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A Comprehensive Laboratory Services Survey of State Public Health Laboratories

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In November 2004, the Association of Public Health Laboratories (APHL) conducted a Comprehensive Laboratory Services Survey of State Public Health Laboratories (SPHLs) in order to establish the baseline data necessary for Healthy People 2010 Objective 23-13. This objective aims to measure the increase in the proportion of health agencies that provide or assure access to comprehensive laboratory services to support essential public health services. This assessment addressed only SPHLs and served as a baseline to periodically evaluate the level of improvement in the provision of laboratory services over the decade ending 2010. The 2004 survey used selected questions that were identified as key indicators of provision of comprehensive laboratory services. The survey was developed in consultation with the Centers for Disease Control and Prevention National Center for Health Statistics, based on newly developed data sources. Forty-seven states and one territory responded to the survey. The survey was based on the 11 core functions of SPHLs as previously defined by APHL. The range of performance among individual laboratories for the 11 core functions (subobjectives) reflects the challenging issues that have confronted SPHLs in the first half of this decade. APHL is now working on a coordinated effort with other stakeholders to create seamless state and national systems for the provision of laboratory services in support of public health programs. These services are necessary to help face the threats raised by the specter of terrorism, emerging infections, and natural disasters.

KEY WORDS: Healthy People 2010, laboratory systems, services survey

Healthy People 2010 (HP2010)¹ Objective 23-13 reads: Increase the proportion of Tribal, State, and local health agencies that provide or assure comprehensive laboratory services to support essential public health services. In 2001, the Leadership Committee (now the Laboratory Systems and Standards [LSS] Committee) of the Association of Public Health Laboratories (APHL) evaluated the impact of and implementation strategies for Healthy People 2010 objectives on public health laboratory practices and partnerships. The LSS committee developed a plan for collecting data to periodically measure the status of Objective 23-13. The measurement of this objective would serve as a baseline for evaluating accomplishments over the decade ending 2010.

Members of the LSS committee recognized in mid-2001 that there were few databases that could provide meaningful information on the ability of tribal, state, and local health departments to provide comprehensive laboratory services. The problem was determined to be more complex because any evaluation system would require

- defining “assure,”
- defining “comprehensive,”

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- identifying measurement tools or standards to use in establishing the baseline data and progress in meeting this objective, and
- identifying a comprehensive list of tribal, state, and local public health laboratories.

Thus, the committee faced the daunting challenge of evaluating tribal, state, and local health department provision of or access to laboratory services with no established measurement toolbox. The solution required identifying all health departments in the United States and determining what services they provided or assured. At the time of this survey (May 2001), the Association of State and Territorial Health Officials, the National Association of County and City Health Officials, the Centers for Disease Control and Prevention (CDC), and the Health Resources and Service Administration (HRSA) were exploring the use of state and local health department assessment materials, but no appropriate assessment tools for public health laboratories were available for the State Public Health Laboratories (SPHLs) survey.

In 2000, when the core functions and capabilities of SPHLs were being further defined by APHL,² it was recognized that SPHLs vary greatly in size, resources, scope of operations, funding, and organizational structure. In some states, environmental testing and personal health testing are carried out in separate facilities within different agencies. Several states have branch laboratories, while most conduct all activities in a central facility. In addition, SPHLs face changing demands from the constituent users of their services as public health priorities evolve. Another influence on SPHLs operation is the rapid increase in scientific technology and information systems available for both public and private/commercial laboratories. In addition, SPHL directors continually face the decisions of which tests should be performed in their facilities and which should be referred to other testing organizations. In many states, the legislature plays a direct role in determining the test menu offered by the SPHL.

