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 health care system in the U.S. requires that the impetus for developing successful public health laboratory systems must come from the SPHLs. The cost of developing a fully integrated, mature system is unknown and all SPHLs face customary budget constraints and competing priorities. How many resources should be allocated for manpower, electronic networking, partner meetings, and laboratory training? There are many other unknowns, including state and municipal budgetary shortfalls as a result of periodic economic downturns, as well as other competing priorities in health departments.

The SPH Laboratory System may benefit from new interest in public health services and systems research. An editorial in the American Journal of Preventive Medicine by FD Scutchfield and colleagues[88] describes the brief history of public health systems research (PHSR) and the pivotal role of CDC since the release of the 1988 Institute of Medicine

report, *The Future of Public Health*.[89] The CDC response to this report included the development of the Public Health Practice and Program Office to stimulate efforts to improve delivery of public health services. Scutchfield also points out that Chapter 23 in Healthy People 2010 lists objectives for developing public health infrastructure. Many investigators are now proposing that an understanding of the complex systems involved in both causing and solving public health problems is required to improve public health. SJ Leischow and collaborators note that systems thinking perspectives shared across different disciplines of human enterprise may allow team members representing different fields of endeavor to overcome challenges.[90] They suggest that improving public health will require new approaches to team science that have a trans-disciplinary orientation.

Success in developing and maturing SPH Laboratory Systems throughout the U.S. will depend on strong leadership at the national level primarily by CDC, at the organizational level by APHL, and at the state level by the SPHL. States with large SPHLs and more resources clearly have an advantage since they generally have greater latitude in allocating personnel and communication expertise to sustaining 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 successful SPH Laboratory Systems 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 the SPH Laboratory System Improvement Program has defined the required components, competencies, and capacities of state and local public health laboratory systems at a “Gold Standard” level. Performance standards assessments

allow participants to determine the strengths and weaknesses of the individual system. As noted in the User's Guide,[8] information gathered at the assessment meetings can help to improve and better coordinate public health laboratory 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 public health laboratory practice and response.

Acknowledgements

This article was the collaborative effort of many dedicated public health professionals, including staff of the Association of Public Health Laboratories, chairs of APHL committees, and colleagues at the Centers for Disease Control and Prevention. This publication was supported by Cooperative Agreement Number CCU303019 from the Centers for Disease Control and Prevention (CDC). The findings and conclusions in this report are those of the author(s) and do not necessarily represent the official position of the Centers for Disease Control and Prevention/the Agency for Toxic Substances and Disease Registry.

References

1. Association of Public Health Laboratories. Core Functions and Capabilities of State Public Health Laboratories. Silver Spring, MD: Association of Public Health Laboratories; 2000:1-13.
2. Baker EL, Melton RJ, Stange PV et al. Health reform and the health of the public. JAMA 1994;272(16):1276-1282.
3. Witt-Kushner J, Astles JR, Ridderhof JC, et al. Core functions and capabilities of state public health laboratories: a report of the Association of Public Health Laboratories. MMWR 2002;51(RR14):1-8.
4. Centers for Disease Control and Prevention. Toward a National Laboratory System for Public Health. Atlanta, GA: Centers for Disease Control and Prevention. Available at: http://www.cdc.gov/ncidod/eid/vol7no3_supp/skeels.htm Accessed January 19, 2009.
5. Association of Public Health Laboratories. Building a National Laboratory System. Silver Spring, MD: Association of Public Health Laboratories. Available at: http://www.aphl.org/aphlprograms/lss/projects/publicprivate/nlsp2004/Documents/lab_systems_3-06.pdf Accessed January 21, 2009.
6. Centers for Disease Control and Prevention. National Public Health Performance Standards Program Atlanta, GA: Centers for Disease Control and Prevention. Available at: http://www.cdc.gov/od/ocphp/nphpsp Accessed January 19, 2009.

7. Association of Maternal and Child Health Programs. Capacity Assessment for State Title V (CAST-5) Washington, DC: Association of Maternal and Child Health Programs. Available at: http://www.amchp.org/MCH-Topics/A-G/CAST5/Pages/default.aspx Accessed January 19, 2009.
8. Association of Public Health Laboratories. Promoting System Improvement. Silver Spring, MD: Association of Public Health Laboratories. Available at: http://www.aphl.org/aphlprograms/lss/projects/performance/Pages/default.aspx Accessed January 19, 2009.
9. US Department of Health and Human Services. Healthy People 2010. Conference edition, in two volumes. Washington, DC: US Department of Health and Human Services; 2000.
10. Inhorn SL, Wilcke BW, Downes FP, et al. A comprehensive laboratory services survey. J Public Health Manag Pract. 2006;12(6):514-521.
11. Association of Public Health Laboratories. Definition of a State Public Health Laboratory System. Silver Spring, MD: Association of Public Health Laboratories. Available at: http://www.aphl.org/aphlprograms/lss/proj/performance/Documents/LSpdf0607_definition.pdf Accessed January 21, 2009.
12. Association of Public Health Laboratories. Assessing America's Local Public Health Laboratory Capacity. Silver Spring, MD: Association of Public Health Laboratories. Available at: http://www.aphl.org/AboutAPHL/publications/Documents/Assessing_Americas_Local_PHL_Capacity.pdf Accessed February 4, 2009.

13. Centers for Disease Control and Prevention, Council of State and Territorial Epidemiologists, and the Association of State and Territorial Chronic Disease Program Directors. Indicators for chronic disease surveillance. MMWR 2004;53(RR11):1-6. Available at: http://cdc.gov/mmwr/preview/mmwrhtml/rr5311a1.htm Accessed February 6, 2009.
14. Ritz B, Tager I, Balmes J. Can lessons learned from public health disease surveillance be applied to environmental public health tracking. Environ Health Perspect. 2005;113(3):243-249.
15. Association of Public Health Laboratories. Public Health Laboratories and Newborn Screening. Silver Spring, MD: Association of Public Health Laboratories. Available at: http://www.aphl.org/aphlprograms/nsg/Pages/PublicHealthLaboratoriesandNewbornScreening.aspx Accessed February 6, 2009.
16. Association of Public Health Laboratories. Public Health Laboratory Interoperability Project (PHLIP). Silver Spring, MD: Association of Public Health Laboratories. Available at: http://www.aphl.org/AboutAPHL/publications/Documents/PHLIP_05_07.pdf Accessed January 19, 2009.
17. Centers for Disease Control and Prevention. National Respiratory and Enteric Virus Surveillance System (NREVSS). Available at http://www.cdc.gov/surveillance/nrevss/ Accessed February 6, 2009.

18. US Environmental Protection Agency. Laboratory Certification Program Available at http://www.epa.gov/safewater/methods/laboratorycertification.html Accessed February 9, 2009. US Environmental Protection Agency. Drinking Water Standards –Available at: http://www.epa.gov/OGWDW/standards.html Accessed January 14, 2008.
19. US Environmental Protection Agency. Drinking Water Contaminant Candidate List and Regulatory Determinations. Available at: http://www.epa.gov/safewater/ccl/basicinformation.html Accessed February 6,2009.
20. Standridge J. Protecting the waters of Wisconsin from microbiological threats. Wisc Med J 2003;102:76-78.
21. Centers for Disease Control and Protection, Environmental Protection Agency, Council of State and Territorial Epidemiologists. Surveillance for waterborne disease outbreaks associated with recreational water, drinking water, and water not intended for drinking – United States, 2003-2004. MMWR 2006;55(NoSS-12).
22. .Schauer JJ, Lough GC, Sonzogni WC. Outdoor air pollution activities at the Wisconsin State Laboratory of Hygiene. Wisc Med J 2003;102:84-88.
23. Centers for Disease Control and Prevention. Third National Report on Human Exposure to Environmental Chemicals. Atlanta, GA. Centers for Disease Control and Prevention: 2006. Available at: http://www.cdc.gov/exposurereport/report.htm Accessed February 6, 2009.