Even prior to September 11, 2001, and the anthrax terrorist events in October 2001, CDC and APHL recognized the need to develop a seamless laboratory network responsive to threats to the public's health. The need for a comprehensive national system for responding to man-made or naturally occurring health risks such as terrorist attacks, outbreaks of food-borne illness, environmental catastrophes, exposure to harmful chemicals, and emerging infectious diseases was apparent. A Laboratory Response Network (LRN) was developed by CDC³ to respond to a possible bioterrorism threat such as anthrax. Accurate and timely laboratory analyses are required to identify and track such occurrences (ie, surveillance). Even though SPHLs play

a key role in any public health system, the need for public-private coordination is essential, because much of the testing of public health significance is done in nonpublic health laboratories. Furthermore, bioterrorism or other such events could occur anywhere in the United States and could affect many jurisdictions. With approximately 175,000 clinical laboratory entities in this country identified under the federal Clinical Laboratory Improvement Amendments of 1988⁴ and a large number of environmental laboratories, the attempt to create an effective response system for testing of public health significance presents a major challenge.

One obvious challenge to APHL in assuring a comprehensive and coordinated reporting system was to further define the roles of SPHLs. Accordingly, APHL and CDC clarified the 11 "Core Functions of State Public Health Laboratories"⁵ in order to define their role in a national laboratory system. Since the CDC-supported National Laboratory System is dependant on establishing a nation-wide network, the pivotal role of SPHLs in building partnerships between public and private laboratories is crucial. By implementing the National Laboratory System concept within their states, SPHLs help to enhance the 10 essential services of public health⁶ and contribute to many of the goals of HP2010.

In 2002, the LSS committee embarked on developing a plan for collecting data to periodically measure the status of HP2010 Objective 23-13. It reviewed models such as the one developed by the Council of State and Territorial Epidemiologists to measure HP Objective 23-14. At the same time, other APHL committees were designing surveys to measure SPHLs' readiness to respond to threats to the food chain security and intentional exposures to pathogenic microbes and toxic chemicals. Since results were available from these three topic-specific surveys, these data could be used as a part of the baseline comprehensive survey.

Methods

For several decades, APHL collaborated with CDC to conduct and publish the Consolidated Annual Report (CAR). As the name implies, the CAR was an annual report on the workloads and activities of the SPHLs covering the fiscal year July 1 through June 30. Although the CAR was not conducted in all years, the majority of states and territories contributed to the survey. The aggregated data presented a broad picture of changes in infectious disease surveillance activity, emergence of new public health threats and practices, and other public health issues in which laboratory testing was critical. In some years, large city/county public health laboratories were also included. Each year, new questions were introduced about specific aspects of laboratory

operations such as new technologies and administrative challenges.

In 1997, APHL replaced the CAR with the Core Functions Survey (CFS) to assess the status of public health laboratories, with questions related to the 11 core functions of SPHLs and to other aspects of laboratory systems. The survey was designed to identify needs, gaps, threats, and risks to public health laboratory practice. The CFS was repeated in 1999 and 2002. The 2004 Comprehensive Laboratory Services Survey reported here⁷ is an extension of the CFS that was modified to serve as a data source in determining the degree to which SPHLs were meeting the HP2010 Objective 23-13. The 11 core functions of an SPHL form the basis for the Comprehensive Laboratory Services Survey (CLSS).

The design of the 2004 survey was developed by the LSS committee using questions based on indicators of comprehensiveness, defined as "the extent to which the state is assuring the provision of the 11 core functions of state public health laboratories."^{2,5} Public health guidelines or peer-developed standards were used where they exist. The primary source of questions was the 2002 CFS from which some questions were left intact and others modified. The LSS committee developed new questions where needed. For core functions of food safety and emergency preparedness, questions were selected from three recently conducted surveys (all in 2004)—Food Safety, Bioterrorism Preparedness & Response, and Chemical Terrorism Preparedness. The survey used indicators to evaluate the extent to which each state is providing or assuring services that satisfy each of the core functions. The number of indicators varied by section, related to the complexity and activity within that core function (Table 1). Laboratories needed to satisfy 70 percent of the indicator activities for each of the 11 core function areas in order to receive an acceptable score. This achievement level was based on (1) the concept of continuous improvement, with the goal that SPHLs would improve performance over the decade, and (2) the model of the National Public Health Performance Standards Program. In this program, an agency achieves the desired level of performance when 75 percent of the activity described within a question is met. The end-of-decade targets were based on information from past surveys and evaluation of SPHL activities by the various committees of APHL.