24. Centers for Disease Control and Prevention. CDC's Environmental Public Health Tracking Program: National Network Implementation Plan (NNIP). Atlanta, GA. Centers for Disease Control and Prevention: 2006. Available at: http://www.cdc.gov/nceh/tracking/pdfs/nnip.pdf Accessed February6, 2009.
25. Brody JG, Morella-Frosch R, Brown P, et al: "Is it safe?' New ethics for reporting personal exposure to environmental chemicals. Am J Public Health 2007;97:1547-1554.
26. Centers for Disease Control and Prevention. Interpreting and managing blood lead levels < 10 μg/dL in children and reducing childhood exposures to lead. MMWR 2007;56(No. RR-8):1-16.
27. Burk TL, Loughrin JT, Powell CJ, Knight JJ. Occupational and industrial health at the Wisconsin State Laboratory of Hygiene. Wisc Med J 2003;102:71-75.
28. New York State Hazardous Waste Management Available at http://www.dec.ny.gov/chemical/8486.html Accessed February 6, 2009.
29. US Environmental Protection Agency. Wastewater Management Available at http://www.epa.gov/OW-OWM.html Accessed February 7, 2009.
30. Eaton AL, Clescari, Rice, EW, Greenberg AE, eds. Standard Methods for the Examination of Water and Wastewater, 21st Ed. American Public Health Association 2005. 800 I Street MW, Washington, DC.
31. Centers for Disease Control and Prevention. Surveillance for Foodborne –Disease Outbreaks – United States; Surveillance Summaries, 1998-2002. MMWR 2006;55 (No. SS-10);1-34. Also available at:

http://www.cdc.gov/mmwr/preview/mmwrhtml/ss5510a1.htm Accessed February 7, 2009.

32. Allos BM, Moore MR, Griffin PM, Tauxe RV. Surveillance for sporadic foodborne disease in the 21st century: the FoodNet Perspective. Chronic Infect Dis 2004;38(Suppl 3):S115-S120.

33. National Association of County & City Health Officials. Council to Improve Foodborne Outbreak Response Available at http://www.naccho.org/topics/environmental/foodsafety/cifor.cfm Accessed February 7, 2009.

34. US Department of Homeland Security. FoodSHIELD Available at http://foodshield.org Accessed October 18, 2008.

35. Association of Public Health Laboratories. A Recipe for Stronger Food Safety Testing Programs. Available at: http://aphl.org/Documents/Global_docs/food_safety_report.pdf Accessed February 7, 2009.

36. National Environmental Health Association. Epi-Ready Team Training Program Available at http://www.neha.org/epi_ready/index.html Accessed February 7, 2009.

37. Association of Public Health Laboratories. State Public Health Laboratory Food Safety Capacity Available at http://www.aphl.org/aphlprograms/food/Documents/food_safety_issue_9_04.pdf Accessed February 7, 2009.

38. Association of Public Health Laboratories Food Safety Capabilities. Available at: http://www.aphl.org/aphlprograms/food/Documents/Food_Safety_Brief_2008.pdf Accessed February 7, 2009.
39. Centers for Disease Control and Prevention. PulseNet. Available at http://www.cdc.gov/pulsenet Accessed February 7, 2009.
40. Association of Public Health Laboratories. From spinach suspicion to Salinas cows: how PulseNet broke the E. coli investigation. The APHL Minute 2006;6:3-5,16-18. Silver Spring, MD: Association of Public Health Laboratories.
41. Food Emergency Response Network FERN Available at http://www.fernlab.org Accessed February 7, 2009.
42. Food and Drug Administration. eLEXNET Training. Available at http://www.fda.gov/ora/training/computer/eLEXNET/default.htm Accessed February 7, 2009.
43. Harding P, LiddicoatLJ. Forensic toxicology program: alcohol and drug testing in Wisconsin drivers. Wisc Med J 2003;102:79-83.
44. Hassemer, DJ. Wisconsin State Laboratory of Hygiene's role in clinical laboratory improvement. Wisc Med J 2003;102;56-59.
45. Centers for Disease Control and Prevention. Newborn Screening Quality Assurance Program. 2006 Annual Summary Report. 2007;24;1-71. Available at: http://www.cdc.gov/labstandards/pdf/nsqap/nsqap_summaryreport_2007.pdf Accessed February 9, 2009.