During the development of the survey, the LSS committee consulted with the CDC staff responsible for the HP 2010 initiative at the National Center for Health Statistics in order to assure that the APHL survey and data collection strategy would meet criteria for inclusion in HP 2010 reports and further HP 2010 activities. During the process, the 11 core functions were incorporated as the 11 subobjectives for Objective 23-13. CDC and HRSA noted that Public Health Infrastructure is

TABLE 1 ❖ Indicators for subobjectives of Healthy People 2010 objective 23-13

Subobjective		Number of indicators	70% passing score
23-13a	Disease Prevention, Control and Surveillance	22	16
23-13b	Integrated Data Management	5	4
23-13c	Reference & Specialized Testing	8	6
23-13d	Environmental Health and Protection	12	9
23-13e	Food Safety	9	7
23-13f	Laboratory Improvement and Regulation	2	2
23-13g	Policy Development	3	3
23-13h	Emergency Response	12	9
23-13i	Public Health-Related Research	4	3
23-13j	Training and Education	6	5
23-13k	Partnerships and Communication	6	5

a new focus area in HP 2010. This focus area is cross-cutting and vital to strengthening the public health infrastructure because of the major health crises and preparedness demands of the past few years. Baseline data for the new objectives did not exist at the beginning of the decade. Since then, the lead agencies have worked to identify data sources and support development of data sources wherever possible. CDC and HRSA proposed a revised Objective 23-13—"Increase the proportion of Tribal and State public health agencies that provide or assure comprehensive laboratory services to support essential public health services." CDC and HRSA recognized that data sources do not exist for local public health departments and none would likely be available during the decade. A footnote to this revised objective also stated that there are currently no data sources at the tribal level, but if data should become available before the end of the decade, the tribal level will be included.

The CLSS was distributed in November 2004 to all state and territorial public health laboratories using the APHL Web-based survey tool LabNet. SPHL directors were asked to complete the self-assessment within 3 weeks. Respondents were told that each state would receive a confidential summary report of its performance, and only anonymous-aggregated data would be reported publicly.

❖ Results

In December 2004, a summary of the survey results was sent to the HP 2010 program at the CDC Office of Program Planning and Evaluation and the National Center for Health Statistics. The summary

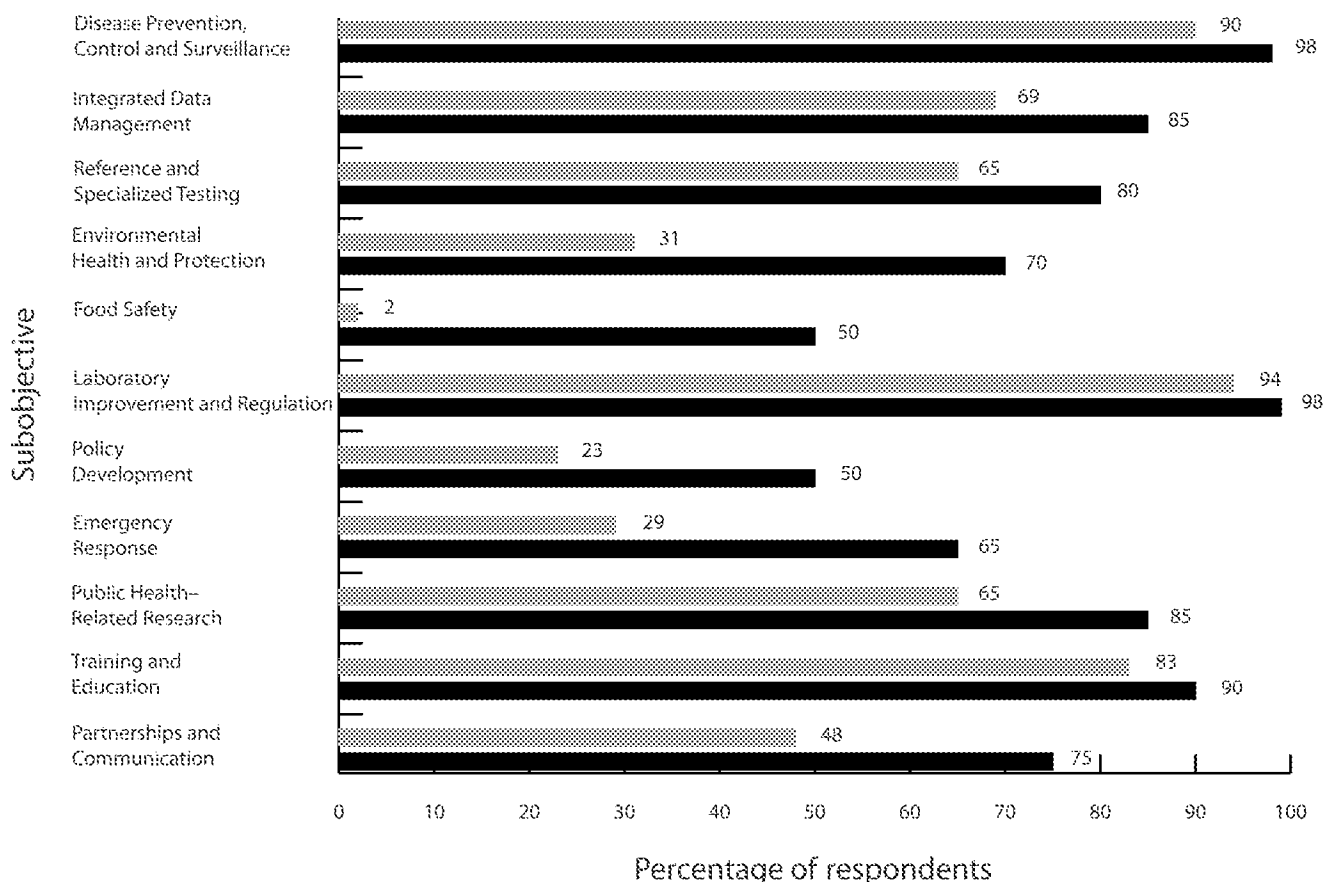


FIGURE 1. Percentage of respondents meeting subobjective with end of decade targets. Light gray indicates percentage of respondents meeting subobjective; black, end of decade targets.

reported a response rate of 86 percent (47 states and 1 territory, of a total 56 possible respondents). The proportion of states/territories meeting the defined standards/criteria for each of the subobjectives is presented in Figure 1. Other information provided to CDC included the weighting/scoring mechanism, an operational definition and rationale for scoring at the 70 percent level, the end of decade targets based on the improvement over baseline scores, a description of the LabNet survey system, and the designation of a 2-year periodicity for future data collection.

The wide range of scores for core functions reflects the diversity of SPHL operational mandates along with a variety of challenges that SPHLs have faced within the first half of the decade. These issues were analyzed and will be illustrated by referring to specific questions in the survey and by noting the system challenges facing SPHLs. These challenges have led to efforts by APHL to improve the federal/state/private laboratory system and to assist SPHLs in meeting these contemporary public health demands.

The Disease Prevention, Control, and Surveillance (23-13a) section contained the most questions—22, reflecting the fact that infectious disease testing has been

the major scientific activity of SPHLs. Two additional questions were not scored but were included for information gathering. Of these 22 indicators, 3 questions dealt with laboratory quality control, participation in CDC disease surveillance programs, and regular communication with the state epidemiologist's office.

Two infectious diseases were used as surrogates for the provision of comprehensive laboratory services for the core function of disease prevention, control, and surveillance—gonorrhea (GC) and tuberculosis (TB). Gonorrhea and TB testing is an activity that all SPHLs perform and where disease control programs involve interdisciplinary public health systems that include clinicians, private-sector laboratories, public health departments, and epidemiologists. For these two diseases, the survey evaluated the individual laboratory's performance in the larger public health system. Five questions explored whether the systems in place for GC testing follow national guidelines.⁸ For example, although the survey indicates that 93.5 percent of SPHLs provide identification of GC isolates, only 53.2 percent provide or assure antibiotic susceptibility testing. Ten questions assessed the adequacy of tuberculosis-testing protocols. Many organizations and agencies

have devoted considerable effort to developing a national plan for reliable TB laboratory services in the United States, especially since the advent of multiply resistant organisms.^{9,10} A significant finding was that only 9 of 48 respondents provide 7 days a week processing of specimens required by new protocols identified as a best practice by these guidelines.¹¹ Although all states participate in newborn screening, there is considerable variation in state programs. Of 35 disorders that could be screened for in newborns, 9 were selected for inclusion in scoring.