46. Clinical and Laboratory Standards Institute. About CLSI. Available at http://www.clsi.org/AM/Template.cfm?Section=About_CLSI accessed February 9, 2009.
47. US Environmental Protection Agency. Drinking Water Standards. Available at: http://www.epa.gov/OGWDW/standards.html Accessed January 14, 2008.
48. US Environmental Protection Agency. Clean Air Act Available at http://www.epa.gov/air/caa Accessed February 9, 2009.
49. US Environmental Protection Agency. Laboratory Certification Program. Available at http://www.epa.gov/safewater/methods/laboratory certification.html Accessed February 9, 2009.
50. The NELAC Institute (TNI). TNI Mission. Available at http://www.nelac-institute.org Accessed February 9, 2009.
51. US Environmental Protection Agency. The National Lead Laboratory Accreditation Program (NLLAP). Available at http://www.epa.gov/lead/pubs/nllap.htm Accessed February 9, 2009.
52. US Environmental Protection Agency. Laboratory Quality Assurance Evaluation Program for Analysis of Cryptosporidium Under the Safe Drinking Water Act. Available at http://www.epa.gov/safewater/disinfection/lt2/lab_home.html Accessed February 9, 2009.
53. Centers for Medicare and Medicaid Services. Clinical Laboratory Improvement Amendments (CLIA) Available at http://www.cms.hhs.gov/clia Accessed February 9, 2009.

54. National Select Agent Registry Select Agent Regulations. Available at http://www.selectagent.gov/selagentRegulation.htm Accessed February 9, 2009.
55. US Department of Agriculture. Agricultural Select Agent. Available at http://www.aphis.usda.gov/programs/ag_selectagent Accessed February 9, 2009.
56. Association of Public Health Laboratories. Status of federal public health appropriations. The APHL Minute 2006;6:13. Silver Spring, MD: Association of Public Health Laboratories.
57. Hoffman GL, Laessig RH. Screening newborns for congenital disorders. Wisc Med J 2003:102;45-50.
58. Association of Public Health Laboratories EPR committee meets with congressional staff. Lab Matters 2007;2:14. Silver Spring, MD: Association of Public Health Laboratories.
59. McDade J, Hughes J. The U.S. needs a national laboratory system. U.S. Medicine 1998;34:9.
60. Centers for Disease Control and Prevention. Facts about the Laboratory Response Network. Available at: http://www.bt.cdc.gov/lrn/factsheet.asp Accessed February 10, 2008.
61. Association of Public Health Laboratories. Partnerships for Preparedness. Available at http://www.aphl.org/aphlprograms/ep/Pages/partnerships.aspx Accessed February 10, 2009.
62. Association of Public Health Laboratories. Public Health Laboratory Issues in Brief: Bioterrorism Capacity. April 2005. Available at:

http://www.aphl.org/Documents/Global_docs/bioterrorism_05.pdf Accessed February 10, 2009.

63. Association of Public Health Laboratories. Public Health Laboratory Preparedness: Ready, Set, Respond. Available at http://aphl.org/AboutAPHL/publications/Documents/All_Hazards_2008.pdf Accessed February 10, 2009.

64. Association of Public Health Laboratories. Ready or Not: Chemical Terrorism Project. Available at http://www.aphl.org/aphlprograms/ep/Documents/chemical_terrorism_7-03.pdf Accessed February 10, 2009.

65. Association of Public Health Laboratories. Chemical Terrorism Preparedness in the Nation's State Public Health Laboratories, May 2007. Available at: http://www.aphl.org/aphlprograms/eh/Documents/Chemical_Terrorism_Preparedness_Issue_Brief_2007.pdf Accessed February 12, 2009.

66. Association of Public Health Laboratories. Developing a Laboratory Continuity of Operations Plan. Available at: http://www.aphl.org/aphlprograms/ep/Documents/PHL_COOP_Guidelines.pdf Accessed February 12, 2009.

67. Hoffman GL, Laessig RH. Screening newborns for congenital disorders. Wisc Med J 2003;102:45.50.

68. Association of Public Health Laboratories. 2008 Newborn Screening and Genetics Testing Symposium. Available at

http://www.aphl.org/profdev/conferences/proceedings/Pages/2008APHLNBSGTSymposium.aspx Accessed February 13, 2009.

69. Association of Public Health Laboratories. Public Health Labs and Newborn Screening. Available at http://www.aphl.org/aphlprograms/nsg/Pages/PublicHealthLaboratoriesandNewbornScreening.aspx Accessed February 13, 2009.