For the core function of Integrated Data Management (23-13b), more than two thirds of respondents met or exceeded the target of a positive response to four of five indicators. These questions explored the availability of Laboratory Information Management Systems (LIMS). The majority (89%) of SPHLs have at least one LIMS, but only 41 percent have an enterprise system covering all technical functions of the laboratory. At present, 75 percent provide electronic laboratory reporting to clients and many incorporate one or more national standards in their systems.¹²

Reference and Specialized Testing (23-13c) are services that historically have been provided by SPHLs to private laboratories and to local units of government. Most (65%) SPHLs are engaged in serving as a reference laboratory for these entities within their states. All SPHLs provide services for identifying unusual bacterial isolates, and 98 percent for subtyping influenza A virus. Sixty-six percent confirm unusual serology results, 53 percent perform Brucella serology, and 43 percent identify botulinum toxin. Rabies testing on suspect animal and human tissue is offered by 81 percent of respondents. Indicators for availability of emerging infections testing in the survey were severe acute respiratory syndrome (SARS) and vancomycin-resistant *Staphylococcus aureus*. Most (98%) tested for SARS, while 60 percent provided analyses for resistant *S aureus*.

In the core function of Environmental Health and Protection (23-13d), the survey showed that about three-quarters of SPHLs conduct environmental lead testing, safe drinking water compliance testing, and recreational water analyses. A smaller number conduct air quality testing or soil analyses for toxic compounds. In clinical samples, lead and other heavy metal testing is performed more frequently than examination for organic compounds or pesticides. Of the respondents, only 15 of 48 satisfied the overall goal for the environmental health & protection subobjective.

For the Food Safety core function (23-13e), questions from a previous APHL Food Safety Committee survey were used. Nine practices and capacities were assessed, and SPHLs were required to provide or assure seven to achieve a passing score. Only one state met this stan-

dard, although several others showed marginal performance by providing five or six of the capacities or services.

For the core function of Laboratory Improvement and Regulation (23-13f), the survey was limited in scope and may not reflect the true situation since the regulatory atmosphere is complex and evolving. Although 94 percent of SPHLs met the acceptable target, this high level of achievement may not accurately evaluate the regulatory environment since only two indicators were scored and many questions were considered to be for information gathering only. Currently, there are a number of associations and agencies that accredit laboratories. Some accreditation programs evaluate clinical laboratory activities. Others examine environmental laboratories, industrial laboratories, forensic laboratories, or other entities. Most (94%) SPHLs or their health agencies state that they are involved in the regulation, certification, or accreditation of laboratories within their area of responsibility. The survey did not distinguish between oversight activities and direct statutory authority. In many cases, it is possible that SPHLs are involved in deficiency correction or technical assistance activities such as those offered by the APHL National Laboratory Training Network. At present, no accreditation or regulatory program specifically addresses the unique activities of public health laboratories such as epidemiological testing. Therefore, APHL is investigating the development of performance standards and voluntary accreditation for public health laboratories.

Although 94 percent of SPHLs provide data for Policy Development (23-13g) at the state level and 77 percent participate in establishing health policy for their respective states, only 60 percent participate in developing policy standards/models for health-related laboratories.

For the core function of Emergency Response (23-13h), only 29 percent of SPHLs met the subobjective target of 9 out of 12 indicators. This goal required laboratories to fulfill both bioterrorism and chemical terrorism preparedness criteria. Approximately half the states have triage areas for receiving unknown samples. Ninety-eight percent maintain an active database for all sentinel laboratories within the state, and 86 percent maintain an active communication system for these laboratories. The number of SPHLs analyzing for chemical threat agents and/or metabolites in clinical samples is 64 percent and in environmental samples is 62 percent. The survey showed that SPHLs vary in their capabilities for screening multihazard environmental samples for chemical agents, biological agents, radionuclides, or explosives.

Sixty-five percent of SPHLs reported that they participate in Public Health-Related Research (23-13i). The majority do not conduct basic research, but

28 respondents reported that they participate in or conduct applied research resulting in published reports. The most common types of applied research were evaluation of testing methodologies or collaboration with academic or private sector investigators. One possible source of inconsistent responses to research questions may be a variation in the interpretation of what studies were considered research by the laboratory. New test introduction or test replacement validation studies are an integral part of normal laboratory operation in a regulated quality assurance environment and should not be considered applied research. This survey was not able to determine whether true applied research or method validation was being performed. In future surveys, clarification of the definition of research will be provided.

The Training and Education (23-13j) core function is closely related to the laboratory improvement and regulation core function in the sense that many laboratory personnel are certified or credentialed by the state government and/or by professional societies. However, even in states where laboratory professionals are not credentialed, training opportunities improve the quality of testing. The survey evaluated the SPHL involvement in training of laboratory personnel, and 85 percent responded that they provide training seminars, support employee education, or are involved in other educational activities. It was encouraging that 94 percent have a designated state training coordinator to address employee and peer training issues. Furthermore, 89 percent have cosponsored training activities within the National Laboratory Training Network during the survey period. Every respondent SPHL provides staff access to a satellite downlink site. It is clear that SPHL directors recognize that training activities constitute a major priority for maintaining partnerships with laboratories within their jurisdictions.

Approximately half the respondents responded positively to five of six questions for the Partnerships and Communication (23-13k) subobjective. The indicators in this category included making oral presentations, conferring with other public health laboratories, providing a directory of testing services, and publishing newsletters. SPHLs were asked whether there were regular meetings with partners such as the state epidemiologist, the state health officer, or the maternal and child health director. The overwhelming majority of laboratories indicated that they maintain close lines of communication with these associates.

Discussion

The Comprehensive Laboratory Services Survey provides a baseline picture of the status of SPHLs re-

garding their capabilities of providing essential services for public health in this decade. The first 5 years have seen emergence of infectious diseases (eg, West Nile Virus, SARS) and terrorist actions that have had an impact on SPHLs in a number of ways. Political leaders should recognize that the public health infrastructure at the state and local levels is fragile and has been poorly funded for many years. Although increased federal funding has been provided to SPHLs for training, equipment acquisition, and overall infrastructure improvement, any progress toward laboratory preparedness is threatened by decreasing federal support expected as priorities change. The survey confirms that, in addition to food safety, major weaknesses still exist in environmental health and protection, policy development, and emergency response areas.

Poor response to the food safety subobjective is attributed to SPHLs having a limited role in testing food as a substrate for food-borne bacterial, viral, parasitic agents and organic and inorganic chemical contaminants and toxins.¹³⁻¹⁵ In most jurisdictions, food testing is performed by other governmental laboratories. Agencies such as federal and state agricultural departments and the federal Food and Drug Administration (FDA) are responsible for the majority of food analysis in the United States. SPHLs have been primarily concerned with testing clinical samples such as feces and blood when outbreaks of food-borne diseases are encountered. In the past, SPHLs have collaborated with other governmental agencies in agriculture and the environment when such events occur. Programs are underway to enhance the capacity of SPHLs to analyze food samples, especially with the threat of terrorism affecting the food supply a possibility. In future surveys, this tool will need revision to capture state assurance that a critical food-testing activity is available in the state or region.

The historically limited role of SPHLs in food safety is not sufficient to meet current national food safety goals or public expectations. The recognition of emerging food-borne disease-causing microbiological agents, expanded appreciation that food may be a target of intentional biological or chemical contamination,¹⁶ increased globalization of the food supply, emerging antibiotic resistance of food-borne bacterial pathogens, and developments in laboratory and information technology predict that the public health laboratory will have an increasing role to play in detecting and investigating food-borne disease activity. The success of the CDC/APHL partnership in PulseNet, the standardized molecular typing of organisms isolated from patients and contaminated food combined with a data-sharing scheme, proves that morbidity and mortality can be prevented through public health use of innovative laboratory technology. The survey clearly indicates that

investment and prioritization of food testing in SPHLs are needed to meet national food safety goals. In addition, the 2004 Food Safety Survey that was used to determine the provision or assurance of food-testing services was intended to measure capacity and not assurance. In future surveys, questions will be formatted to also collect data on the capacity of public health food testing in other laboratories serving the state.