70. Khoury MJ, McCabe LL, McCabe ERB. Population screening in the age of genomic medicine. N Engl J Med 2003:348;50-57.

71. Wand P. Laboratory role in tuberculosis control. Wisc Med J 2003;102:31-34.

72. Association of Public Health Laboratories. The Future of TB Laboratory Services. Available at http://www.aphl.org/aphlprograms/infectious/tuberculosis/Documents/tb_task_force_future.pdf Accessed February 13, 2009.

73. US Department of Health and Human Services – Bureau of Health Professions. The Clinical Laboratory Workforce: The Changing Picture of Supply, Demand, Education, and Practice. July 2005. Available at http://bhpr.hrsa.gov/healthworkforce/reports/clinical/default.htm#demand Accessed February 13, 2009.

74. Kibak P. The worsening shortage of lab staff. Clin Lab News 2008;34:1-4. Also available at http://www.aacc.org/publications/cln/2008/may/Pages/cover1_0508.aspx Accessed February 13, 2009.

75. Hilborne L. The Other Big Workforce Shortage. Available at http://www.modernhealthcare.com/apps/pbcs.dll/article?AID=/20080602/SUB/204791857/0/toc02.06.08&nocache=1 Accessed February 13, 2009.

76. Coordinating Council on the Clinical Laboratory Workforce. Strategic Draft Accessed at http://wwwn.cdc.gov/cliac/pdf/Addenda/cliac0208/Addendum%20Q.pdf Accessed February 13, 2009.

77. Association of Public Health Laboratories. National Laboratory Training Network. Available at http://www.aphl.org/member/training/Pages/nltn.aspx Accessed February 13, 2009.

78. Association of Public Health Laboratories. Continuing Education and Training. Available at http://www.aphl.org/pr /training/Pages/default.aspx Accessed February 13, 2009.

79. Association of Public Health Laboratories. Fellowships. Available at http://www.aphl.org/search/Results.aspx?k=Fellowships Accessed February 13, 2009.

80. Association of Public Health Laboratories. Environmental Health Traineeship and Fellowship Programs. Available at http://www.aphl.org/profdev/fellowships/eh/Pages/default.aspx Accessed February 13, 2009.

81. Association of Public Health Laboratories. National Center for Public Health Laboratory Leadership. Available at

http://www.aphl.org/member/training/Pages/centerphl.aspx Accessed February 13, 2009.

82. Association of Public Health Laboratories. Finding Leaders for Public Health Laboratories: A Strategic Plan. Available at http://www.rwjf.org/pr/product.jsp?id=37010 Accessed February 13, 2009.

83. Association of Public Health Laboratories. A Practical Guide for Public Health Laboratory Leaders. Available at http://www.aphl.org/AboutAPHL/publications/Documents/A_Practical_Guide_for_Public_Health_Laboratory_Leaders.pdf Accessed February 13, 2009.

84. Association of Public Health Laboratories. APHL Boosts Kenya's PHL System. Available at http://www.aphl.org/aboutaphl/success/5/Pages/default.aspx Accessed February 13, 2009.

85. Association of Public Health Laboratories. Mozambique. Available at http://www.aphl.org/aphlprograms/global/countries/Pages/mozambique.aspx Accessed February 13, 2009.

86. Association of Public Health Laboratories. APHL Laboratory Partnership Program. Available at http://www.aphl.org/aphlprograms/lss/projects/publicprivate/Pages/default.aspx Accessed February 13, 2009.

87. Association of Public Health Laboratories. Laboratory Advisory Committee. Available at http://www.aphl.org/aphlprograms/lss/projects/lac/pages/default.aspx Accessed February 13, 2009.

88. Scutchfield FD, Marks JS, Perez DJ, Mays GP. Public health services and systems research. Am J Prev Med 2007,33:169-171.

89. Institute of Medicine. The Future of Public Health. Institute of Medicine, Washington, DC. Also available at http://www.iom.edu/CMS/3809/15244.aspx Accessed February 13, 2009.

90. Leischow SJ, Best A, Trochim WM, et al. Systems thinking to improve the public's health. Am J Prev Med 2008;35(2S):S196-S202.