The environmental health and protection arena has a wide range of participants, including local and state public health departments, state environmental protection agencies, a variety of professional organizations, a number of federal agencies, and more recently the Department of Homeland Security. It is not surprising, therefore, that SPHLs are facing many challenges,¹⁷ ranging from coordination of services, introduction and standardization of new technologies, to linkage of LIMS. Many SPHLs test for natural and man-made hazardous substances such as air, food, and water contaminants; radiation; toxic chemicals; disease vectors; safety hazards; and habitat alterations. Historically, many SPHLs were focused on testing for infectious agents, whereas chemical testing was less heavily emphasized. In several states, environmental analyses are conducted in laboratories in other governmental agencies. Currently, APHL is working closely with CDC's National Center for Environmental Health to support biomonitoring capacity building for SPHLs. Additional efforts are underway to help states develop and expand their biomonitoring capabilities. APHL's Environmental Health Committee considers laboratory quality and competency to be important concerns that have become amplified by homeland security issues. The Environmental Health Committee has encouraged the Environmental Protection Agency to become a National Environmental Laboratory Accreditation Program agency in order to provide federal accreditation to state environmental laboratory programs.

Regarding policy development, in recent years APHL has encouraged members to become proactive in meeting with policy makers, legislators, and other partners in order to influence important decisions affecting laboratory operations. The current APHL strategic plan promotes developing a unified voice on issues that impact the public health community where laboratory services are involved. The poor performance of the respondent SPHLs in this subobjective can be attributed to the small number of indicators and the requirement to satisfy all activities in order to achieve this target.

Federal funding for public health laboratory response to bioterrorism began in the late 1990s. In 1999, five SPHLs were funded for development of chemical terrorism testing. As of 2003, states could use existing preparedness funds for chemical terrorism, but no additional funds were made available. An APHL survey in

November/December 2004 found that 5 of 62 states and territorial laboratories had advanced chemical analysis capacity (level 1), 41 were considered level 2 laboratories, with limited chemical detection capabilities in human samples, and the others had level 3 characterization, which is to handle samples for shipment to an approved laboratory for analysis. In addition to assisting SPHLs in improving analytical capabilities, APHL is working with its members to improve training and awareness of testing issues with first responders and to upgrade their LIMS. The Emergency Preparedness and Response Committee of APHL is engaging federal and state partners to better coordinate all agencies in national level (CDC maintained) and state laboratory response networks.¹⁸

APHL recognizes that surge capacity is still compromised by lack of a stockpile of necessary reagents and planning for increased demands on analytical systems. In addition to expanding Laboratory Response Network capabilities, another effort of APHL promotes SPHL participation in the Food Emergency Response Network, which is jointly overseen by the FDA and the USDA. At the national level, 10 federal agencies have formed the Integrated Consortium of Laboratory Networks to facilitate collaboration among the systems. The participation of APHL and SPHLs in national systems is essential for coordination of testing since states and local public health agencies are ultimately responsible for local coordination. They should be the focal point for private/public health laboratory integration.

The APHL Informatics Committee is working to help develop a comprehensive and integrated information management system at the local, state, and national levels. APHL is developing a framework for integrating newborn screening laboratory information with child health program information systems to assure comprehensive follow-up and notification of screening results to the medical home. The Public Health Informatics Institute has also collaborated with APHL to adopt a strategy for developing Public Health LIMS. Partnerships will be developed with appropriate federal agencies and other health partners. Seamlessly weaving SPHLs into the health safety net is seen as an urgent national priority.

With the development of an integrated National Laboratory System, Laboratory Response Networks, and other related activities, developing close partnerships with professional colleagues will require increasing efforts by SPHL directors. As SPHLs become more integrated into federal/state systems for facing the challenges of global terrorism and the threat of national disasters, effective partnerships become an essential ingredient. As the APHL Laboratory Systems and Standards Committee plans its work for the latter half of this decade, it recognizes that better survey tools and

targets are needed. Eventually, the survey should expand to local public health laboratories and other governmental laboratories performing testing of public health significance.

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